Module 1
Overview and History
Historical Perspective

- In the past laboratory quality was not questioned – it was assumed
  - Until the mid-1970’s regulatory agencies assumed that reports of ‘test’ data were accurate and were generated according to expected quality standards
- Similarly, the invisible ‘hazards’ of working in a laboratory were largely ignored

Poor Quality

- US FDA and US EPA audit of laboratory data supporting two new drug applications showed:
  - Experiments were
    - Poorly conceived
    - Carelessly executed
    - Inaccurately reported
  - Technical personnel were unaware of the importance of:
    - Protocol adherence
    - Accurate observations
    - Accurate record keeping
Poor Quality (cont.)

- Management did not assure critical review of data or proper supervision of personnel
- Assurance could not be given for the scientific qualifications and adequate training of staff
- Disregard for the need to observe proper and safe laboratory and data management procedures
- Sponsors failed to adequately monitor the studies
- Sponsors failed to verify the accuracy and completeness of the scientific data before submission to regulatory agencies

- Led to the passing of the first laboratory quality regulations in the early 1980’s

Safety

- Laboratories, especially microbiology laboratories are special, often unique work environments that may pose real or potential hazards
  - Electric shock
  - Toxic vapors
  - Compressed gases
  - Flammable liquids
  - Radioactive material
  - Corrosive substances
  - Mechanical trauma
  - Poisons
  - Biological materials
Reports of Laboratory Acquired Infections

- Infections (and injuries) have been contracted in laboratories throughout history in spite of safe practices being first published in 1913 by J. Eyre
  - 1941: Meyer and Eddie
    - 74 lab associated brucellosis infections in the US
  - 1949: Sulkin and Pike
    - 222 viral infections (21 fatal)
  - Surveys for lab-associated infections
    - More than 5,000 labs
    - Cumulative total of 3,821 cases reported
    - Most commonly reported:
      - Hepatitis, Brucellosis, Tuberculosis, Tularemia, Venezuelan equine encephalitis
    - Fewer than 20% associated with known accidents
    - Exposure to infectious aerosols plausible (but unconfirmed) for >80% of reported cases

Focus for ‘New’ Safety Regulations

- Laboratory safety necessitates:
  - Recognition of hazards
  - Effective control of hazards
  - Safety-focused attitude
  - Good personal behavior
  - Good housekeeping
  - Continual practice of good laboratory technique
- Accidents can usually be traced to:
  - Unsafe acts
  - Unsafe environment
Quality Regulations

International Quality Standards

• Good Laboratory Practice (21 CFR 58)
• The Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice
• ISO 9001 - Management Standards
• ISO 17025 - Competency of Testing and Calibration Lab
• ISO 43 - Proficiency Testing Lab
• ISO 15189 - Medical Lab
21 CFR 58: The GLP Regulation

• Relates to the conduct of non-clinical (animal) studies
• Sets requirements for:
  ➢ Establishing a Quality Assurance Unit
  ➢ Investigational Facilities
  ➢ Standard Operating Procedures
  ➢ GLP Inspections and Audits

ISO 17025: Competency Requirements for Carrying out Tests and Calibrations

• Contains management requirements and technical requirements
• Requires:
  ➢ Quality Management Plan and associated written procedures and policies
  ➢ Implementation of a full laboratory quality system
  ➢ Internal audits
  ➢ Correction of non-conformities and improvement in laboratory efficiency with respect to quality systems
  ➢ Continuing review of quality systems to ensure their continued suitability and effectiveness
ISO/IEC 15189: Medical Laboratories, Particular requirements for quality and compliance

- Sample collection, transportation and identification
- Sample processing
- Test validation and interpretation
- Reporting and advice
- Disease and patient management and advice
- Laboratory management
- Staff experience and training
- Quality Assurance and Quality Control systems
- Non-conformances

Safety Regulations
Laboratory Standards and Guidelines

- Many standards and guidelines published to guide and/or regulate laboratory safe working practices:
  - Title 21 Code of Federal Regulations, Part 58 (Good Laboratory Practices)
  - ISO 15190: Medical laboratories - Requirements for safety
  - ISO 15189: Medical laboratories – Particular requirements for quality and compliance
  - Clinical and Laboratory Standards Institute (CLSI): Clinical Laboratory Safety (GP17 guideline)
  - CLSI: Protection of Laboratory Workers from Occupationally Acquired Infections (M29)

Laboratory Standards and Guidelines (cont.)

