

Audit



SOFTWARE QUALITY

AUDIT

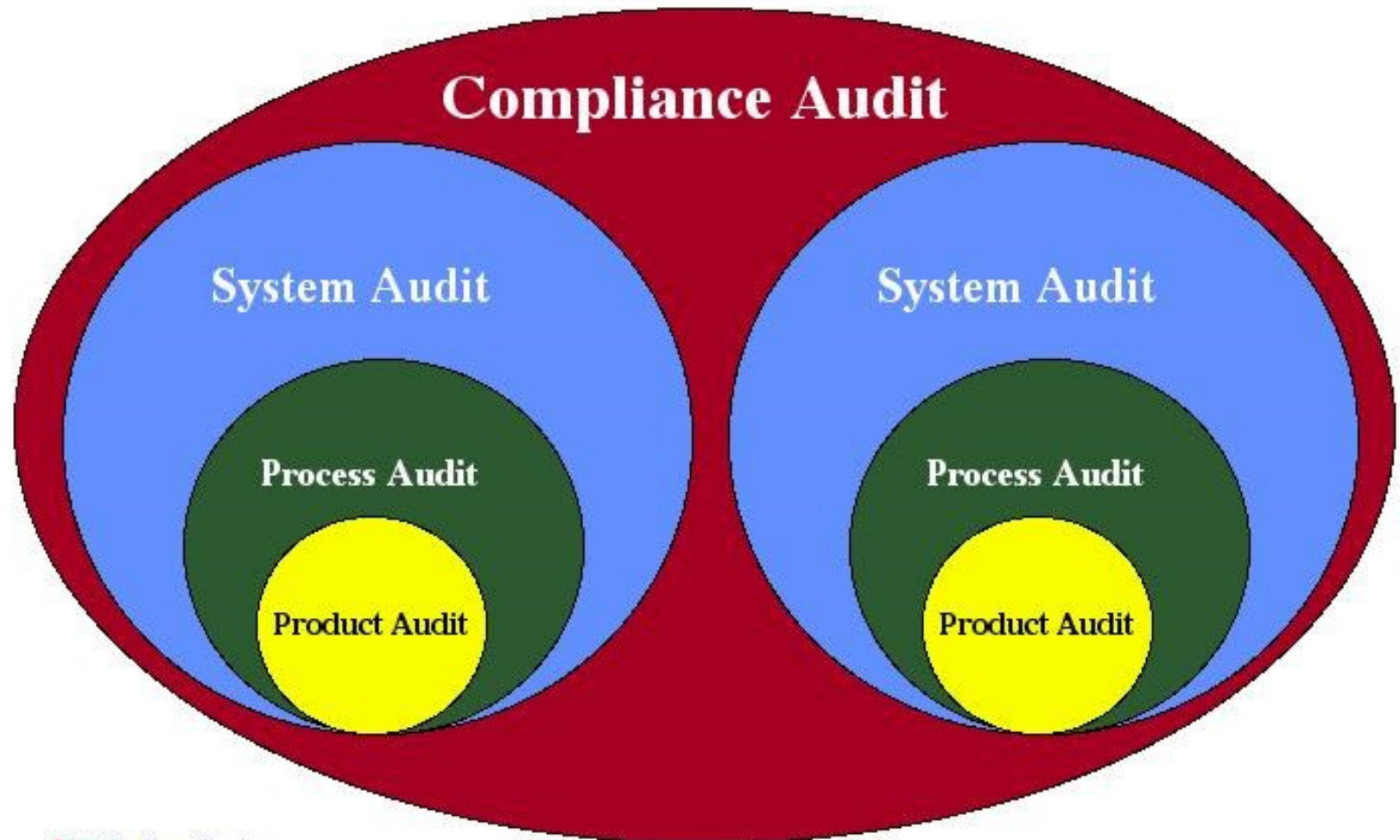


- The general definition of an **audit** is an evaluation of a person, organization, system, process, enterprise, project or product.
- **Quality audit** is the process of systematic examination of a quality system
 - ❖ carried out by an internal or external quality auditor or an audit team
 - ❖ It is an important part of organization's quality management system and is a key element in the ISO quality system standard, ISO 9001.

