Process Control: Sample Management

CO-3

- Apply knowledge on quality control sample preparation,sample collection,storage,transportation

Learning Objectives

At the end of this activity, participants will be able to:

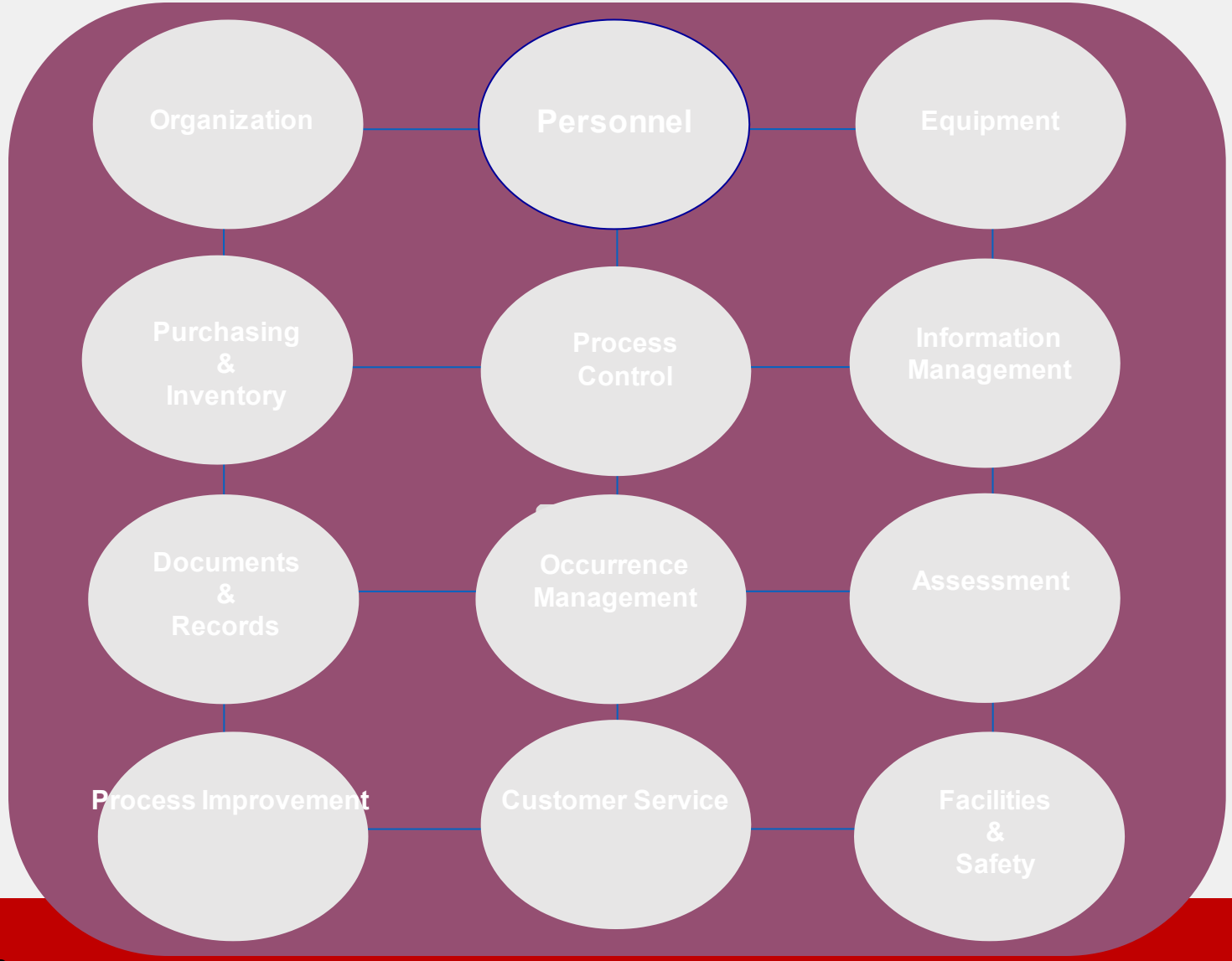
- name sample collection errors that could lead to incorrect laboratory examination results;
- list contents that should be included in a handbook designed for people who collect samples off-site;
- provide a rationale for rejecting unsatisfactory samples;
- describe a system for sample handling, including collection, transport, storage, and disposal;
- explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples.