- US DHHS/NIH/CDC: Biosafety in Microbiological and Biomedical Laboratories
- WHO Laboratory Biosafety Manual
- US Department of Labor, Occupational Safety and Health Administration (OSHA): Occupational Exposure to Bloodborne Pathogens
- National Committee for Clinical Laboratory Standards (NCCLS): Protection of Laboratory Workers from instrument biohazards and infectious disease transmitted by blood, body fluids and tissue
- College of American Pathologists: Laboratory Safety, a component of accreditation

- Many common themes, principles and practices
Module 2
Laboratory Safety

Famous Quotes

• “Not a gift of a cow, nor a gift of land, nor yet a gift of food, is so important as the gift of safety, which is declared to be the great gift among all gifts in this world” Anon.

• “Don’t learn safety rules simply by accident” Abraham Lincoln

• “Safety is something that happens between your ears, not something you hold in your hands.” Aristotle
Who is Responsible?

- Employer and employee **share** responsibility
  - Employer has ultimate responsibility
  - Supervisors should lead **by example**
- Safety management starts with a safety policy

Employer’s Responsibilities

- Establish work methods and safety policies
- Provide supervision and guidance to staff
- Provide safety information, training, PPE, and medical surveillance
- Provide and maintain equipment and facilities that are adequate to the task
- Establish an Exposure Control Plan
Exposure Control Plan

• Often a legal requirement
• Identifies tasks that are hazardous, safety control measures, and promotes safety through:
  ➢ Employee education and orientation
  ➢ Appropriate disposal of waste
  ➢ Standard (Universal Precautions)
  ➢ Engineering controls and safe practices
  ➢ Personal Protective Equipment (PPE)
  ➢ Post exposure plan

Employee’s Responsibilities

• Know and comply with the established work safety practices
• Positive attitude towards supervisors, coworkers, facilities and safety training
• Give prompt notification of unsafe conditions or practices
• Engage in the conduct of safe work practices and use of PPE
Types of Hazards

- Biologic/Biosafety
- Chemical
- Radiation
- Electrical
- Fire
- Compressed gases
- Ergonomic
Biologic/Biosafety Hazards

• Individuals potentially exposed through:
  ➢ Rubbing eyes or nose with contaminated hands
  ➢ Inhaling aerosols
  ➢ Accidentally ingesting microorganisms
  ➢ Needle stick or other injuries that break the surface of the skin

Principles of Biosafety

• Containment: Describes safe methods for managing infectious materials
  ➢ To reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents
• Primary containment: Protection of laboratory personnel and the immediate laboratory environment
• Secondary containment: Protection of the environment external to the laboratory
Infective Agent Risk Groups

• Risk Group 1 (no or low individual and community risk)
  ➢ A microorganism that is unlikely to cause human or animal disease
    • e.g. *Bacillus subtilis*

Infective Agent Risk Groups (*cont.*)

• Risk Group 2 (moderate individual risk, low community risk)
  ➢ A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, live stock or the environment.
    • e.g. Hepatitis B, HIV, salmonellae
  ➢ Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the spread of infection is limited.
Infective Agent Risk Groups (cont.)

• Risk Group 3 (high individual risk, low community risk)
  - A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another.
    - e.g. *Mycobacterium tuberculosis* (aerosol spread), *Coxiella burnetii*
  - Effective treatment and preventive measures are available

Infective Agent Risk Groups (cont.)

• Risk Group 4 (high individual and community risk)
  - A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly.
    - e.g. Marburg virus, Congo-Crimean hemorrhagic fever
  - Effective treatment and preventive measures are not usually available
Overview of Biosafety Levels

• Four biosafety levels which consist of a combination of:
  ➢ Laboratory practices and techniques
  ➢ Safety equipment
  ➢ Laboratory facilities

• Conditions under which the agent can ordinarily be handled safely

• Laboratory director responsible for assessing risk and applying recommended biosafety controls

Laboratory Practice and Techniques

• **Strict** adherence to standard and accepted practices
  ➢ Staff trained and proficient in procedures and the practices and techniques required to handle the materials safely

• Biosafety or Operations Manual that identifies possible hazards and specifies practices and procedures to minimize or eliminate hazards

• Scientists trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards should perform the work
Laboratory Practice and Techniques (cont.)

