FOR414
Chapter 5
Quality Management

Jamie Kim
Department of Chemistry
Buffalo State College

Potential Issues of Chemical Analysis

For drug test (crime lab or workplace requirement)

- Where do I get tested?
- How do they test (sampling, analysis, and report)?
- Can I trust their test results (accuracy, consistency)?
- Who allowed them to conduct drug test (accreditation, licensing or permission)?
- How authorities (gov or org) make them practice properly?

>> more than chemistry issues

Quality

- ISO (International Organization for Standardization): *The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs*.
- A product has good quality when it *"complies with the requirements specified by the client".*
- For chemical analysis, quality can be defined as *"delivery of reliable information within an agreed span of time under agreed conditions, at agreed costs, and with necessary aftercare".*
- The "agreed conditions" should include a specification as to the precision and accuracy of the data which is directly related to "fitness of use" and which may differ for different applications

QA vs QC

- Quality Assurance (QA): the planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled.

- Quality Control (QC): the operational techniques and activities that are used to satisfy quality requirements for products or services.

For Discovered Errors or Mistakes

- what error was made?
- where was it made?
- when was it made?
- who made it?
- why was it made?

These questions should be answered to avoid same errors/mistakes

Activities involved in Quality Control

1. First-line control: Instrument performance check.

2. Second-line control: Check of calibration or standardization.

3. Third-line control: Batch control (control sample, identity check).

4. Fourth-line control: Overall check (external checks: reference samples, inter-laboratory exchange programs).

Conditions for Quality Work

1. means are available (adequate personnel and facilities)
2. efficient use of time and means (costs aspect)
3. expertise is available (answering questions; aftercare)
4. upholding and improving level of output (continuity)

GLP (Good Laboratory Practice)

1. Similar concept of Quality Management (QM)

2. the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported.

3. prescribes a laboratory to work according to a system of procedures and protocols.

4. a policy for all aspects of the laboratory which influence the quality of the analytical work.

Scopes of GLP

1. allow better laboratory management (including quality management)
2. improve efficiency (thus reducing costs)
3. minimize errors
4. allow quality control (including tracking of errors and their cause)
5. stimulate and motivate all personnel
6. improve safety
7. improve communication possibilities, both internally and externally.

Result: performance of a laboratory is improved and its working effectively controlled

GLP

1. - say what you do
2. - do what you say
3. - do it better
4. - be able to show what you have done

all relevant plans, activities, conditions and situations are recorded and that these records are safely filed, can be produced or retrieved when necessary, and can be demonstrated to authorities and clients.

Quality Manual

It contains information on:

- Organization and Personnel
- Facilities
- Equipment and Working materials
- Analytical or testing systems
- Quality control
- Reporting and filing of results.

Standard Operating Procedure (SOP)

- A SOP is a document which describes the regularly recurring operations relevant to the quality of the investigation.
- The purpose of a SOP is to carry out the operations correctly and always in the same manner.
- A SOP should be available at the place where the work is done.
- The whole process from sampling to the filing of the analytical result should be described by a continuous series of SOPs

Types of SOP

- Fundamental SOPs: These give instructions how to make SOPs of the other categories.
- Methodic SOPs: These describe a complete testing system or method of investigation.
- SOPs for safety precautions.
- SOPs for operating instruments, apparatus and other equipment.
- SOPs for analytical methods.
- SOPs for the preparation of reagents.
- SOPs for receiving and registration of samples.
- SOPs for Quality Assurance.
- SOPs for archiving and how to deal with complaints.

Each SOP Page Contains

All or some of followings,

a. date of approval and/or version number;
b. a unique title (abbreviated if desired);
c. the number of the SOP (preferably with category);
d. page number and total number of pages of the SOP.

First or Title Page of SOP Contains

All or some of followings,

a. general information mentioned in previous slides, including the complete title;
b. a summary of the contents with purpose and field of application (if these are not evident from the title);
c. any related SOPs (of operations used in the present SOP);
d. possible safety instructions;
e. name and signature of author, including date of signing.
f. name and signature of person who authorizes the introduction of the SOP (including date).

SOPs

- SOPs for operating instruments, apparatus and other equipment.
- SOPs for analytical methods.
- SOPs for the preparation of reagents (or samples).

Specific methods for these SOPs are generally adopted (modified) from testing methods developed (approved) by federal agencies (EPA, FDA, FBI, SAMHSA, etc) or authority groups (ASTM, SWGDUG, etc)

Example

- *TestAmerica* has SOPs for testing chemicals

  1. EPA Method 8081 Insecticides
  2. EPA Method 8151 Herbicides
  3. EPA Method 8081 Organochlorine Pesticides
  4. EPA Method 8141 Organophosphorous Pesticides
  5. etc

- Accreditations/Approval/Compliance/Affiliation
  1. DoD Environmental Laboratory Approval Program (ELAP) and Quality Systems Manual (QSM)
  2. ISO 17025:2005
  3. approvals in all 50 U.S. States