Scenario: Your laboratory has performed PCR for influenza virus on patient samples from ‘Clinic A’. Most of these results are negative. The medical staff from ‘Clinic A’ tells you that their patients present all the clinical signs of influenza.

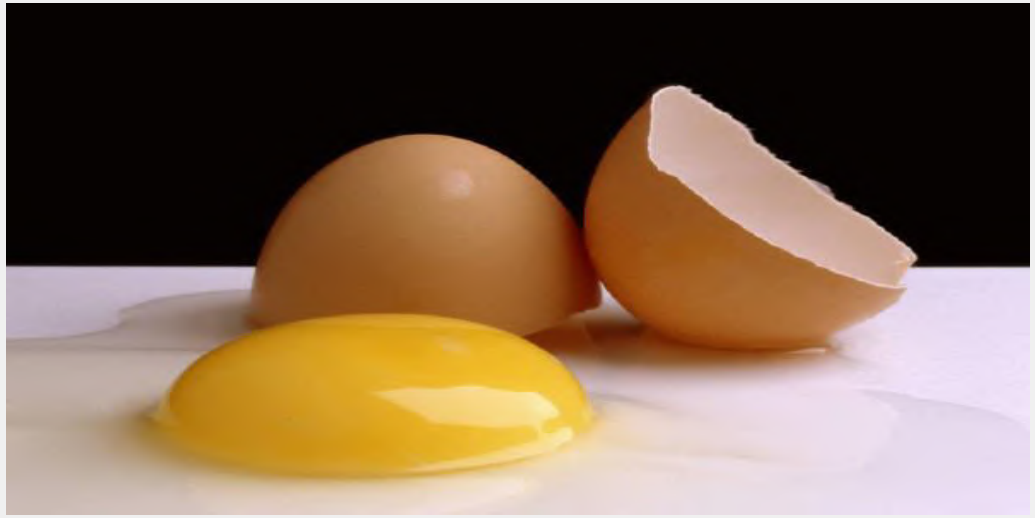
What are you going to check?

What will you do?

The Quality Management System



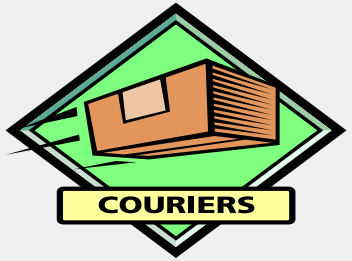
The result of any laboratory examination is only as good as the sample received in the laboratory



Good sample management

Components

Laboratory Handbook
Policies & Practices



The Laboratory Handbook

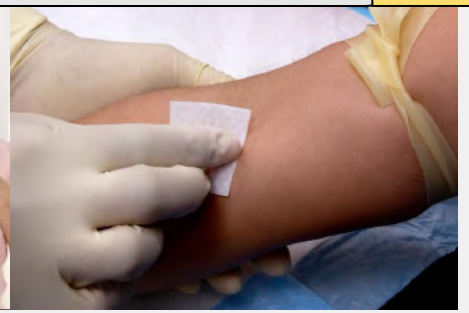
- contains information needed by those who collect samples
- available to all sample collection areas
- must be understood by all laboratory staff
- referenced in the quality manual

Laboratory Handbook Contents

- name and address of laboratory
- contact names and telephone numbers
- hours of operation
- list of tests that can be ordered
- sample collection procedures
- sample transport procedures
- expected turn around times (TAT)
- how urgent requests are handled

