


Differentiating Between Routine Assessments and Investigations

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Major Differences

- Purpose
 - Management Involvement
 - Focus
 - Resolution
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- A decorative graphic consisting of several overlapping, wavy, light gray lines that flow from the right side of the slide towards the left, positioned in the lower right quadrant.

Purpose

□ The purpose of a laboratory assessment is to determine the ability of the laboratory to perform sample analyses while following all of the appropriate state and federal protocols.

□ An investigation is an inquiry to determine the validity of an allegation or accusation about a laboratory and the data it produces

Management Involvement

- Laboratory assessments
 - Encourage management to be involved
 - Laboratory managers retain control over data and personnel during an assessment
 - Management and assessors come to an agreement on how to resolve issues
 - Exchange of information on both sides

 - Investigations
 - leave managers with very little control over personnel or data
 - Investigators are not obligated and in some instances forbidden to share information
 - Resolution often involves attorneys
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Focus



- Review the same documents
 - Interview the same lab personnel
 - Verify compliance
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Document Review

The investigation picks up where the assessment leaves off

- assessors review SOPs to determine if the laboratory knows what the proper procedure is for a given method
 - They are used to demonstrate that the laboratory intends to conduct business in an ethical manner and requires the same of its employees
 - Investigators use SOPs to prove the laboratory knew what the proper procedure was and therefore any deviation was intentional
 - They are used to prove that the laboratory or analyst was aware that their behavior was improper
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Quality Assurance Manual

□ The quality assurance manual is reviewed to ensure the laboratory has auxiliary procedures in place to ensure data are of known quality and scientifically valid

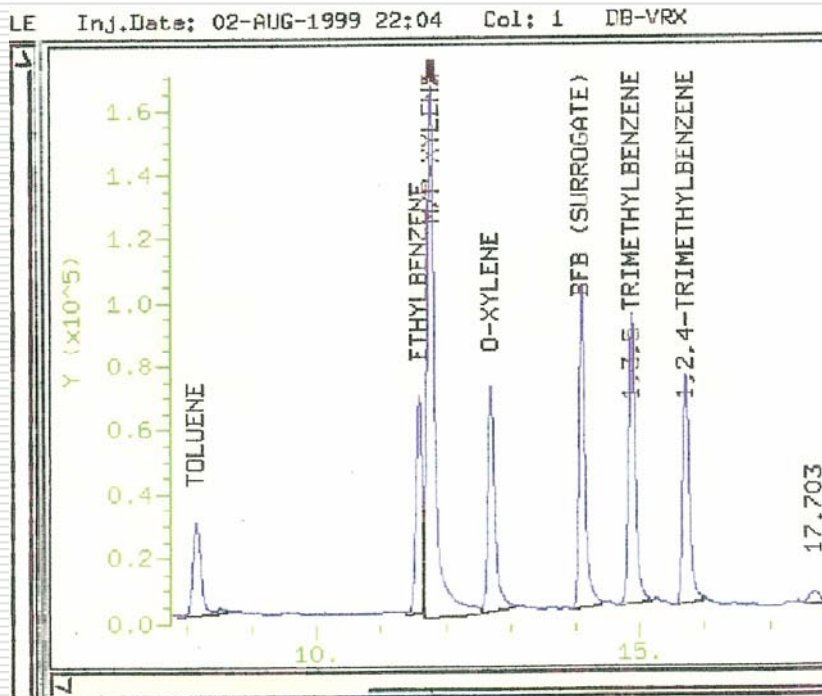
□ The quality assurance manual is used to demonstrate that the laboratory understands what makes data acceptable, that data review procedures are in place and that corrective actions are detailed. Failure to properly review data or take appropriate corrective action when data were known to be unacceptable constitutes intent and in some cases fraud and conspiracy

Training Records

- ❑ assessors use training records to ensure that analysts know how to perform a method and thus can have a measure of confidence in future data.
- ❑ Investigators use training records to prevent analysts from using ignorance as a defense. Lack of training can be used to demonstrate management negligence.

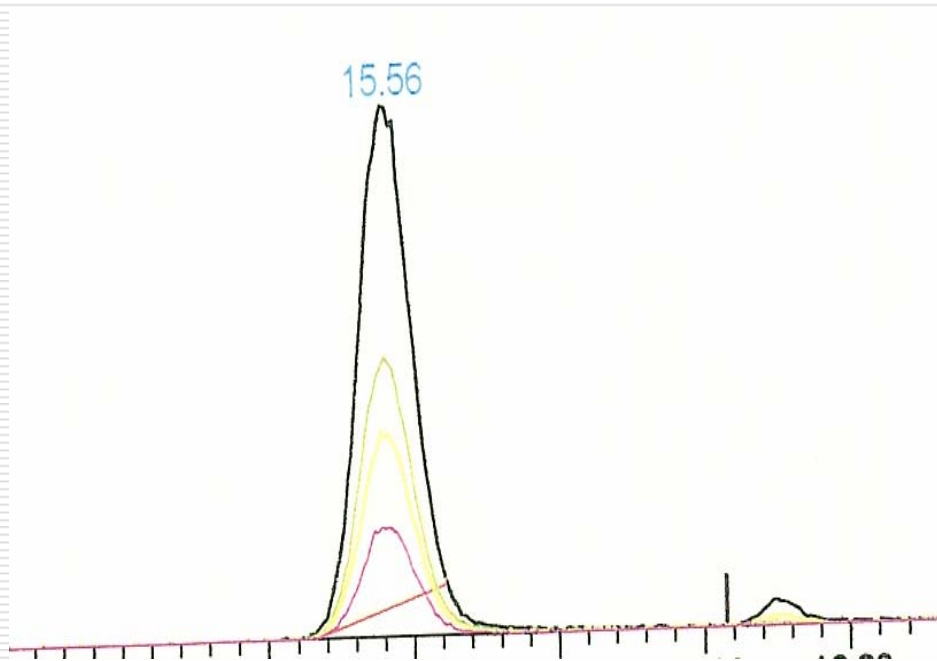


Data Review



- assessors look at a snapshot of data to make sure it is being done *right*

Data Review



- ❑ Investigators look at months to years of data to determine what is *wrong* and the scope
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Interviews

- assessors interview analysts to ensure they have the knowledge and skills to perform the methods correctly and safely
- Investigators interview to determine what an analyst knows about the wrongdoing and if applicable, get a confession



assessment Resolution



- assessments focus on compliance
 - Informing/teaching
 - Corrective action
 - Prevention

Investigation Resolution

- Investigation resolution is focused on enforcement
 - Restitution (money)
 - Prosecutorial Action (criminal charges)
 - Determent