Basic Types of Audits

- **Internal** (First Party, Self)
 - This type includes audits by your company employees, consultants and contractors.
- **External**
 - **Supplier Audit**
 - ✦ **Second Party**
 - This is where: 1. Customer employee(s) audit your company or where 2. Your employee(s) audit a company which supplies your company with a product or service.
 - **Independent Organization**
 - ✦ **Third Party - Registrar**
 - A customer wants an audit of your company but wants your company to pay for it.
 - This type of audit is described as independent. In QS-9000 this is not really the case.

Audit Types



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Auditing and Being Audited

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- ***Audit of product***

- *quantitative evaluation of conformity of product requirement.*

- ✦ Quantitative [evaluation](#) is an assessment process that answers the question, "How *much* did we do?"
 - ✦ Qualitative [evaluation](#) is an assessment process that answers the question, "How *well* did we do?"

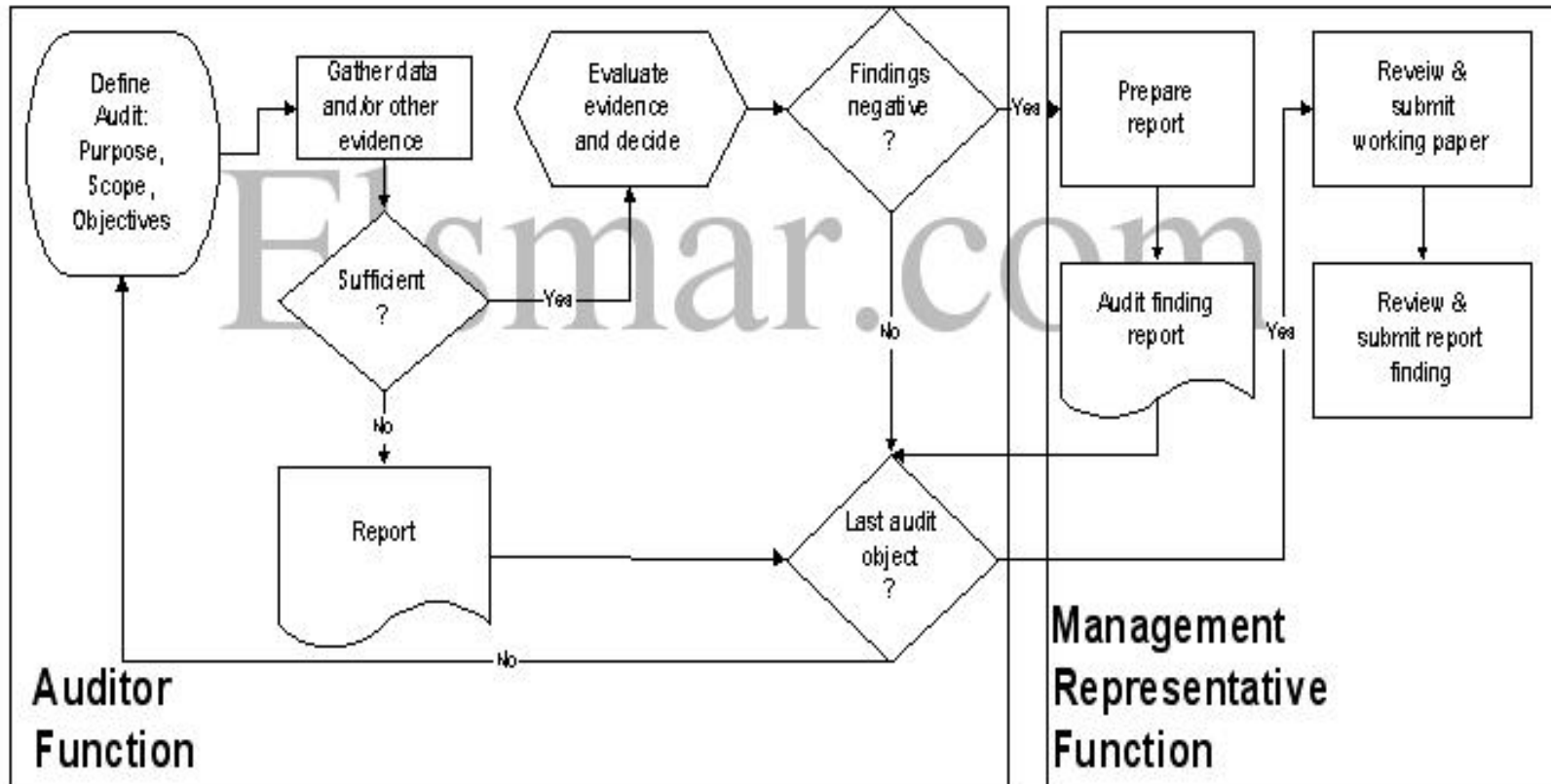
- ***Audit of process***

- *process and test for completeness, effectiveness, improvement*

- ***System Audit***

- *Examine the existing elements of a quality assurance are complete, effective and documented in compliance with specifications.*

A Typical Audit System



Definitions: “Who”

- **Auditor:** A person who has the appropriate qualifications and performs audits.
- **Client:** A person or organization requesting the audit. For internal audits, this is the *Management Representative*.
- **Auditee:** An organization, facility or person being audited.