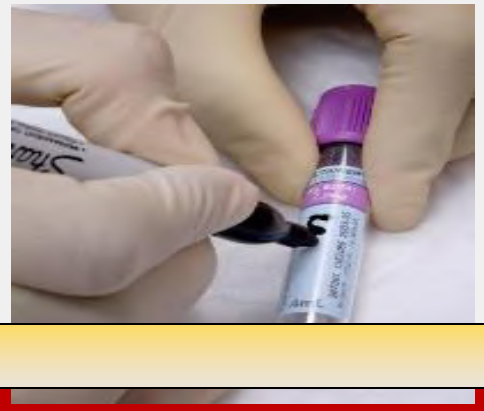
The Laboratory's Responsibilities

Provide sample collection information
What- When- How



Provide appropriate containers and supplies

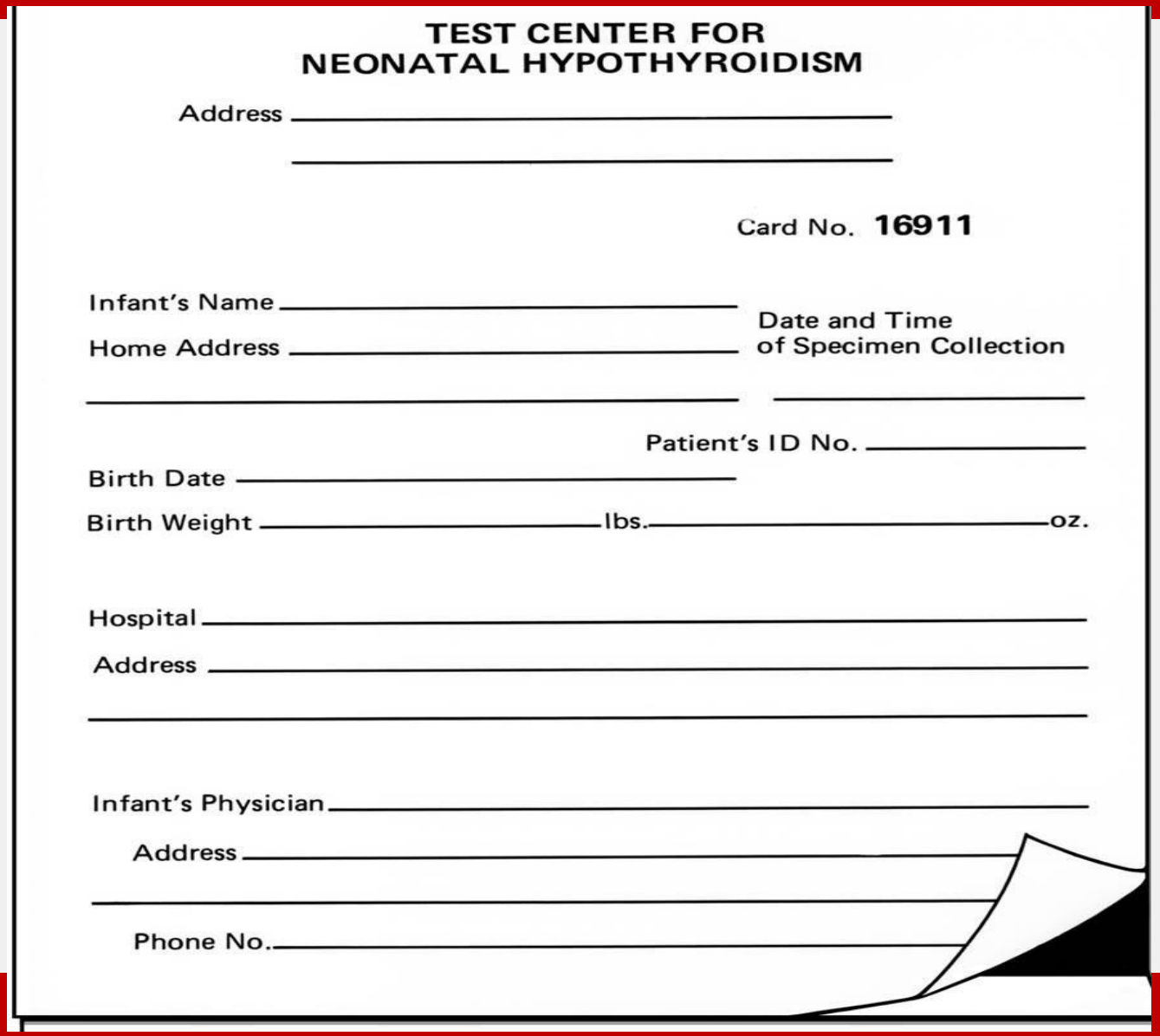
Define a good labeling system



Assess all samples - preexamination

Test Requisition

- patient ID
- tests requested
- time and date of sample collection
- source of sample, when appropriate
- clinical data, where indicated
- contact information of requesting physician or authorized individual



TEST CENTER FOR
NEONATAL HYPOTHYROIDISM

Address _____

_____

Card No. **16911**

Infant's Name _____

Home Address _____

Date and Time
of Specimen Collection

_____ _____

Patient's ID No. _____

Birth Date _____

Birth Weight _____ lbs. _____ oz.

