Auditing a Quality System Process

Cambridge 2007

Quality System Requirements

- The laboratory's quality system is the process by which the laboratory conducts its activities so as to provide the client with data of **known and documented quality** with which to demonstrate regulatory compliance and for other decision-making purposes.

Known and Documented Quality

BOSE

i'm lovin' it

OUTBACK RESTAURANT

Auditing a Quality System

- Training
- Records
- Corrective Action & Complaints

Training - Requirement

- The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. (5.5.2.2)
- The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training skills, and experience of all technical personnel. (5.5.2.5)

Training Files – What to look at?

- **Training files documentation**
  1. Ethics and Data Integrity training (initial and annual)
  2. Initial Demonstration of Capability (DOC)
  3. Continuing DOC
  4. Documentation of reading SOP
  5. Additional relevant training

Training

- If possible review the training file with analyst

Training – Other Clues

- Interviews with analyst – Ask how they got the responsibility to run a particular method
- Who taught and trained them. Was the training a “Crash Course”?
- Interviews with Director and QAO – “We just lost our metals analyst…”

Training – Follow up

- When a lab adds a new technology, Follow up is a must.

Training

- Being “UNDERSTOOD” is met when elements are read and signed off as being understood, by definition.
- Having competency to perform the task goes beyond the training files!

Corrective Action & Complaints

- The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified. (5.4.10.1)

Corrective Action & Complaints

- Purpose of evaluation of CA system is NOT to punish a lab for self discovery.
- Should not use laboratory CA system to write findings.
- We want the labs to correct the problems before we find them.
- The purpose is to make sure that the lab has an effective CA system.

Corrective Action & Complaints

- **5.4.10.2 Cause Analysis**
- The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem
- Not assessment teams responsibility to ensure that labs get to the root cause, only that problems are being taken care of.

Corrective Action & Complaints

- Some labs truly don’t have that many corrective actions and complaints. (Single method labs)
- Some labs should have better corrective action systems.

Corrective Action & Complaints

- Help labs see the value to self discovery and correction.
- Good labs see the value of internal audits and use them as a tool.


Records Review

Records Review

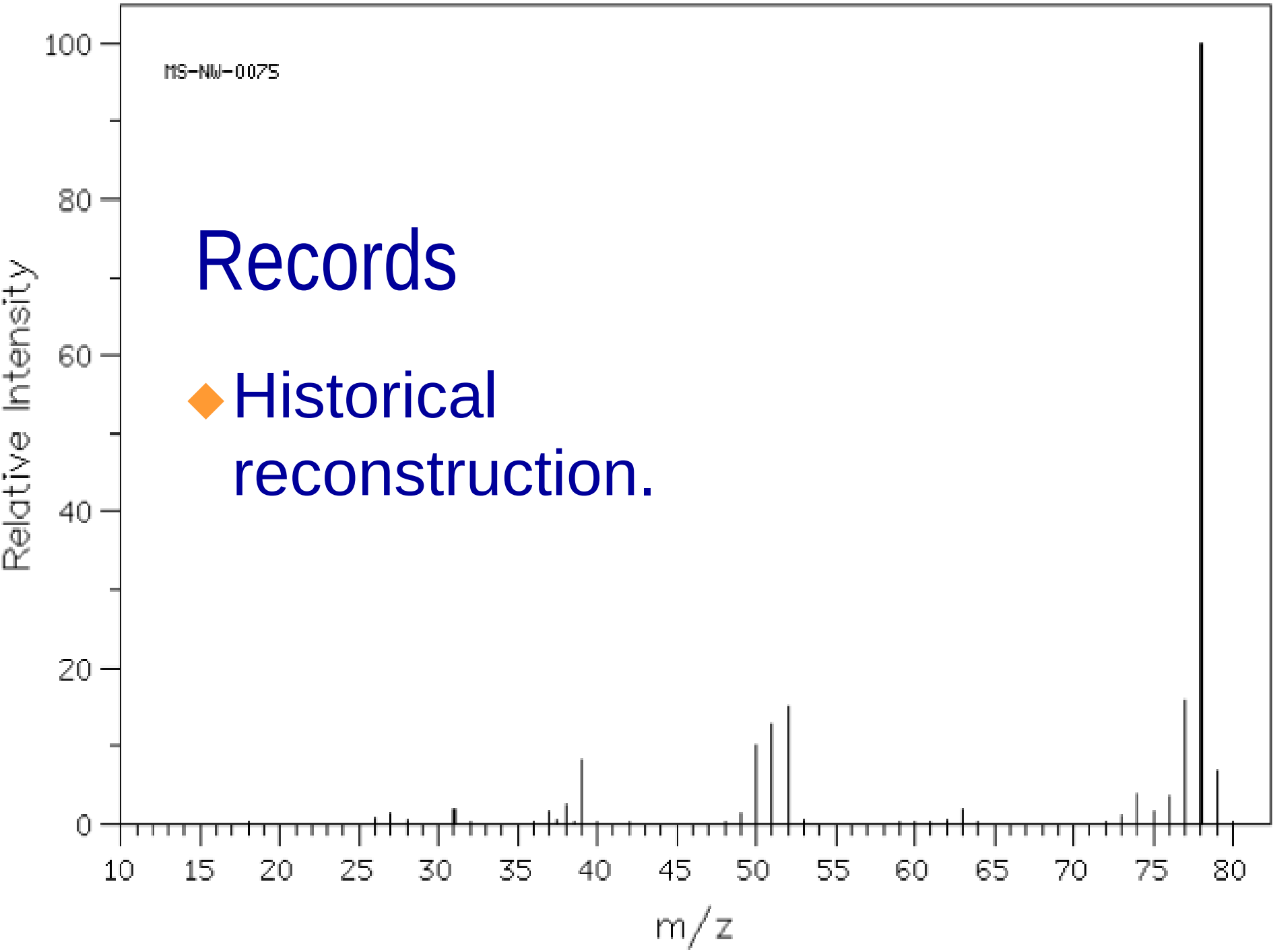
- maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal
- legible and readily retrievable

Records

- Training files
- Equipment, standards & certificates
- Historical reconstruction

Records

- Support equipment



Records

- Historical reconstruction.

Records

- The point of record review is to make sure the data is of a “known and documented quality”


Questions