

SEED ENTERPRISE MANAGEMENT INSTITUTE (SEMIs)
Seed Quality Assurance, Management and Control Processes

24th April – 6th May 2017

**Introduction to Process
Management**

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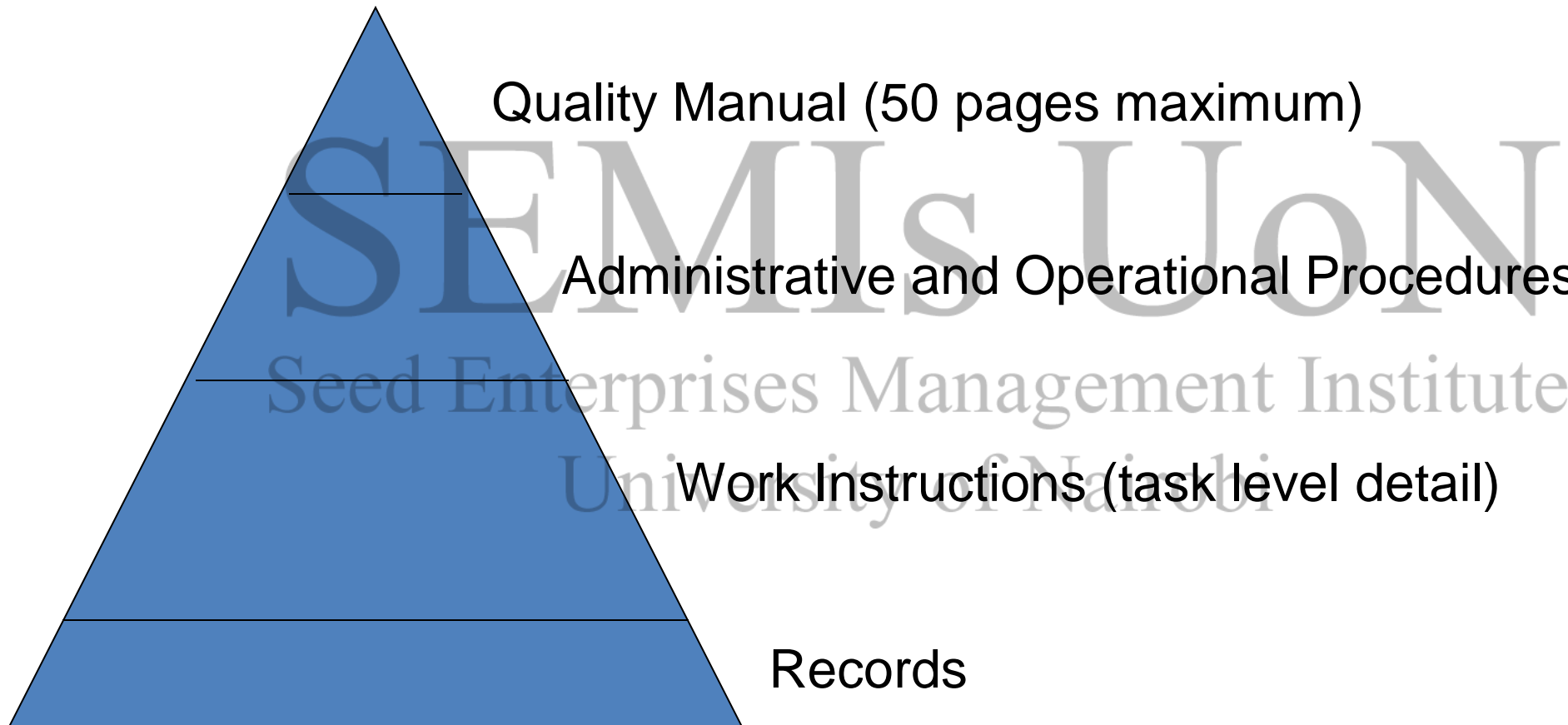
Objectives of internal quality control

- Confirmation we have alignment with business objectives and customer expectations
- Audit/Measurement/Validation
- Managing cost and productivity
- Identification of process improvement opportunities
- Reduction in employee stress
- Possible leveraging opportunities related to regulatory compliance.

