AUDITING

Principles

AQS 115
QUALITY SYSTEMS & AUDITING PRINCIPLES

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AUDITING

- PRINCIPLES (Overview)

Developed as part of NSF ATE Grant #1304474

AUDIT

- Definition (Merriam-Webster dictionary)

  Audit (noun): a methodical examination and review

  - Financial (accounting)
  - **Quality Management**
  - Project Management
  - Energy Conservation
  - Forensic
  - Etc.

AUDIT

- a methodical examination and review
- Quality Management Audit – WHY?
  - Provide feedback for improvement
    - Differs from
      inspection which focusses on accept/reject or
      surveillance which is continuous monitoring

AUDIT

- a methodical examination and review
- QMS audits provide feedback for improvement
- Sources
  - Regulatory Inspections (new products, on-going surveillance)
  - ISO Registrar
  - Customer
  - Internal

1st Party Audit - Organization audits themselves Internal Audit
2nd Party Audit – Customer audits (supplier audits) External Audit
3rd Part Audit - Registrar (Regulatory) audits External Audit

INTERNAL AUDIT - Reference

- ISO9001:2015

  Section 9 Performance Evaluation

  9.2 Internal Audit

  9.2.1 "The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

  a) conforms to:

  1. the organization's own requirements for its quality management system;
  2. The requirements of this International Standard

  b) is effectively implemented and maintained……"