• Laboratory Director responsible for selecting additional safety practices in keeping with the level of hazard

• Staff, practices and techniques must be supplemented by appropriate facility design, layout, equipment and management practices

Safety Equipment

• Primary barriers
  ➢ Biological safety cabinets
  ➢ Enclosed containers, e.g., capped centrifuge bucket
  ➢ Personal protective equipment (PPE)

• Secondary barriers
  ➢ Design, construction and use of the laboratory
  ➢ Separation of work areas

• Combination of primary and secondary barriers based on results of the safety risk assessment
### Relation of Risk Groups to Biosafety Levels, Practices, and Equipment

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Biosafety Level</th>
<th>Laboratory type</th>
<th>Laboratory Practices</th>
<th>Safety Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Basic – Biosafety level 1</td>
<td>Basic teaching, research</td>
<td>GMT</td>
<td>None; open bench work</td>
</tr>
<tr>
<td>2</td>
<td>Basic – Biosafety level 2</td>
<td>Primary health services, diagnostic services, research</td>
<td>GMT plus protective clothing, biohazard sign</td>
<td>Open bench plus BSC for aerosols</td>
</tr>
<tr>
<td>3</td>
<td>Containment – Biosafety level 3</td>
<td>Special diagnostic services, research</td>
<td>As Level 2 plus special clothing, controlled access, directional airflow</td>
<td>BSC and/or other primary devices for all activities</td>
</tr>
<tr>
<td>4</td>
<td>Maximum containment – Biosafety level 4</td>
<td>Dangerous pathogen units</td>
<td>As level 3 plus airlock entry, shower exit, special waste disposal</td>
<td>Class III BSC, or protective pressure suits in conjunction with Class II BSCs, double-ended autoclave, filtered air</td>
</tr>
</tbody>
</table>

**BSL**: Biological safety level  
**GMT**: Good microbiological techniques

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### When Biosafety Containment Level Should Increase

<table>
<thead>
<tr>
<th>Agent</th>
<th>BSL 2</th>
<th>BSL 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacillus anthracis</strong></td>
<td>Handling clinical material</td>
<td>Concentrated cultures and procedures likely to generate aerosols</td>
</tr>
<tr>
<td><strong>Bordetella pertussis</strong></td>
<td>Handling clinical material and cultures</td>
<td>Large scale production</td>
</tr>
<tr>
<td><strong>Francisella tularensis</strong></td>
<td>Handling clinical material</td>
<td>Manipulation of cultures</td>
</tr>
<tr>
<td><strong>Legionella pneumophila</strong></td>
<td>Handling clinical material and cultures</td>
<td>Activities likely to generate aerosols</td>
</tr>
<tr>
<td><strong>Mycobacterium tuberculosis</strong></td>
<td>Non-aerosol producing manipulations of clinical material</td>
<td>Manipulation or propagation of cultures, All manipulations for possible MDR or XDR material.</td>
</tr>
<tr>
<td><strong>Coccidioides immitis</strong></td>
<td>Handling clinical material and isolates</td>
<td>Manipulating or propagating sporulating cultures</td>
</tr>
<tr>
<td><strong>Coxiella burnetii</strong></td>
<td>Nonpropagative procedures</td>
<td>Cell culture techniques and manipulation of infected tissue</td>
</tr>
<tr>
<td><strong>Influenza</strong></td>
<td>Handling clinical material</td>
<td>Any procedures where H5N1 is suspected</td>
</tr>
</tbody>
</table>

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Universal Precautions

- Assume clinical materials contain pathogens
- Set of precautions to:
  - Reduce the acquisition or transmission of infective agents
  - Prevent potentially harmful agents from leaving the laboratory

Personal Protective Equipment

- Wear a protective laboratory coat and change it if it becomes soiled or splattered
  - Once used, the coat is never worn outside of the laboratory until it is washed. This should never leave the lab
- Wear a disposable apron over a laboratory coat when the hazard level or procedure warrants
- Wear safety glasses except when using a microscope
Personal Protective Equipment (cont.)

- Always wear disposable gloves when working and change them immediately if they become torn
- Wear safety goggles or a face mask for protection against splatters or aerosols
- Dispose of used gloves and other materials into biohazard containers for destruction or sterilization
  - Never re-use disposable personal protective clothing

General Safety Precautions

- Leave all outer clothing and bags outside the lab area
- Wear only closed-toed shoes in the lab
- Never touch your face
- Tie long hair back to prevent it catching in equipment or catching fire over bunsen burner flames
- Do not wear jewelry that could become caught in equipment, hang into infective materials or could tear/pierce disposable PPE
General Safety Precautions (cont.)