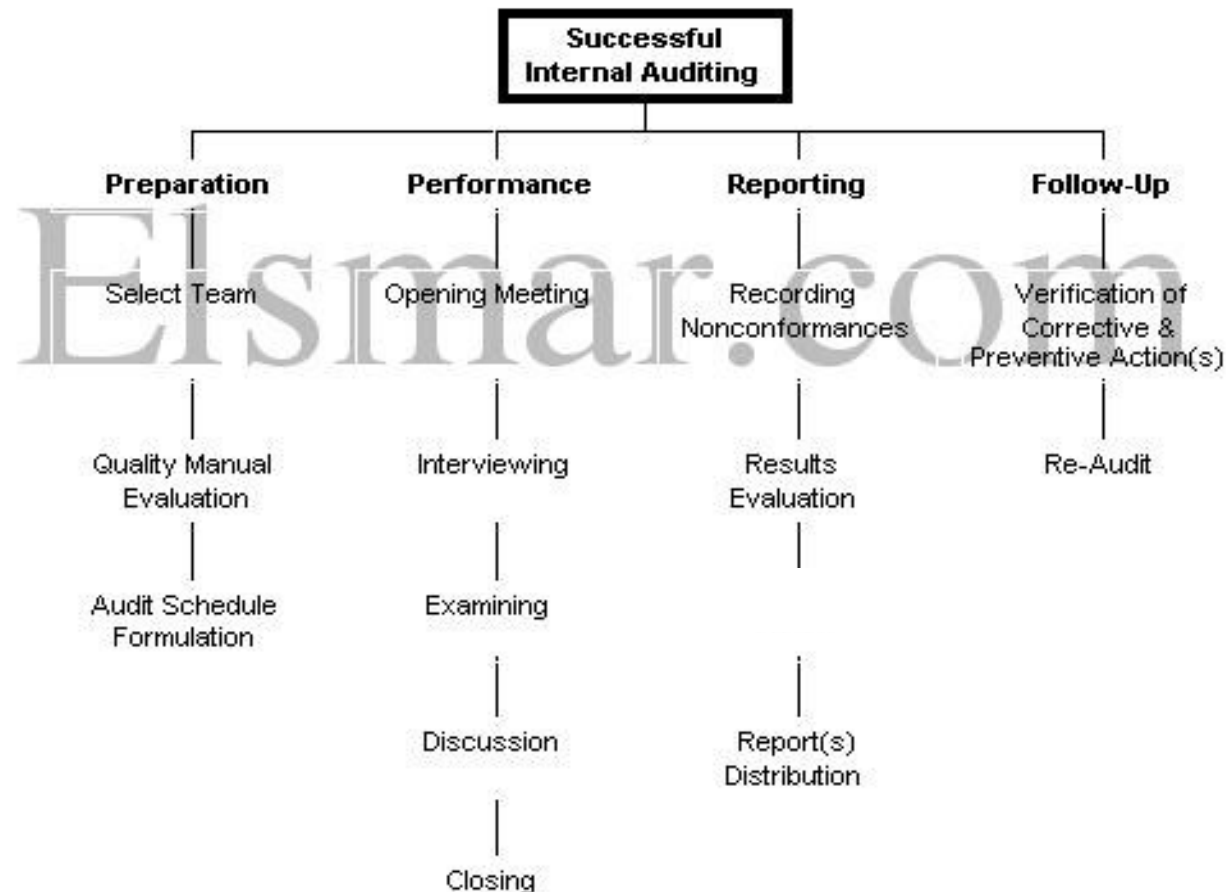
Definitions: “What”

- **Quality System:** The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.
- **Observation:** A statement of fact made during an audit and substantiated by objective evidence.
- **Objective Evidence:** Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.
- **Nonconformity:** The nonfulfillment of specified requirements.