CUSTOMER AUDIT - Reference

- ISO9001:2015

  Section 8.4 Control of externally provided processes, products and services

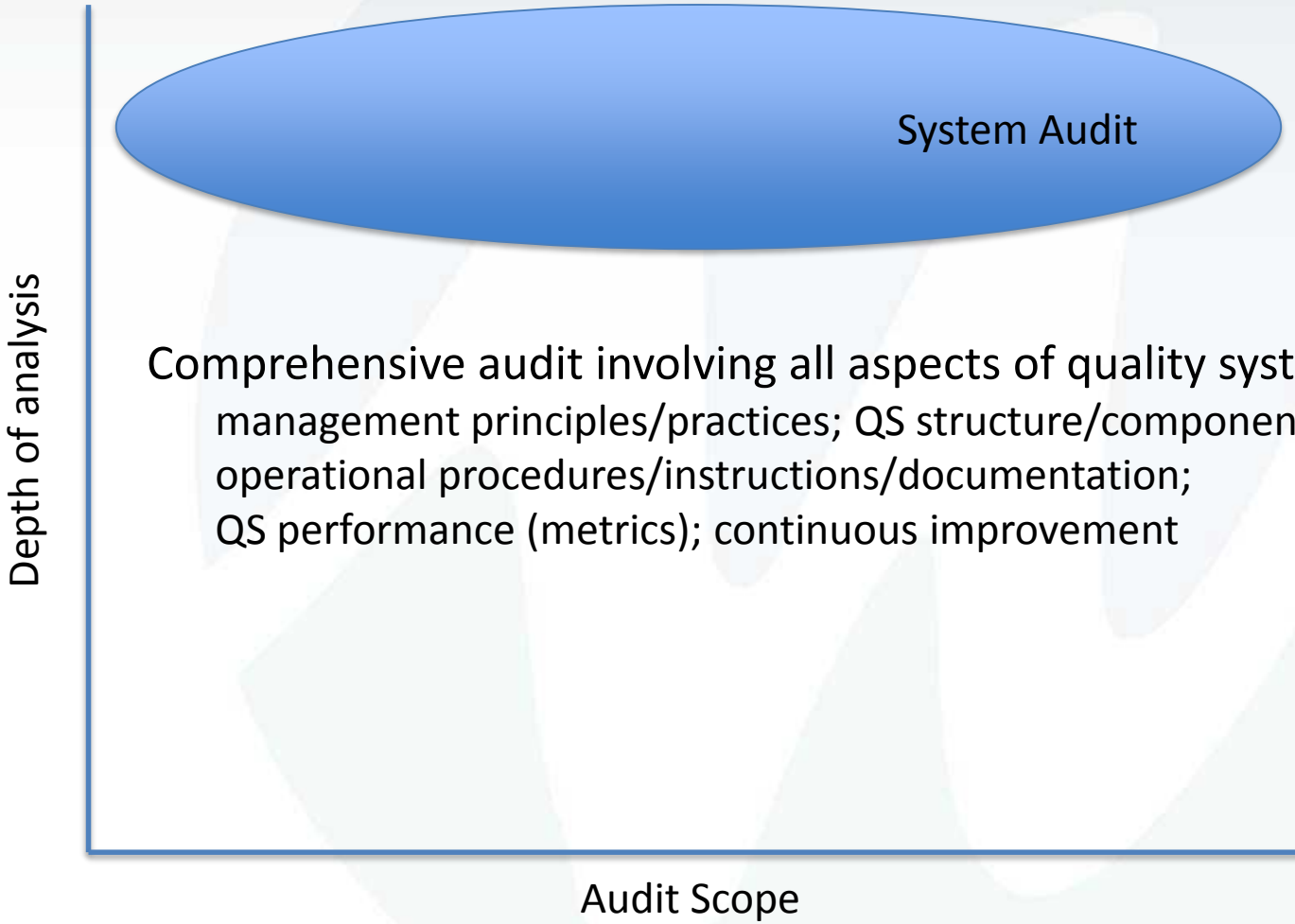
  8.4.1 General

  "…organization shall determine and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of eternal providers based on their ability to provided….in accordance with requirements."

AUDIT

- a methodical examination and review
  - QMS audits provide feedback for improvement
- Sources
  - Regulatory Inspections
  - ISO Registrar
  - Customer
  - Internal
- Types
  - System
  - Process
  - Product