Methods

- EPA (Environmental Protection Agency): Environmental related chemicals (e.g. Method 8081 Insecticides)
- FDA: Food/Drug related chemicals (e.g., Pesticide Analytical Manual (PAM))
- SAMHSA (Substance Abuse and Mental Health Services Administration : Drug of abuse (cocaine in urine, etc)
- Modified methods from these agencies

Environmental Laboratory Accreditation

- NELAP (Environmental Laboratory Accreditation Program) accreditation for agricultural chemicals

http://www.epa.gov/fem/accredit.htm

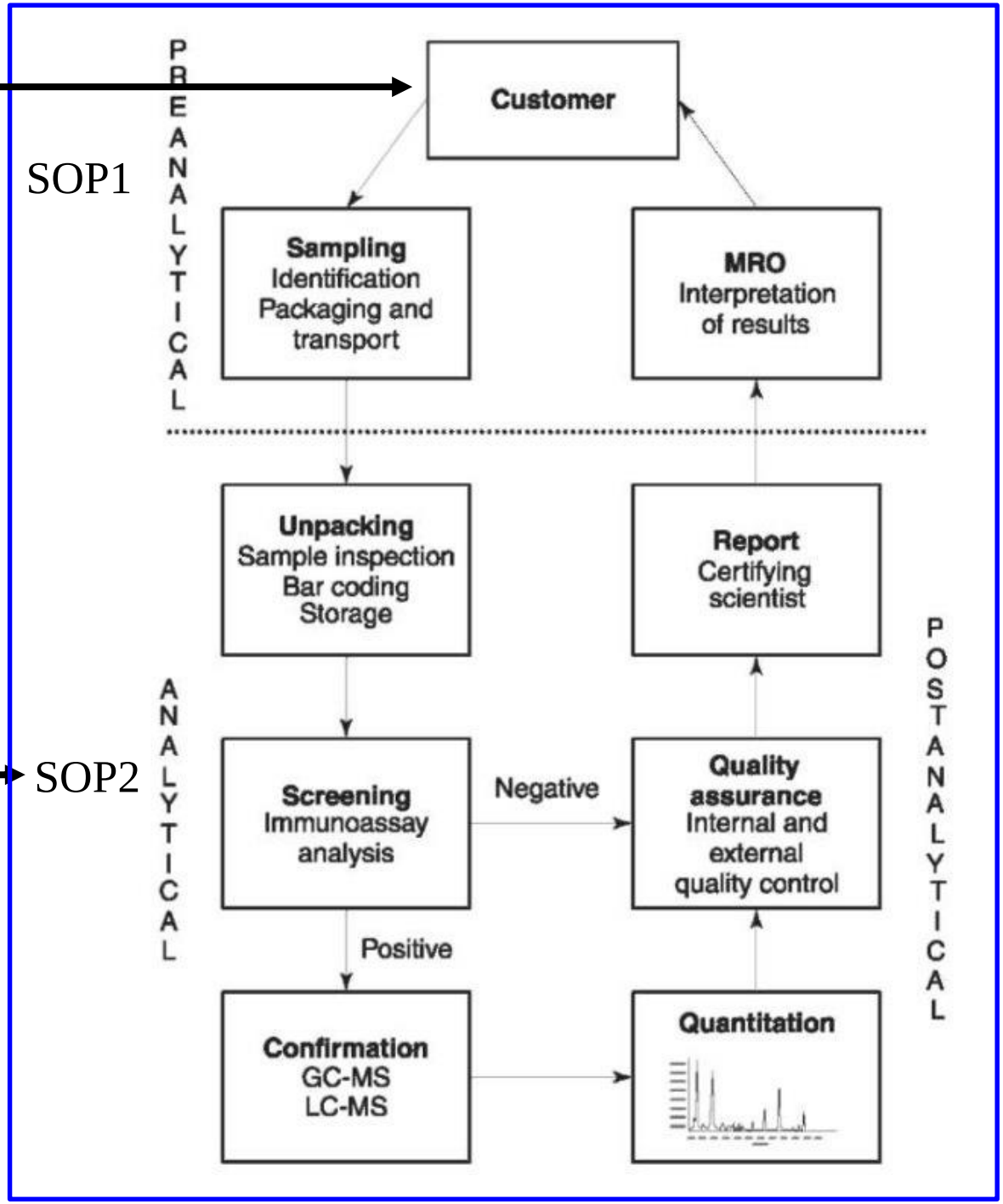
Accreditation of Forensic Lab

- The Crime Laboratory Accreditation Program of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)

- ABFT (Accredited Forensic Toxicology Laboratories)

LAW (CSA)

SOP1



Medical Review Officer (MRO)

permission

NYS

accreditation

ASCLD/LAB

FDA
SAMHSA

SOP2

method

Chain of Custody

- A chain of custody is a mechanism for tracing the lineage of a sample from the time of collection through reporting of results to sample disposal.

- Forensics: Chain-of-custody is the ability to give an accurate accounting in a court of law as to the manner in which evidence was acquired, maintained, transported, examined, etc., by whom, when, where, and for what purpose..