- Do not eat or drink in the laboratory and do not store food or drink in the laboratory
- Avoid the use of electronic devices, including cell phones, laptops as they could become contaminated
- Post a biohazard sign on the door of the lab to alert visitors to possible risks
- Know the locations of the first aid kit, the eye wash station, the fire extinguisher, and shower.
- Know the emergency exit route out of the building
- Keep the lab clean, tidy and clutter free

Hazard Signage
Important Administrative Controls for Respiratory Pathogens

- Written policies and procedures to rapidly identify, isolate and treat infected persons
- Annual risk assessments
- Implementation of safe working practices
- Adequate respiratory protection
- Annually educating, training, and counseling healthcare workers about occupationally acquired infections
- Screening healthcare workers for infections and health surveillance program

Important Engineering Controls for Respiratory Pathogens

- Measures to prevent and reduce the concentration of infectious particles
  - Controlled ventilation system that maintains a directional air control
  - Air cleaning by filtration using a high-efficiency particulate air (HEPA) filter
  - Use of UV germicidal irradiation
- Anteroom for separating clean and dirty clothing with a shower
  - Self-closing and interlocking
- Sealable for decontamination
Important Engineering Controls for Respiratory Pathogens (cont.)

- Windows sealed, closed and break resistant
- Hand-washing station with hands-free controls close to the exit door
- Installation of audible or clearly visible alarms
- BSC sited away from walking areas and cross currents
- Autoclave for the decontamination of contaminated materials
- Backflow-precaution devices fitted to the water supply

Important Personal Controls for Respiratory Pathogens

- PPE
  - Solid-front or wrap around gown, scrub suit, coveralls, head covering, face masks, shoe covering or dedicated shoes
  - Front buttoned laboratory coats are not suitable
  - Disposable gloves that cover the hand over the arms of the coat so that no skin is exposed
BSL 2 Laboratory

BSL 3 Laboratory

Containers with Closures

Layout of Equipment in a BSC
Safety Risk Assessment

• Professional judgment is the backbone!

• Consider:
  ➢ Risk group of potential agents
  ➢ Pathogenicity of the agent and infectious dose
  ➢ Potential outcome of exposure
  ➢ Natural and other routes of infection
  ➢ Stability of the agent in the environment
  ➢ Concentration of the agent and the volume to be manipulated
  ➢ Reports of laboratory acquired infections
  ➢ Laboratory activity planned
  ➢ Any manipulations that may enhance the agent’s sensitivity to effective treatment
  ➢ Local availability of effective prophylaxis or therapeutic interventions

Safety Risk Assessment (cont.)

• Biosafety level assigned – appropriate PPE and SOPs to ensure the safest possible conduct of the work
Limited Information on Risk

- Situations where there is insufficient information to perform an adequate risk assessment, e.g., samples collected in the field
- Prudent to take a cautious approach:
  - Standard precautions should always be followed
  - Barrier precautions (gloves, gowns, eye protection) whenever samples are obtained from patients
  - Basic containment – Biosafety Level 2 practices and procedures should be the minimum
  - Transport of specimens should follow national rules and regulations

Chemical Hazards: General Principles

- Properly label all chemicals including secondary containers
  - Do not use an improperly labeled chemical
- Follow all handling and storage requirements
- Store alcohol and other flammable chemicals in approved storage cans or cabinets
- Use adequate ventilation
Chemical Hazards: General Principles (cont.)

- Use PPE as appropriate
- Ensure safety showers and eye wash stations are readily available
- Use bottle carriers for bottles containing over 500 mL
- Wearing of contact lenses prohibited when working with noxious solvents, e.g. xylene, acetone, formaldehyde
- Include spill response procedures in the safety procedures
- Ensure staff are familiar with Material Safety Data Sheets (MSDS)

MSDS

- For every chemical
- Readily available
- Online resources
- Provides standard information
MSDS (cont.)

• Section 1. Chemical product and company identification
• Section 2. Composition/information on ingredients
• Section 3. Hazards identification (including emergency overview)
• Section 4. First aid measures
• Section 5. Fire fighting measures
• Section 6. Accidental release measures
• Section 7. Handling and storage
• Section 8. Exposure controls/personal protection

MSDS (cont.)