Hospital _____

Address _____

_____

Infant's Physician _____

Address _____

_____

Phone No. _____

Field Data Collection Form

General patient information
Name:
Address:
Country:
County:
City/town/village:

Tracking record number
Date of Birth (dd/mm/yyyy):
Sex: M [ ] F [ ]
Nationality:
Occupation:

Date of onset of illness (dd/mm/yyyy):

Clinical specimens

Unique ID No.	Type	Date of collection	Clinical diagnosis	Health status when specimens collected	Remarks

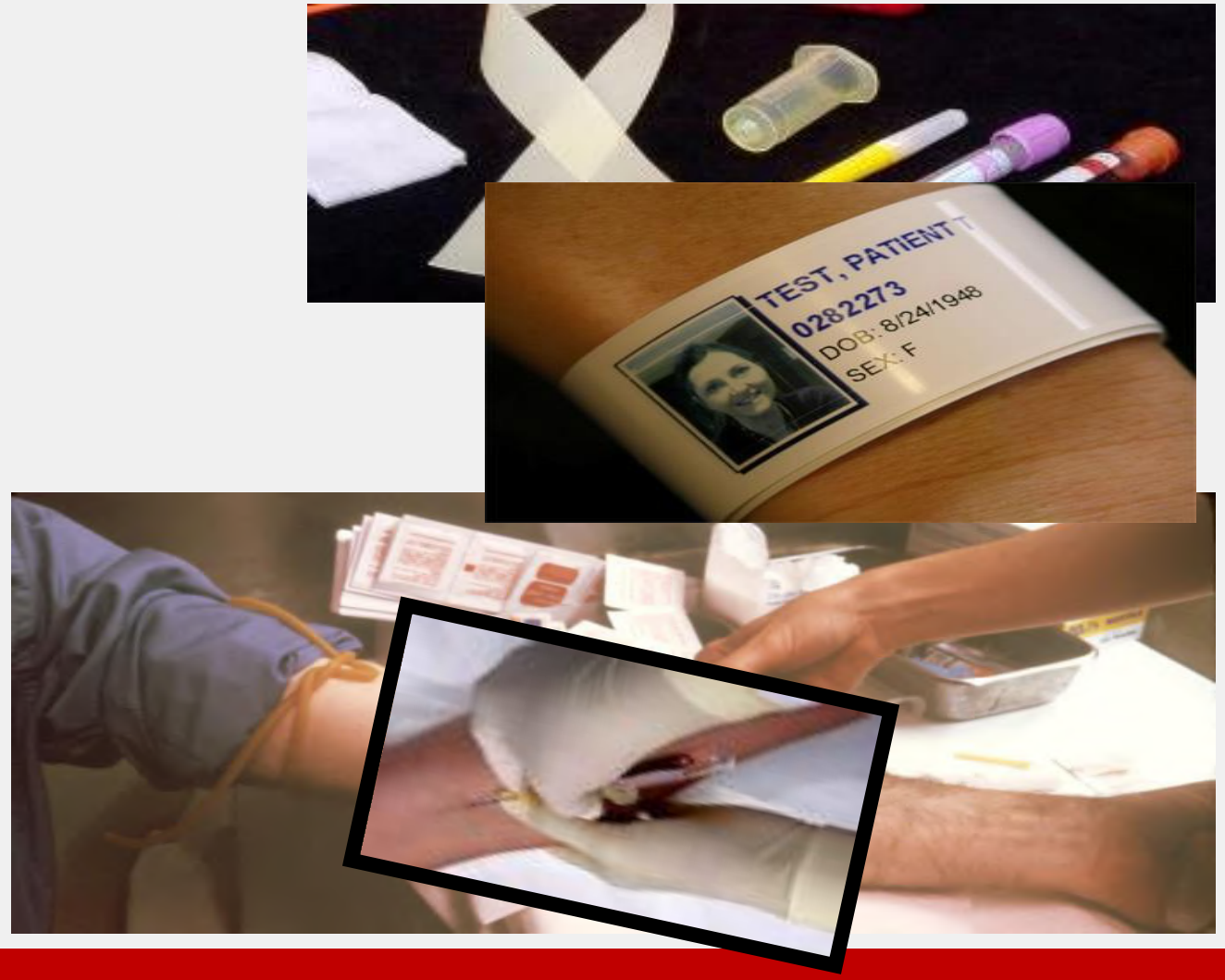
Post-mortem specimens

Date of death(dd/mm/yyyy): ____/____/____

Name of person completing form:_____
Institutional affiliation: _____
Contact details: _____
Date(dd/mm/yyyy): ____/_____/_____

Collection Requirements

- patient preparation
- patient identification
- type of sample required
- type of container needed
- labeling
- special handling
- safety precautions



Provide sample collection information

Finger Prick

Always use universal safety precautions.