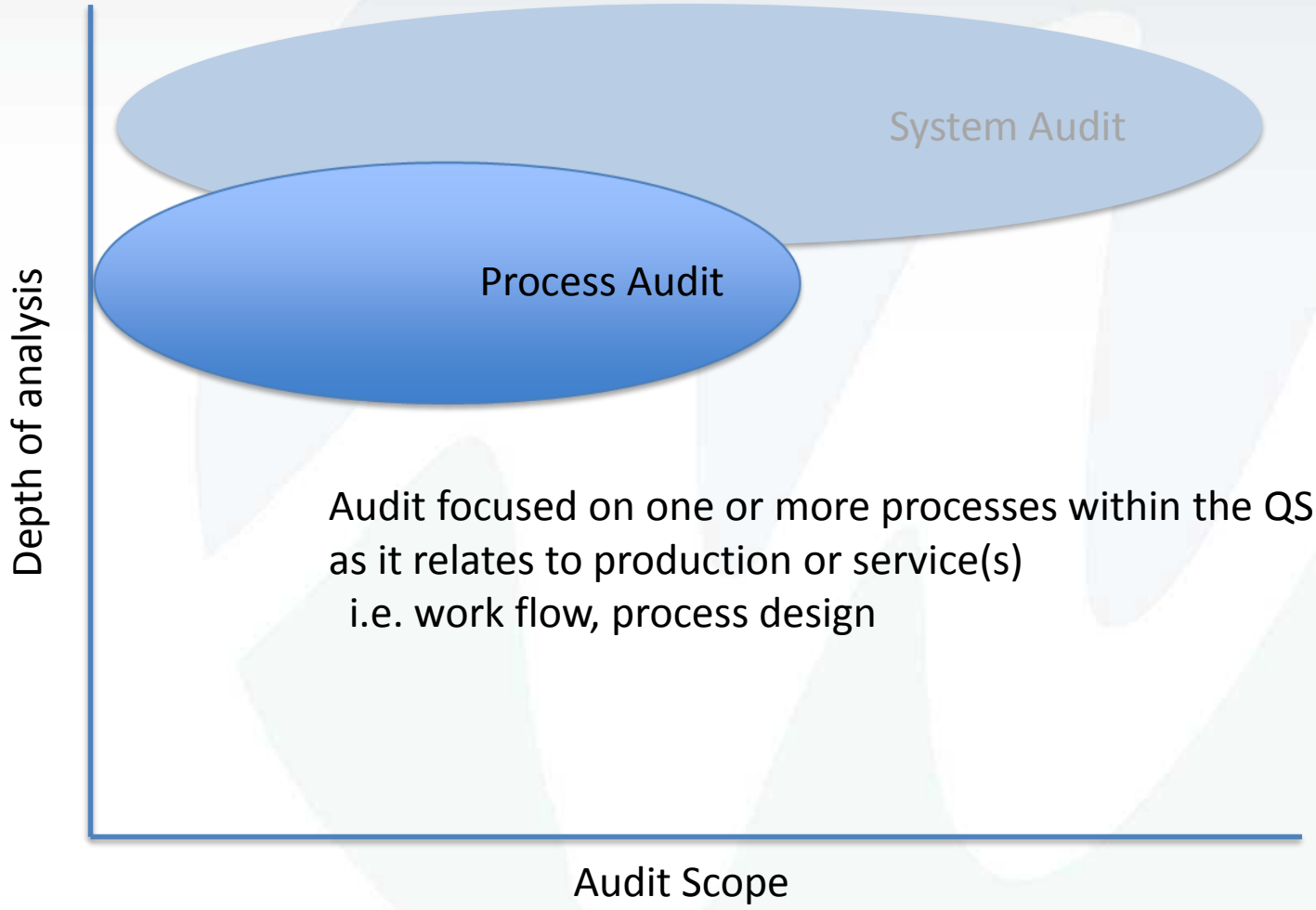
AUDIT TYPES



Comprehensive audit involving all aspects of quality system (QS):
management principles/practices; QS structure/components;
operational procedures/instructions/documentation;
QS performance (metrics); continuous improvement