• Section 9. Physical and chemical properties
• Section 10. Stability and reactivity
• Section 11. Toxicological information
• Section 12. Ecological information
• Section 13. Disposal considerations
• Section 14. Transport information
• Section 15. Regulatory information
• Section 16. Other information
Radiation Hazards

• Strictly regulated by Nuclear Regulatory Commission
• Procedures depend on:
  ➢ Type of material (soluble, solid etc.)
  ➢ Level of radioactivity
  ➢ Radio-toxicity
  ➢ Half-life
  ➢ Consult local regulations and laws

Electrical Hazards

• Direct
  ➢ Death, shock, burns
• Indirect
  ➢ Lead to fire or explosion
Electrical Hazard Precautions

• Use explosion-proof equipment
• Take special care when operating high voltage equipment, e.g. electrophoresis apparatus
• Use only properly grounded equipment (three-prong plug)
• Check for frayed cords

Electrical Hazard Precautions (cont.)

• Promptly report any malfunctions or equipment producing a “tingling” for repair
• Do not work on “live” electrical equipment
• Never operate electrical equipment with wet hands
  Use only approved electrical extension cords
• Have ground checks and other periodic preventive maintenance performed
Fire Hazards

• Fire is a chemical reaction that involves the rapid oxidation of a combustible material liberating heat and light
• In many laboratories, all the elements essential for fire to begin are present
  ➢ Fuel
  ➢ Heat or ignition source
  ➢ Oxygen

Classification of Fires

• Class A: Ordinary combustible solid materials, such as paper, wood, plastic and fabric
• Class B: Flammable liquids/gases and combustible petroleum products
• Class C: Energized electrical equipment
• Class D: Combustible/reactive metals, such as magnesium, sodium and potassium
Fire Extinguishers

- Divided into four classes depending on the type of fire to be extinguished
  - Using the wrong type can be dangerous
  - Pressurized water extinguishers, foam and multi-purpose dry chemicals are used for Class A fires
  - Multi-purpose dry chemicals and carbon dioxide are used for Class B and C fires
  - Halogenated hydrocarbon are particularly recommended for Class D fires

How to Use a Fire Extinguisher

It’s easy to remember how to use a fire extinguisher if you remember the acronym PASS:

- Pull
- Aim
- Squeeze
- Sweep
Fire Safety

• Know the location and class of fire extinguishers
• How to use an extinguisher
• Know the nearest and alternate fire exits
• In the event of fire
  ➢ Sound the alarm
  ➢ Evacuate
  ➢ Only if safe, attempt to tackle the fire

Compressed Gas Hazards

• Unique combination of hazards
  ➢ Danger of fire
  ➢ Explosion
  ➢ Asphyxiation
  ➢ Toxicity
  ➢ Mechanical injuries
Safe Handling of Compressed Gases

- Know the gas that you will use
- Store tanks vertical
- Keep cylinders secure
- Never store flammable liquids and compressed gases in the same area
- Use the proper regulator (and know how to use it)
- Keep removable protection caps in place until the cylinder is in use

Safe Handling of Compressed Gases (cont.)

- Make certain that acetylene tanks are properly piped
- Do not “force” a frozen or stuck cylinder valve
- Use a hand truck to transport large tanks
- Check tanks on receipt and periodically for leaks
- Label cylinders to properly identify the contents
- Empty tanks should be marked “empty”
Ergonomic Hazards

• Laboratory processes often require repeated manipulation of instruments, containers and equipment
  ➢ Repeated actions over time can contribute to repetitive strain disorders
• Primary contributing factors are:
  ➢ Position
  ➢ Posture
  ➢ Applied force
  ➢ Frequency
• Consider use of tools to aid work and review work practices for ergonomic improvements
• See medical advice for chronic symptoms of pain, numbness, or tingling and report to the laboratory supervisor

Module 3
Research Ethics
Famous Quotes

• “Ethics is nothing else than reverence for life.” Albert Schweitzer
• “The purpose of human life is to serve and to show compassion and the will to help others.” Christian Barnard

Research Ethics

• History
• Institutional Review Board
• Consent Form
• Annual review
• Good Clinical Practice (GCP)
Module 4
Laboratory Quality Management Requirements

Famous Quotes

• “Quality is not an act, it is a habit.” Aristotle

• “Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skilful execution; it represents the wise choice of many alternatives.” William A Foster

• “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

• “Quality means doing it right when no one is looking.” Henry Ford
The Quality Cycle