Phases of Auditing

- **P**lanning and **P**reparing for the audit
- **E**xecution of the audit plan
- **R**eporting the audit results
- **C**lose out of corrective actions

The 'Standard' Four Phases



Quality Audit

A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the stated objectives.

One Definition



Objective Evidence



- Auditing is ALL about Objective Evidence. As in a police investigation, you have to have evidence and it has to be objective.

- It exists and is 'retrievable'
- Not influenced by emotion or prejudice
- Based on observation
- Verbal or documented
- Verifiable
- May be quantitative
- Within the systems being audited
- Take Detailed Notes!!!

Objective Evidence II

Registrar Non-Conformance Record

| | |
|--|----------------------------------|
| Customer Name: _____ | Date: _____ |
| Registrar Auditor: _____ | Auditor Initials / Number: _____ |
| Location of Nonconformance: _____ | Non-conformance Number: _____ |
| Customer Escort: _____ | Previously written up: YES or NO |
| If YES Non-conformance Number & Date: _____ | |
| Nonconformance written by registrar auditor: _____ | |
| Classified by Registrar X assessment term as: Major Minor Opportunity | |
| ISO 9000 Standard number and clause: _____ | |
| Non-conformance and Evidence: | |
| Customer Acknowledging the Evidence and Facts: _____ | |
| Response to nonconformance by customer: _____ | |
| Note: The plan or action to correct the non-conformance is due within 30 days. Please always reference the non-conformance number if responding on a separate sheet. | |

By signing here you should only be agreeing to what was found / observed. You should NOT be agreeing that there is definitely a nonconformance.

Reasons For Audits

One Purpose of Audits



Is To Remove Bear Traps

Audits, both internal and external, should be cited as a part of your company's **Preventive Action program**. They are in part meant to **detect problems early**. Identified nonconformances typically should trigger an investigation.

More Reasons For Audits

- ISO 9001 Requires Them (QS-9000 4.17 and ISO 9001:2000 8.2.2)
- A Control Mechanism Used By Management
- Tool For Continuous Improvement
- Correct Nonconformities In Systems
- Helps Assure Ongoing Systems Operate As Intended And Required

The Audit Must Be



Open, Honest, and Constructive

The Person or Activity Being Audited **Always** Gets the Benefit of the Doubt.

Validation



- Random Basis
- Auditor Chosen
- Permission
- Factual Agreement
- Objectivity
- Be Polite
- Be Professional

Auditors Are *Not*....

- Inquisitors
- Fault Finders
- Rock Throwers
- Avenging Angels
(Biased For or Against)
- Dishonest
- Overactive



Why A Formal Audit Program?

- To ensure the documented systems meet specified requirements.
- To ensure the documented systems are practical, understood, and followed throughout the business.
- To maintain records of audit activity including areas audited, nonconformances, and corrective and preventive actions.

The Internal Audit

The **Systematic** Investigation
of the **Intent**, **Implementation**, and
Effectiveness
of Selected Aspects of the **Systems**
of an **Organization**
or One or More of It's **Departments**

IIA's Definition Of Internal Audit

Definition according to the **Institute of Internal Auditors**
(IIA)

<http://www.theiia.org>

- ✳ "Internal auditing is an **independent**, **objective assurance** and **consulting activity** designed to **add value** and improve an organization's operations.
- ✳ It helps an organization accomplish its objectives by bringing a **systematic, disciplined approach** to **evaluate** and **improve** the **effectiveness** of **risk management, control**, and **governance processes**."

Internal Audit System Base Requirements

- Documented system
 - Remember 8.2.2 in ISO 9001:2000 and 4.17 in QS-9000
- You must have a Schedule
 - Preferably 1.5 year minimum
- Effective Corrective Element
 - Including An Escalation 'Trigger'
- Verification of Corrective Action
 - You **CAN NOT** close an audit out until the *effectiveness* of the corrective action is **verified** and **validated**!
- Input of results into Management Review
 - This must include any specific problem areas as **this is the highest level in the escalation feature of your system.**
- 'Inclusion of working environment' (QS-9000)

Internal Audit System Base Requirements

There are several **very important features** to bear in mind:

- It is important to consider whether the identified nonconformance is a 'repeater' (recurrent).
- Particularly in internal auditing, disagreements arise which must be resolved by the audit program manager (or the equivalent).
- Not every nonconformance identified requires a formal corrective action.
- Some require a 'minimum' corrective action.
- Some require a serious, in-depth investigation following the 8-D format.