Certified Quality Technician Handbook, 2nd Edition, ASQ press

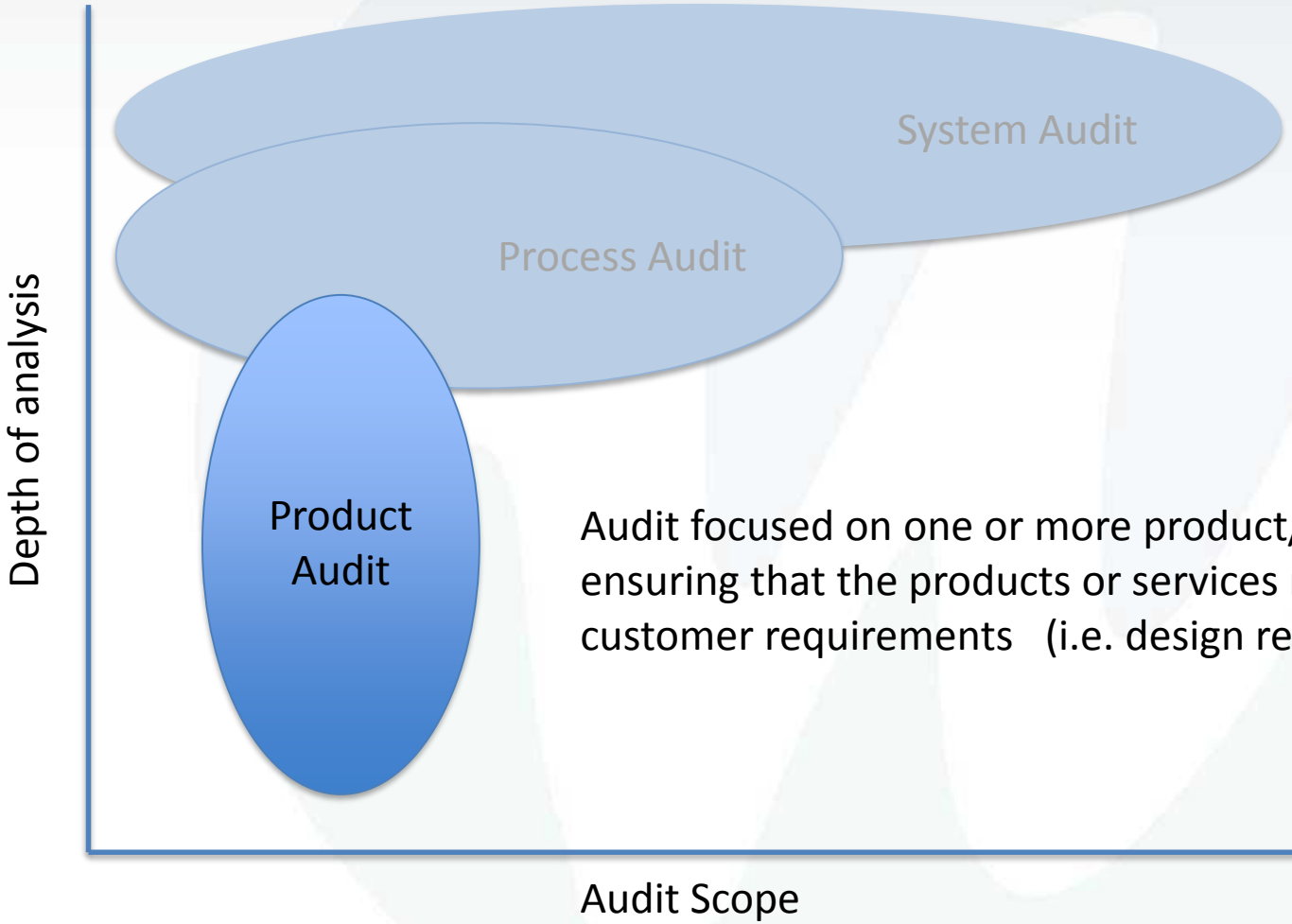
AUDIT TYPES



Audit focused on one or more processes within the QS as it relates to production or service(s)
i.e. work flow, process design

Certified Quality Technician Handbook, 2nd Edition, ASQ press

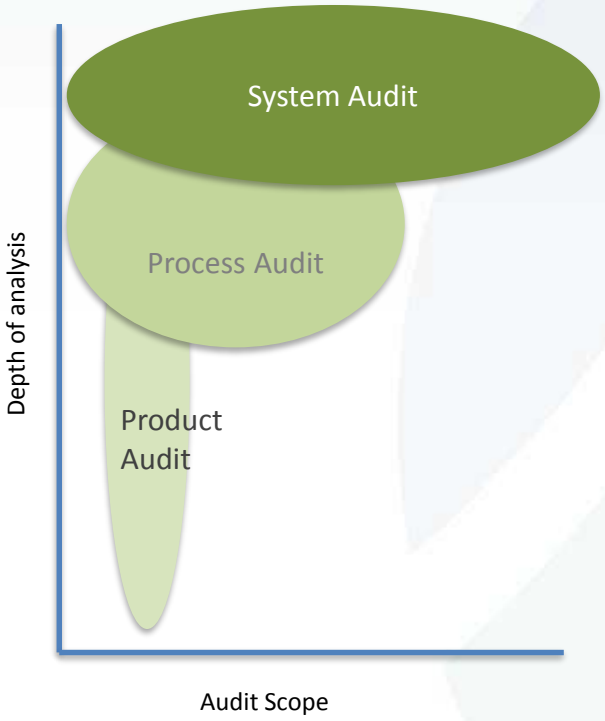
AUDIT TYPES



Audit focused on one or more product/service ensuring that the products or services meet the customer requirements (i.e. design review)

Certified Quality Technician Handbook, 2nd Edition, ASQ press

AUDIT TYPES



Certified Quality Technician Handbook, 2nd Edition, ASQ press

	Compliance	Performance
System	Consistent implementation of a defined system. Promotes stability	Ability to achieve organizational goals. Promote change.
Process	Performance of the ability in accordance with defined processes	Ability of the processes to achieve desired characteristics
Product	Production of goods or services to defined requirements	Suitability of the goods or services for intended use.