- Data and Lab Management
- Safety
- Customer Service

- Patient/Client Prep
- Sample Collection
- Personnel Competency Test Evaluations
- Sample Receipt and Logging
- Sample Transport
- Quality Control Testing
- Record Keeping
- Reporting

Organization and Management

- Designed to meet all needs
- Should meet all standards
- Responsibilities of staff must be defined
- Laboratory management responsible for design, implementation, maintenance and improvement of quality management systems
Quality Management System

• Documented and communicated procedures and policies
• Internal and external QA/QC systems
• Quality policy statement
• Quality manual describing the quality management system
• Program for monitoring equipment, reagents, and analytical systems

Document Control

• Define, document, and maintain quality documentation
• Archival of documents
• Comply with national, regional, and local regulations
• Document Control procedures adopted
Referral Laboratories

- Evaluation and selection of referral services
- Periodic review of procedures
- Registry of referral services
- Responsibility resides with referring laboratory

External Services and Supplies

- Evaluation and selection of purchased external services and supplies
- Acceptance/rejection criteria
- Verification of quality
- Inventory control
Advisory Services

- Appropriate qualified personnel advise on:
  - Choice of examinations
  - Use of services
  - Repeat testing
  - Sample types
  - Result interpretation

- Regular meetings of laboratory professional staff with clinical staff

Identification and Control of Nonconformities

- Procedure for identifying nonconforming examinations
- Root cause analysis
- Release of results
Corrective Action

- Investigative process
- Documented
- Monitor the results
- Review of compliance

Preventive Action

- Needed improvements identified
- Actions initiated
- Controls applied
Continual Improvement

• Systematic and regular review
• Evaluation of effectiveness
• Implement quality indicators
• Education and training

Quality and Technical Records

• Procedure for quality and technical records
  ➢ Identification, collection, indexing, access, storage, maintenance, disposal
• Legible and retrievable
• Retention period
Internal Audits

• Laboratory management review
• Evaluation of contribution to patient care
• Actions determined, documented, and implemented

Module 5
Laboratory Quality
Technical Requirements
Personnel

- Organizational plan
- Educational and professional qualifications
- Laboratory director
- Responsibilities for:
  - Oversight and leadership
  - Laboratory services
- Staff training
- Competency testing
- Confidentiality

Accommodation & Environmental Conditions

- Suitable allocated space
- Efficient and suitable design
- Monitor and record environmental conditions
- Controlled access
- Appropriate storage space
- Clean
- Privacy of patients
Laboratory Equipment

• Furnished with all needed equipment
• Capable of achieving performance required
• Uniquely identified
• Equipment records
• Operation of equipment
• Maintenance and service

Laboratory Equipment (cont.)

• Procedures for defective equipment
• Calibration status
• Validation of computers and automated equipment
• Safeguards against adjustments or tampering
Pre-examination Procedures

- Patient and requestor information
- Instructions for primary samples
  - Primary sample collection manual
- Chain of custody
- Acceptance/rejection criteria for samples
- Procedures for urgent requests
- Storage of samples

Examination Procedures

- Procedures that meet all needs
- Validated procedures
- Documented procedures
Examination Procedures (cont.)

• Performance specifications established
• Biological reference intervals reviewed
• List of examinations offered
• Changes in examinations

Assuring Quality of Examination Procedures

• Internal QC systems that verify quality of results
• Uncertainty of results determined
• Program for calibration of measuring systems and verification of trueness
Assuring Quality of Examination Procedures (cont.)

- Participation in inter-laboratory comparisons
- Method for determining the acceptability of procedures
- Verification of comparability of results

Post-examination Procedures

- Systematic review by authorized personnel
- Storage of samples
- Safe disposal of samples
Reporting of Results

• Management agree on format of report
• Assures reports received by authorized individuals
• Legible and accurate

Reporting of Results (cont.)

• Description of examinations should follow accepted norms and nomenclature
• Indicate quality of sample
• Copies of reports retained
• Alert/critical procedures and parameters
Reporting of Results (cont.)

- Procedure for interim reports
- Turnaround times established
- Procedure for release of results including by telephone
- Changes to reports

Summary

- Safety
  - Develop foresight and accident perception
  - Use common sense
  - Understand hazards and follow all safety procedures
  - Adopt good personal behavior and habits
  - Good housekeeping
  - Good laboratory technique
- Quality
  - Responsibility of all
  - Entire quality cycle
  - Equal focus on management and technical quality
  - Culture of continuous improvement