1. Collect supplies.

2. Position hand palm-side up. Choose whichever finger is least calloused.

3. Apply intermittent pressure to the finger to help the blood to flow.

4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.

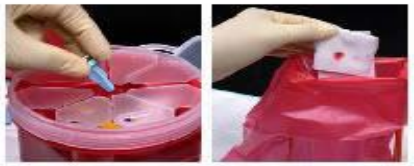
5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.

6. Firmly press the lancet to puncture the fingertip.

7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.

8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.

9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.



10. Properly dispose of all contaminated supplies.

WHO

Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).

CDC

Labeling

Each sample should be labeled with:

- patient's name
- patient's unique ID number
- test ordered
- time and date of collection
- collector's initials

Use computer-generated bar codes when possible

Sample labelling error example

Nurse from different ward

Nurse not familiar with task

Regular staff off sick

Wrong blood group given

Cross-match sample mislabeled

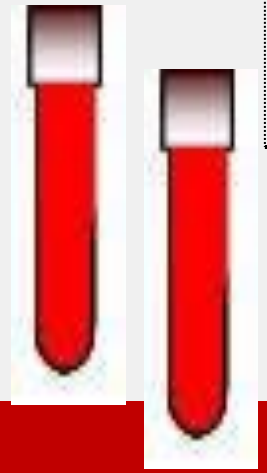
Samples not labeled at bedside

Verbal instruction given

LaboratoryHandbook not easy to locate

Nursing station re-organized

major transfusion reaction



Two patients collected

Shift change patient admit

Delay in admitting dept

Samples taken to nursing station

Switched samples

Outcomes of Improper Collection

- delays in reporting test results
- unnecessary re-draws/re-tests
- decreased customer satisfaction
- increased costs
- incorrect diagnosis / treatment
- injury
- death

Preexamination Steps

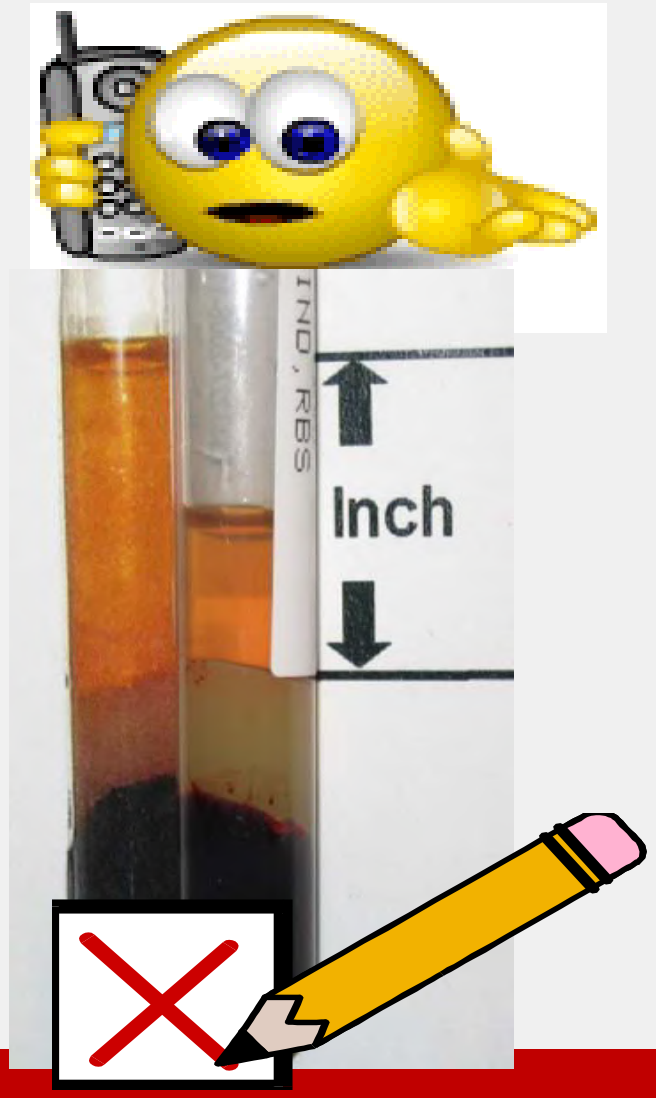
- **Verify**
  - completeness of test request
  - appropriateness of sample
  - information on label
- **Record in register or log**
- **Enforce sample rejection criteria**