- SOP

LABORATORY CHAIN-OF-CUSTODY FORM

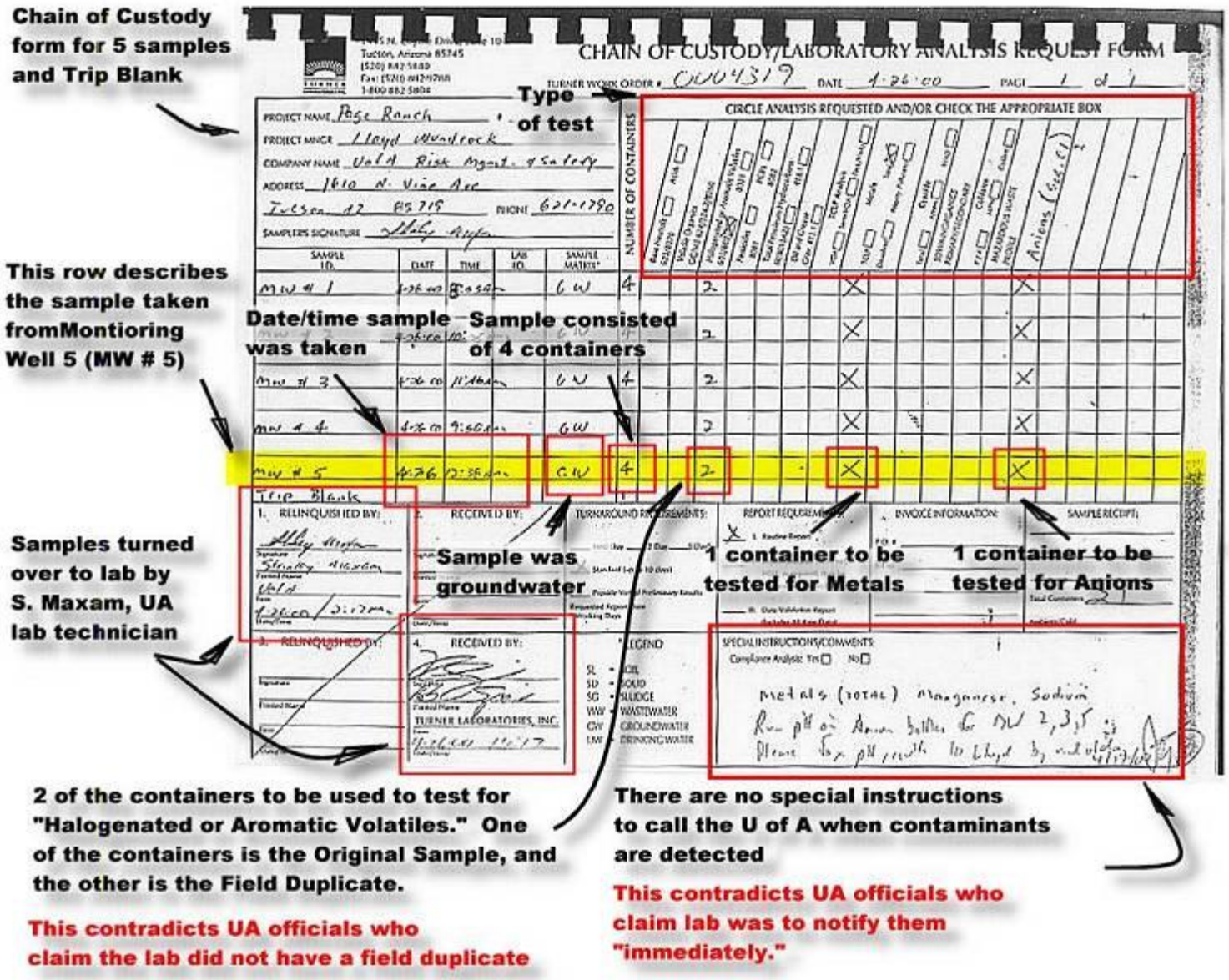
Relinquished By	Organization	Date/Time	Received by	Organization	Date/Time
9. **Signature:** **Print Name:**			**10.** **Signature:** **Print Name:** **Sealed: [ ] Yes [ ] No**		

SECTION 4 **DCLS Use Only**

Laboratory Description of Sample: Include the number of containers, identification number(s) and a physical description of each item submitted for testing.	
Signature:	**Date:**

SECTION 5 – Evidence Disposal (To be completed by Laboratory Evidence Custodian)

Disposition Site:	**Disposition No.:**	**Method of Disposition/Date:**
Performed by:		**Date:**
Witnessed by:		**Date:**


Chain of Custody form for 5 samples and Trip Blank
CHAIN OF CUSTODY/LABORATORY ANALYSIS REQUEST FORM
Type of test
This row describes the sample taken fromMontioring Well 5 (MW # 5)
Date/time sample was taken
Sample consisted of 4 containers
Samples turned over to lab by S. Maxam, UA lab technician
Sample was groundwater
1 container to be tested for Metals
1 container to be tested for Anions
2 of the containers to be used to test for "Halogenated or Aromatic Volatiles." One of the containers is the Original Sample, and the other is the Field Duplicate.
This contradicts UA officials who claim the lab did not have a field duplicate
There are no special instructions to call the U of A when contaminants are detected
This contradicts UA officials who claim lab was to notify them "immediately."