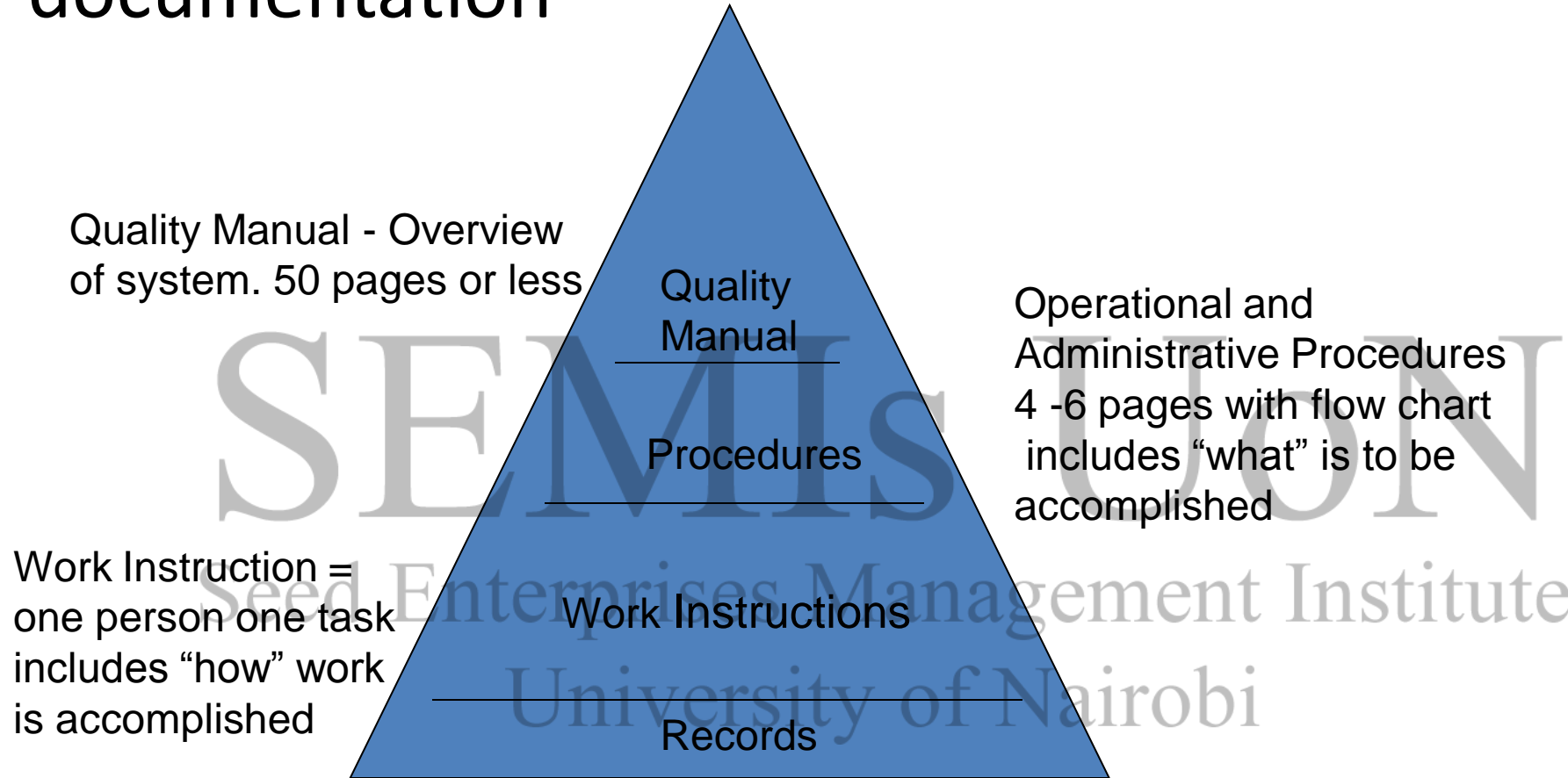
What Is Process Management?