Labeled samples, completed requisitions

Spilled urine sample, a cause for rejection

Actions for Rejected Samples

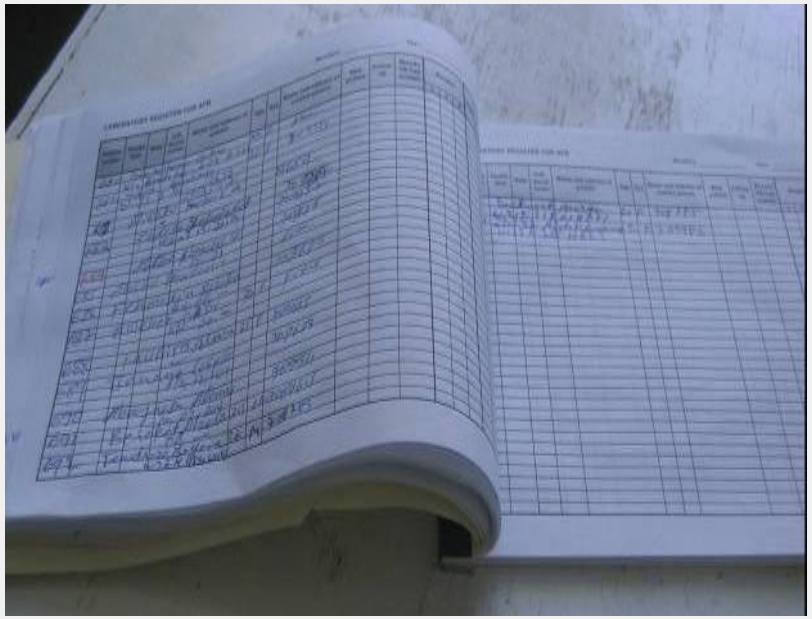
- inform authorized person
- request another sample
- record rejected samples
- retain rejected sample based on preset criteria
- extraordinary circumstances may require testing suboptimal samples



Sample Register or Log

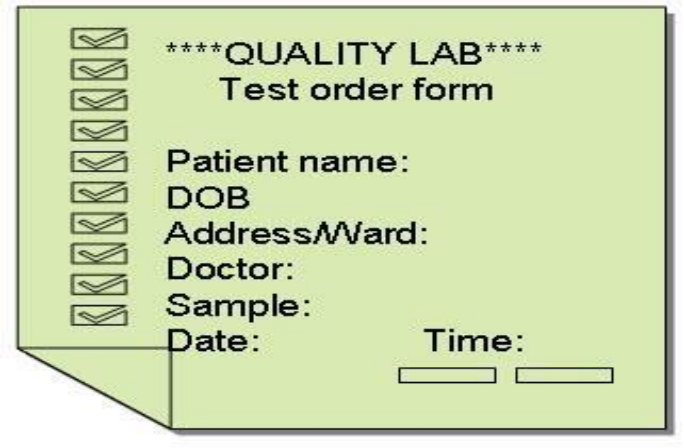
A register should include:

- date and time of collection
- date and time of receipt
- sample type
- patient name
- demographics as required
- laboratory assigned identification
- tests to be performed



Sample Tracking-Manual

- confirm receipt of samples, include date and time
- label samples appropriately; keep with the test requisition until laboratory ID is assigned
- track aliquots–traceable to the original sample



Sample Tracking-Computer

Database entries include:

- identification number
- patient information
- collection date and time
- type of sample
- tests to be performed
- name of health care provider
- location of patient, e.g., ward, clinic, outpatient
- diagnostic test results
- time and date results are reported

Sample Handling

Handle all samples as if infectious

Sample Storage-Written Policy

- describe samples to be stored
- determine retention time
- determine location
- describe proper conditions
- establish method of organizing samples

Sample Retention

- set policy for retention
- monitor stored samples, including freeze/thaw cycles
- maintain an organized, accessible system
- establish a schedule to review all stored samples
- establish tracking procedures

Sample Referral

- Record:
  - samples referred
  - date of referral
  - name of person referring test
- Monitor / Track, and Record:
  - turnaround time
  - results delivery (from referral laboratory, to requestor)
  - problems with referral

Sample Disposal

- set policy for sample disposal
- compliance with local and country regulations
- disinfection procedures

Sample Transport

- Maintain integrity of sample:
  - temperature
  - preservation of sample
  - special transport containers
  - time limitations

- Assure safety regulations are met

Transport Regulations

Where do they come from?