Arter, Quality Audits, 3rd Ed

PROFESSIONAL PRACTICES

Ethics
Confidentiality

Developed as part of NSF ATE Grant #1304474

CODES OF PROFESSIONAL PRACTICE

- Company's Code of Ethics
  - Adopted by companies to enable employees to:
    - Understand difference between 'right' and 'wrong'
    - Apply understanding to their business decisions.
  - Implies documents at three (3) levels:
    - Codes of Business Ethics
    - Codes of Conduct for Employees
    - Codes of Professional Practice

CODES OF PROFESSIONAL PRACTICE

- Honesty
- Integrity
- Confidentiality
- Objectivity
- Transparency
- Accountability
- Respectfulness
- Obedience to the Law

INTEGRITY - ETHICS

- American Society for Quality Code of Ethics (ASQ.org)
  - **Fundamental Principles**: ASQ requires its members and certification holders to conduct themselves ethically by:
    - Being honest and impartial in serving the public, their employers, customers, and clients.
    - Striving to increase the competence and prestige of the quality profession, and
    - Using their knowledge and skill for the enhancement of human welfare.

American Society for Quality Code of Ethics (ASQ.org)

- Members and certification holders are required to observe the tenets set forth below:
  - **Relations With the Public**
    - Article 1 – Hold paramount the safety, health, and welfare of the public in the performance of their professional duties.
  - **Relations With Employers, Customers, and Clients**
    - Article 2 – Perform services only in their areas of competence.
    - Article 3 – Continue their professional development throughout their careers and provide opportunities for the professional and ethical development of others.
    - Article 4 – Act in a professional manner in dealings with ASQ staff and each employer, customer or client.
    - Article 5 – Act as faithful agents or trustees and avoid conflict of interest and the appearance of conflicts of interest.
  - **Relations With Peers**
    - Article 6 – Build their professional reputation on the merit of their services and not compete unfairly with others.
    - Article 7 – Assure that credit for the work of others is given to those to whom it is due