- Identification of critical business areas that must be defined, controlled and maintained.
- Critical business actions must be repeatable and measurable
- System design must allow for changing business needs
- Customer requirements must be identified and incorporated into the system.

Documentation in internal quality control

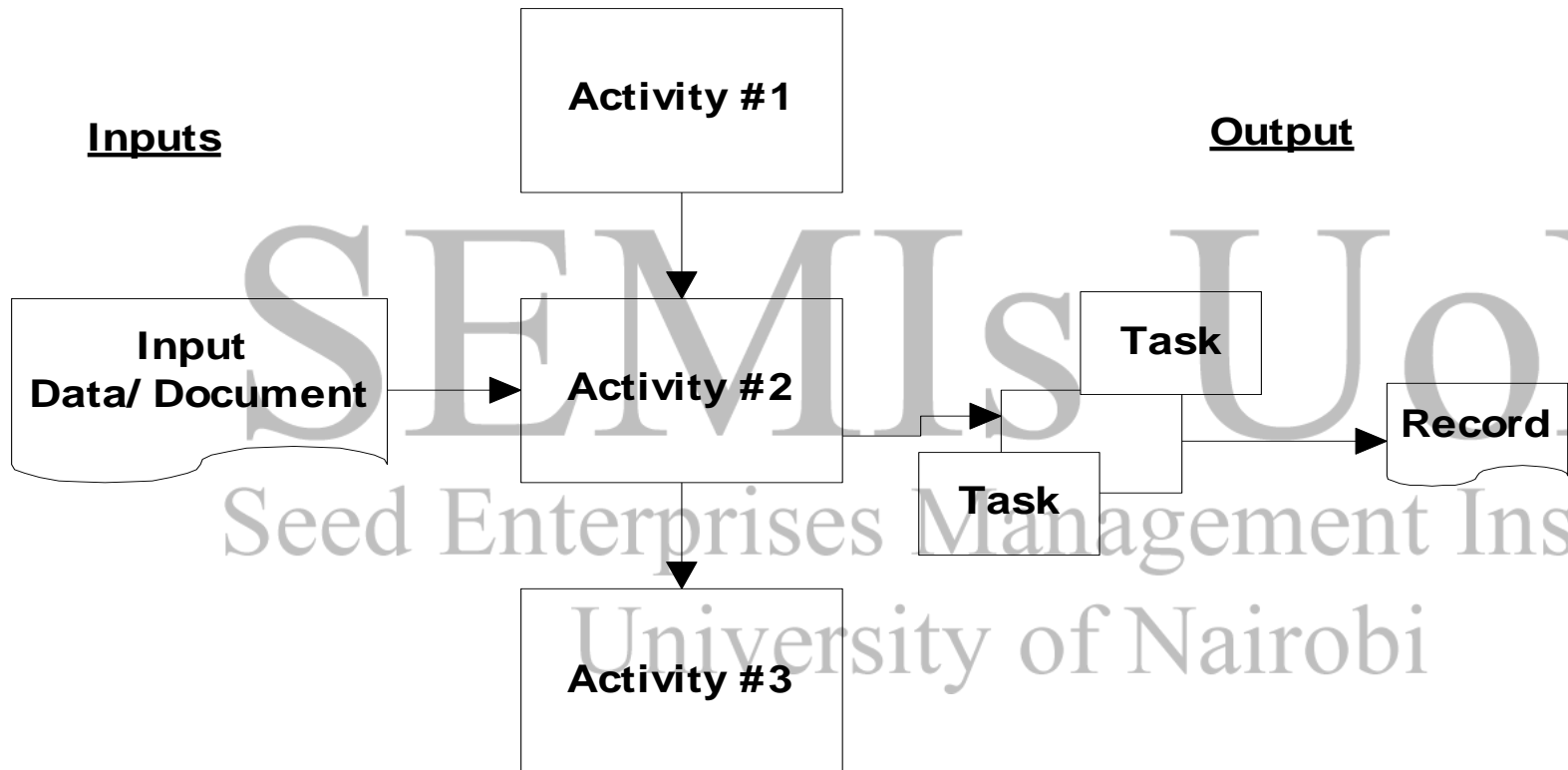


Management system structure - documentation



Business Process

Procedure/ Activity



Inputs

- Specifications
- Data and/or documents
- Manuals
- Regulations/laws
- Policies and guidelines
- Output from a companion process