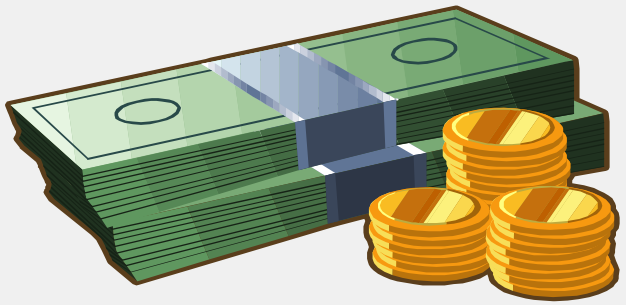
Who develops them?

- ✓ National transport regulations
- ✓ ICAO/IATA transport regulations (air)
- ✓ rail, road, and sea traffic agencies
- ✓ postal services
- ✓ private couriers

Transport Regulations

Mandatory Compliance

- **Violation**
- **Deal with accidents and spills – reduce biohazards**
- **Safety: couriers, laboratory staff, passengers, carriers**



Classification of Infectious Substances

New Classification in 2005: based on two transport categories

Category A: infectious substances capable of causing permanent disability

- life-threatening or fatal disease to humans or both human and animals

Packaging: most durable triple packaging with full **dangerous goods documentation**

Training of transport staff

Classification of Infectious Substances

Category B: infectious substances not included in Category A

- ☑ less stringent triple packaging
- ☑ no dangerous goods documentation required