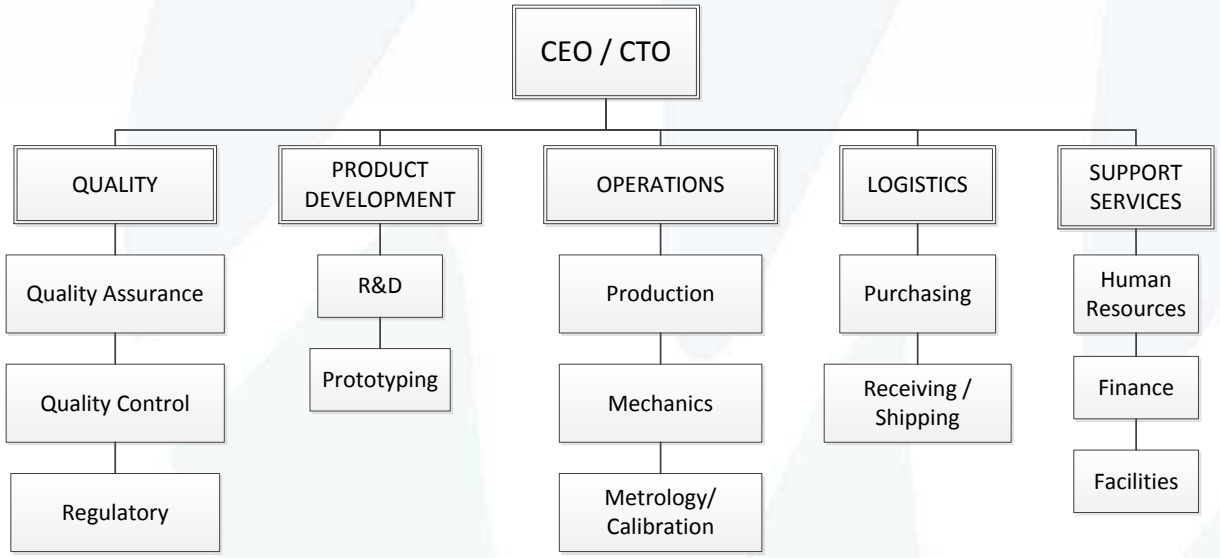
INTEGRITY - ETHICS

- Quality Assurance & Quality Control
  - Voice of the Customer
    - Is the product manufactured properly?
    - Does the product function as expected?
    - Was the product manufactured using the correct materials
  - Regulatory review
    - Does the product/service meet the Regulatory requirements (i.e. government, UL, etc.)
    - Does the product meet the Customer regulatory expectations?
  - Support function
    - Work with manufacturing, purchasing, etc. to meet Customer and Regulatory requirements

INTEGRITY - ETHICS

Quality typically alternate reporting structure

- Avoid conflict of interest
- Required by FDA



…"Being honest and impartial in serving the public…."

…"Using their knowledge and skill for the enhancement of human welfare…."

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CONFIDENTIALITY

- What's the big deal?
- Trade Secret:
  - A formula, practice, process, design, instrument, pattern or compilation of information
  - Not generally known or reasonably ascertainable
  - Require reasonable measures to protect the information
  - Enables a company to obtain an economic advantage over competitors
- Intellectual Property:
  - Copyright
  - Patent
  - Trademark

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CONFIDENTIALITY

- What's the big deal?
  - Trade Secret:
  - Intellectual Property
- Financial Data
  - Accounting Records
  - Sales Figures / Market Share
- Personal Information
  - Health
  - Family

AUDIT - PARTICIPANTS

- Auditee
- Auditor

PARTICIPANTS

- Auditee
  - Person/organization being audited
    - » Company
    - » Division
    - » Department
      - Manager / Supervisor
      - Employee
- Client
  - Person/organization requesting the audit (may be Auditee)
- Interested Party
  - Stakeholder to the audit process or results

PARTICIPANTS

- Auditee: Person/organization being audited
- Auditor
  - Person/organization conducting the audit
    - » Lead
    - » Team Member
    - » Observer

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ROLES & RESPONSIBILITIES

- Client: Requests the audit and uses the results.
  - Selects the auditor
  - Determines reference standard
  - Specifies type and time/duration

- *FDA – determines new product/facility compliance with regulations*
- *Registrar – determines compliance with standard*
- *Customer – reviews supplier systems as relates to their needs/requirements*
  - ✓ *May send own personnel or external firm*
- *Quality Assurance – internal monitoring of quality system*

ROLES & RESPONSIBILITIES

- Auditor: Conducts the audit
  - May be individual or team
  - Maintain objectivity and avoid bias
  - Comply with confidentiality requirements
  - Lead Auditor
    - » Communicates audit requirements
    - » Manages audit activities and team
    - » Reports the results
  - Team Member
    - » Conducts activities as directed by Lead
    - » Provides documented evidence for report
    - » Similar qualifications to Lead, but not as experienced

ROLES & RESPONSIBILITIES

- Auditor: Conducts the audit
  - May be individual or team
  - Maintain objectivity and avoid bias
  - Comply with confidentiality requirements
  - Lead Auditor
  - Team Member
  - Technical Expert
    - » Accompanies team but not part of audit
    - » Knowledge of specific topics
  - Observer
    - » Accompanies team but not part of audit
    - » Cannot interfere or influence conduct of audit
    - » Internal audit – trainee

ROLES & RESPONSIBILITIES

- Auditee: Accommodates the audit and provides
  - Access to facilities, processes, products, documentation
  - Resources necessary
  - Guides (staff members) to accompany Auditor(s)
    - » Establish contacts/timing
    - » Ensures safety/security rules followed
    - » Witness on behalf of Auditee
    - » Clarify / assist in collecting information
  - Follow-up actions as required by Audit Report

Audit (Part 1)
Types, Participants, Roles/Responsibilities