

Auditing in ISO 15189



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What does ISO 15189 say?

- The quality system **must** undergo **internal** and **external** audits.
- ISO 15189 specifically **requires annual internal audits**.
- The **purpose audits** is to verify that the laboratory is in **compliance with the quality system**.
- **Internal audit findings must** be **documented** to **develop a plan to correct**
- Again, **documenting actions taken** creates a quality record.

Different types of audits

- **Internal Audits**
- **Intra Organization Audits**
- **External Audits**

EXTERNAL
AUDITOR



Internal / Intra Organization Audits

- Focus will be on **Internal / Intra Organization Audits**
- Only performed by **competent and trained personnel**
- Important Nigerian Context – no body

Internal Audit
Spotlight

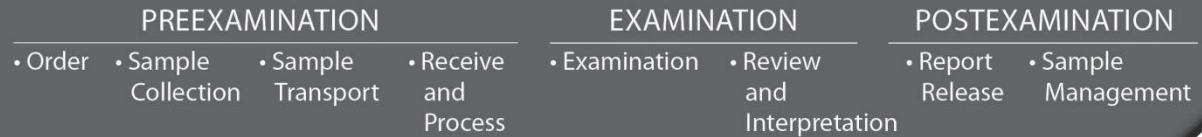


The Quality Management System Model

DISCIPLINES

- Chemistry
- Hematology
- Microbiology
- Transfusion Medicine
- Anatomic Pathology
- Cytology
- Immunology
- Genetics
- Etc.

LABORATORY PATH OF WORKFLOW



QUALITY SYSTEM ESSENTIALS



International • National • Regional • Local • Organizational Requirements

Intended use of Internal Audits

- **Directors**
- **Managers**
- **Supervisors**

- **Applicable to laboratories of all sizes**

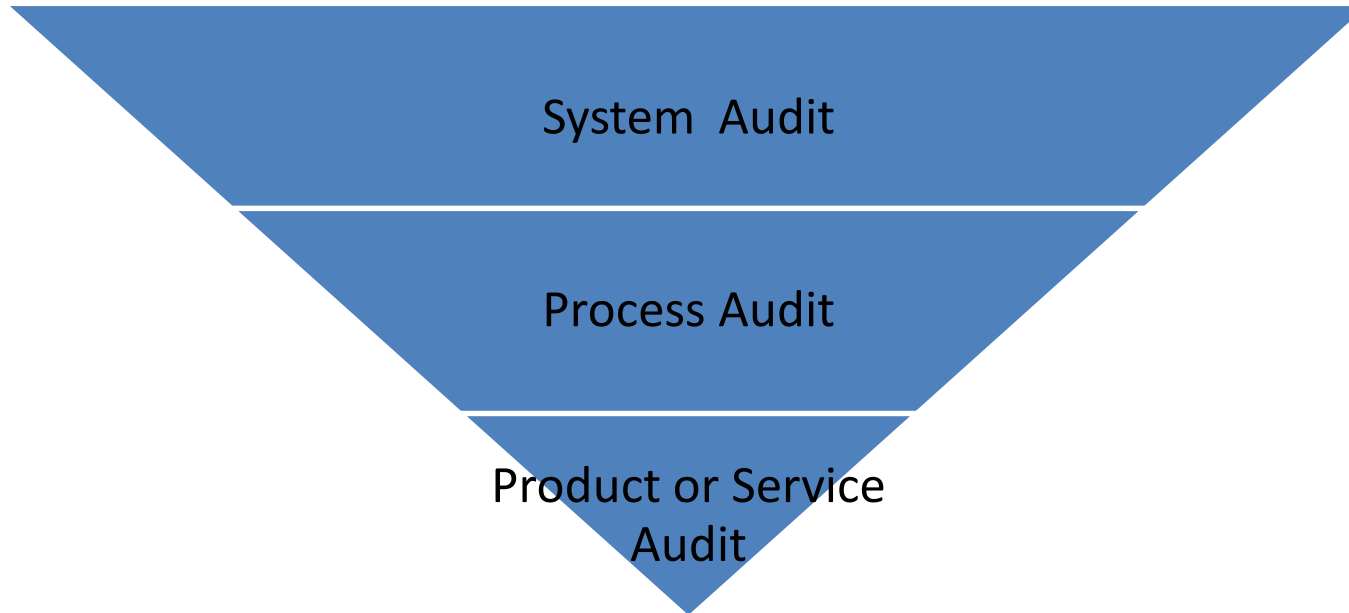
Benefits of Laboratory Internal Audit Program

- There are many... to name a few
- The **benefits** of conducting internal audits are of **astronomical value** to any medical laboratory
- **Regularly scheduled internal audits** of the laboratory's QMS move a laboratory from a **mode of reactive-corrective action** to that of **proactive, continual improvement**.
- The improvements made through internal audits are **directly tied to quality planning, performance**.

Keys to a successful Internal Audit Program

- **Commitment** by leadership
- **Collective desire** to improve quality
- Understanding audit is an **ongoing process**
- **Compressive planning** and resource allocation
- Must have **trained & knowledgeable staff**

Types of audits



- **The audit is further divided into retrospective and prospective types.**
- **A retrospective audit captures information on outcomes that have occurred in the past,**
- **Whereas a prospective audit captures information in real time.**

How audit is conducted...