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Activity

- An action or activity or doing something
- A component of a larger process
- If activity is not initiated, the process will fail
- Typically, made up of several task involving several people

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Work Instruction

- An action or activity
- Doing something
- A subcomponent of a procedure
- Typically, one task that involves one person

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Outputs

- Confirmation that an activity has achieved a defined state of completeness
- Includes:
 - Records
 - Documents
 - Forms
 - Data

Documentation Structure

System Documentation



Quality Manual (50 pages maximum)

Administrative and Operational Procedures

Work Instructions (task level detail)

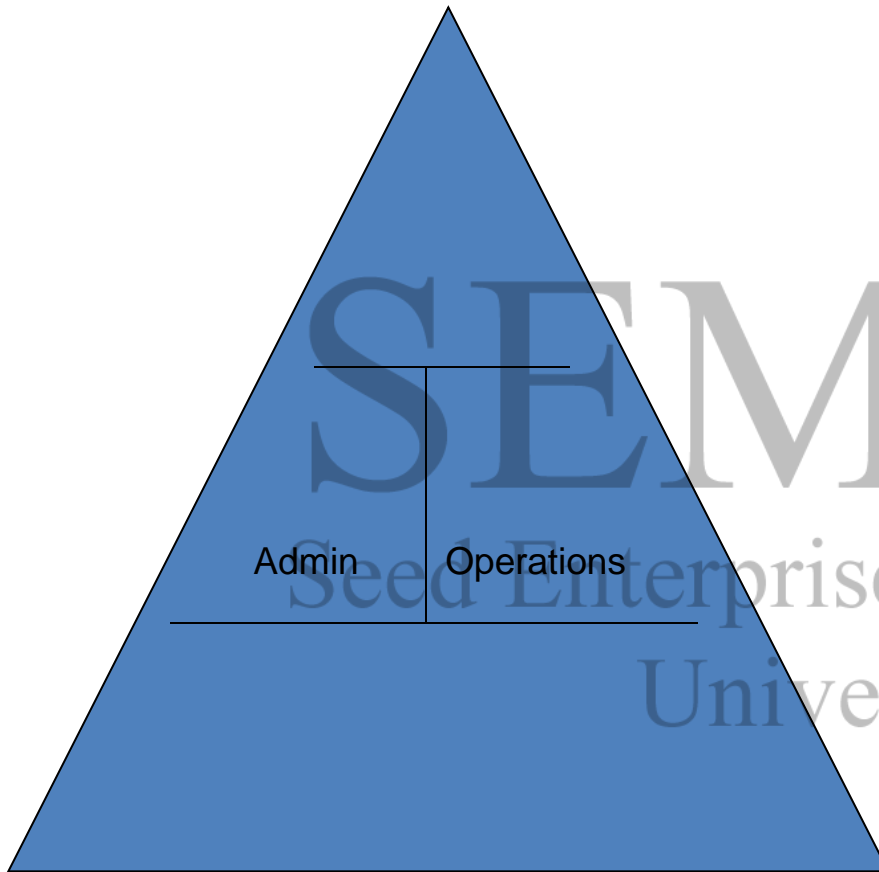
Records

Quality Manual

Overview of business operations including Quality Policy and reference to support documentation. Quality Manual views management system structure from an introductory point of view.

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Procedures



Administrative Procedures

- Document management
- Internal audit
- Corrective action
- Other

Operational Procedures

- What
- When
- Where
- Who

Work Instruction

Work Instruction

- Task level detail
- Viewed as one person one task
- Describes “how” work is accomplished

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Records

Records

- Provides objective evidence
- Demonstrates compliance



Thank you for the
audience

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