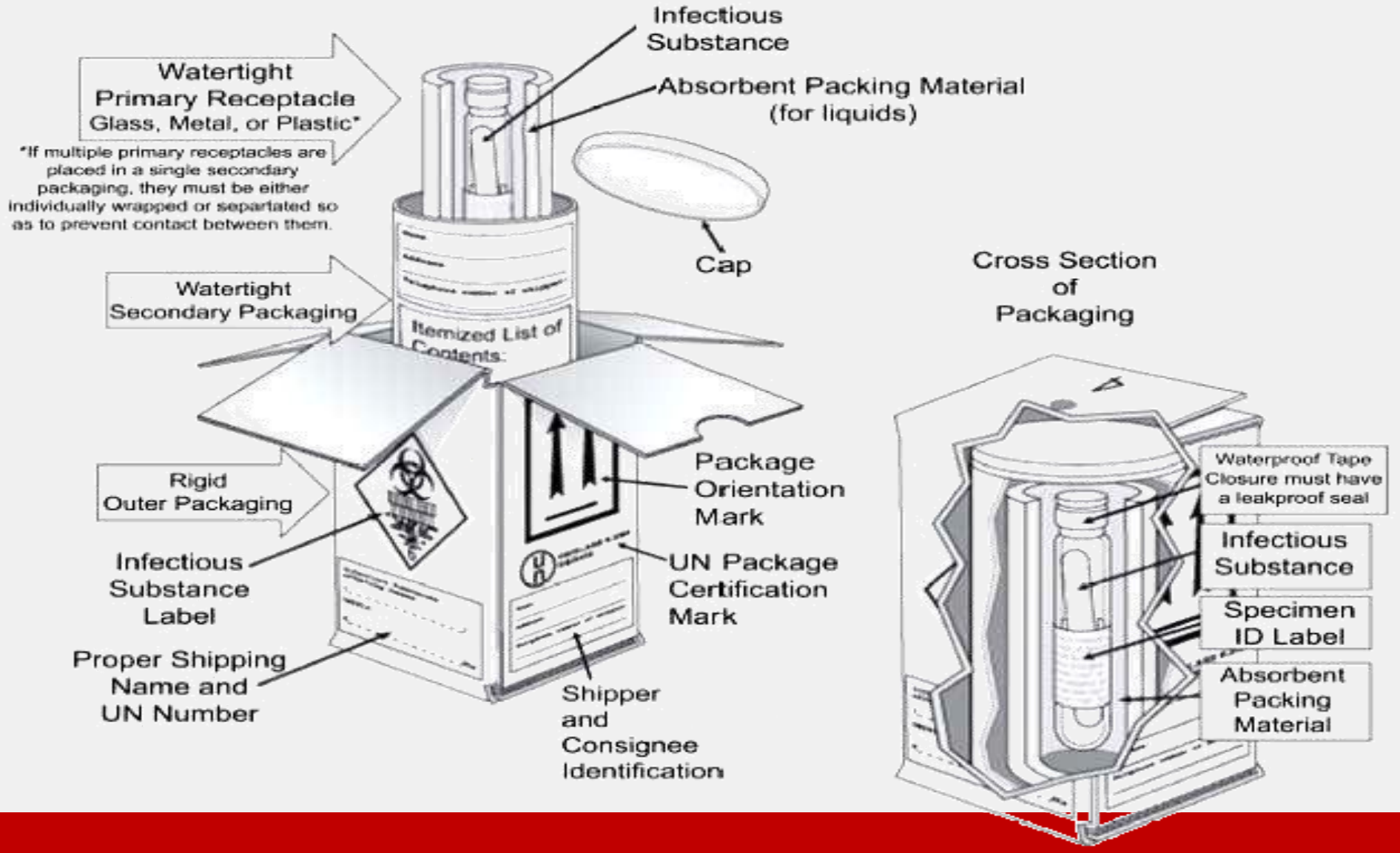
Exemptions

- substances that do not contain infectious substances
- substances containing organisms that are non-pathogenic
- substances containing neutralized or inactivated pathogens
- environmental samples that pose no risk of infection
- blood or blood components collected for transfusion
- tissues or organs cleared for transplantation
- dried blood spots and fecal occult blood screening tests
- decontaminated medical or clinical waste

Triple Packaging (UN 2007)

Category A	Category B	Exempt human or animal specimens
• leakproof primary	• leakproof primary	• leakproof primary
• leakproof secondary	• leakproof secondary	• leakproof secondary
• 95 kPa pressure test	• 95 kPa pressure test	
• rigid outer	• rigid outer	• adequate outer
• minimum 100 mm	• minimum 100 mm	• minimum 100 mm
• absorbent material	• absorbent material	• absorbent material
• 9 meter drop test	• 1.2 meter drop test	
• 7 kg penetration test		
• UN marks and labels	• 3373 label	
• full DG documentation		
• training		

Category A


Infectious Substance
Absorbent Packing Material (for liquids)
Watertight Primary Receptacle Glass, Metal, or Plastic*
*If multiple primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them.
Cap
Watertight Secondary Packaging
Itemized List of Contents
Rigid Outer Packaging
Package Orientation Mark
Infectious Substance Label
UN Package Certification Mark
Proper Shipping Name and UN Number
Shipper and Consignee Identification
Cross Section of Packaging
Waterproof Tape Closure must have a leakproof seal
Infectious Substance
Specimen ID Label
Absorbent Packing Material

Managing Sample Transport

- meet all applicable regulations
- train personnel in all transport procedures
- assure sample is protected:
  - temperature
  - transport time
  - packaging and preservation

Summary

- provide a laboratory handbook with collection information to all users
- have a system for tracking samples as they move through the laboratory
- establish and implement a policy for sample storage and sample disposal
- maintain sample integrity
- assure that all transport regulations and requirements are met

Always follow universal precautions

Key Messages

- the laboratory must have good samples in order to ensure accuracy and reliability of testing and confidence in results
- sample management directly affects patient care and outcome

Questions?

Comments?

References

- Recommended list of e-books.
- https://apps.who.int/iris/bitstream/handle/10665/44665/9789241548274_eng.pdf;jsessionid=86699B950C2CBD7E7EB268F807CEEFDA?sequence=1
- https://books.google.co.in/books?id=FQaOq7Tuc_cC&printsec=frontcover&dq=Laboratory+Quality+Management&hl=en&sa=X&ved=0ahUKEwiSh9u18czjAhXFF3IKHcBgAF4Q6AEILDAB#v=onepage&q=Laboratory%20Quality%20Management&f=false
- https://books.google.co.in/books?id=vGLa5Dy2d24C&printsec=frontcover&dq=Laboratory+Quality+Management&hl=en&sa=X&ved=0ahUKEwiSh9u18czjAhXFF3IKHcBgAF4Q6AEIMTAC#v=onepage&q=Laboratory%20Quality%20Management&f=false