- How the audit is conducted is further divided into retrospective and prospective types.
- A retrospective audit captures information on outcomes that have occurred in the past,
- Whereas a prospective audit captures information in real time.
- Retrospective audits require reviews of selected records
- Whereas prospective audits use direct observation.

Practical Methods of audits as described in ISO 15189

- Traditionally audits finds non-conformities... Fed Up – un constructive...
- Look – what might go wrong
- ... used to find potential non-conformities or opportunities for improvement
- Pathologists...62, 63, 64



4 Management requirements

4.14 Evaluation and audits

Practical Methods of audits as described in ISO 15189

- Horizontal – Contaminated Blood tubes
- Vertical – Vein to Brain
- Witness – Employee competence



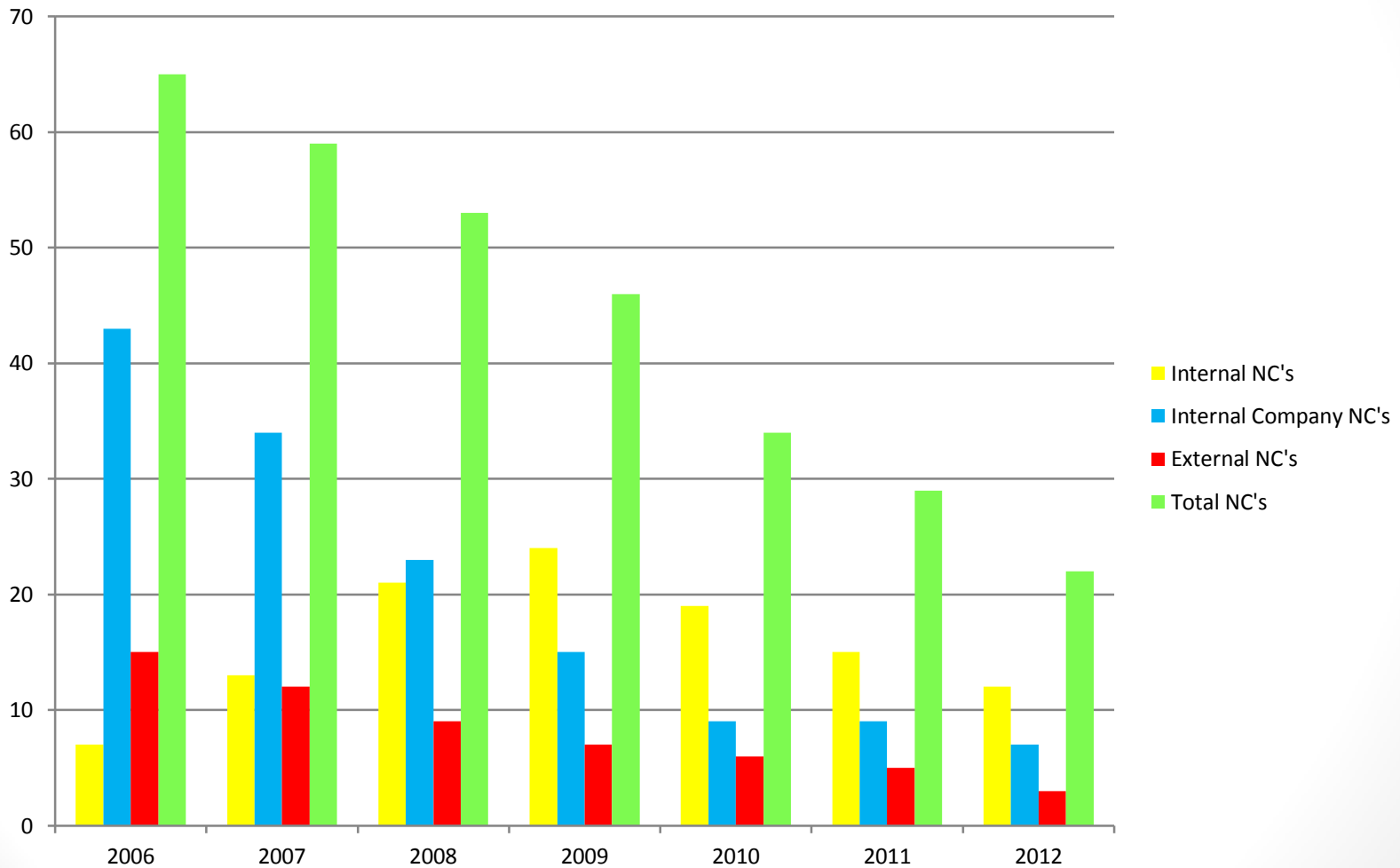
4 Management requirements

4.14 Evaluation and audits

Audit schedule

- Types...
- Annual Scheduled Audits
- Ideally scheduled:
Reduce stress / Elicit staff cooperation
- Unscheduled Audits
Not ideal, only if
- Serious complaint, breach of confidentiality

Example...



Conclusion

The value of internal audits **can not be overstated.**

Internal audits is the **glue** that **bonds** the whole **quality management system together**

.....and **ultimately ensures Quality** in each and every process.

- In the PathCare Internal Audit team...
- ... there is a slogan we use...

In God We Trust and
All Others We Audit.