Role of the Internal Auditor

- A Catalyst
- An Interface Between Different Groups
- An Advisor
- A Reporter of Fact(s)



Internal Quality Auditing

- Is NOT a Police Force
- Is NOT an Inspection of Products
- Is NOT an Interrogation Task Force

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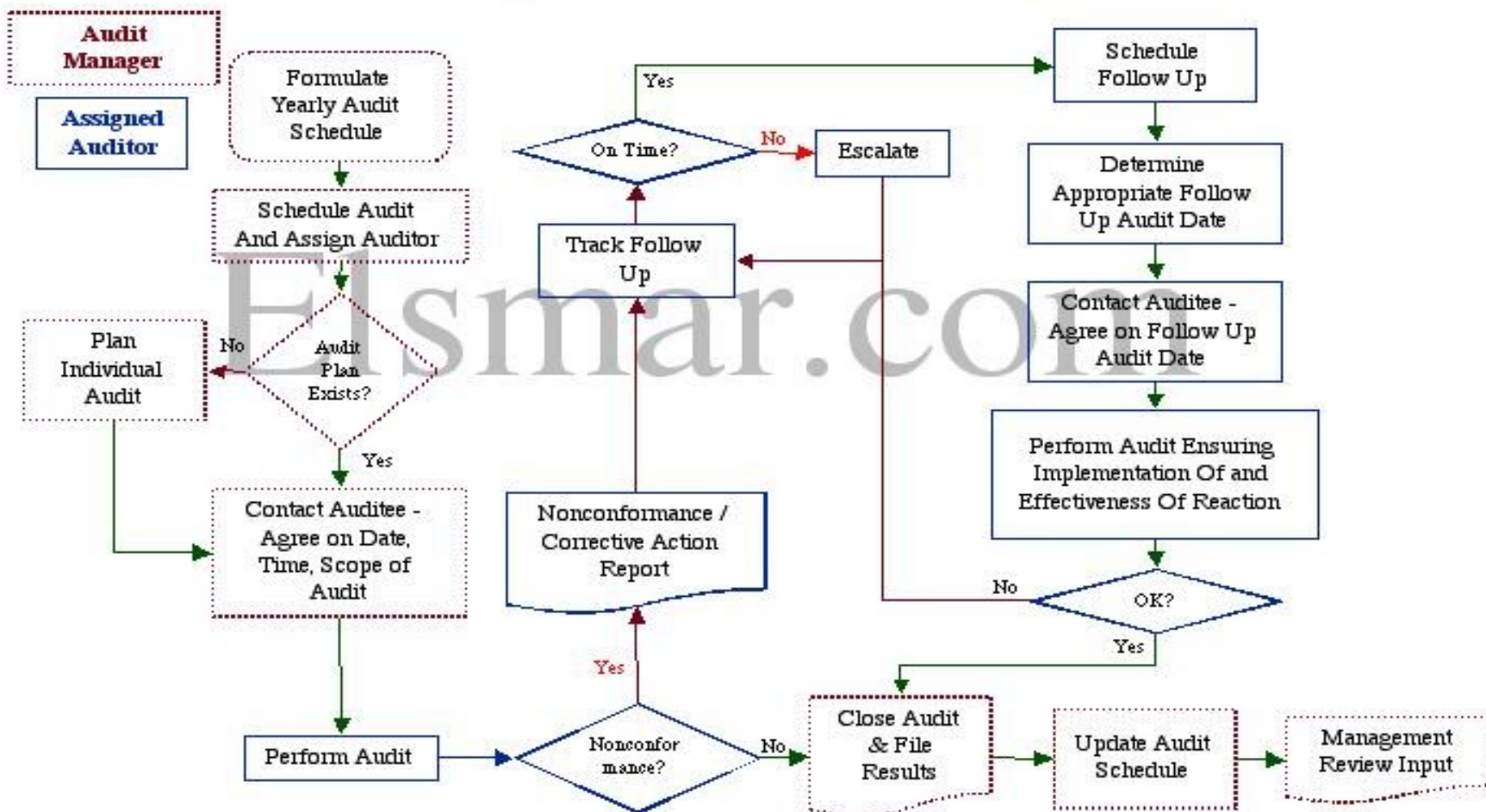
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Auditing and Being Audited

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Key: Box colour / line weight indicates responsibility

Example Internal Audit System





THANK YOU