

dinar.indra | qms | shafco

interpretation of
**QMS ISO
9001:2008**
(for a beginner auditor)



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before we begin, lets agree on
9 common definitions
based on ISO 9000:2008

product is defined as result of a process

process is defined as set of interrelated or interacting activities which transforms inputs into outputs

quality

defined as degree to which a set of inherent characteristics fulfils
requirements

requirement

need or expectation that is stated, generally implied or obligatory

customer satisfaction

customer's perception of the degree to which the customer's requirements
have been fulfilled

conformity

fulfilment of a requirement

nonconformity

non-fulfilment of a requirement

preventive action

action to eliminate the cause of a potential nonconformity or other undesirable potential situation

corrective action

action to eliminate the cause of a detected nonconformity or other undesirable situation



DO
WE
HAVE
TO?

the facts.

QMS is created and maintained by **International Organization of Standardization.**

It's a **National Standard of Indonesia.**

there are no laws indicating any law implication for not having the certification.

the facts.

BUT...

ISO certified **means** the company operate in a way to produce good **quality**, in a good **price**, with reliable **delivery**, and world class **service**

the opinion.



this is Hera.

*She's a merchandiser for a big dept. store,
and currently looking for a new merchandise
to fill her new fashion chain*

*She wanted a company that not only
promise good quality products, but also deliver
fast to prevent stock outs, is nice
to do business with, and all in a good price*

she got two business pitches

SHAFCO



'the' Brand



SHAFCO

*strive to satisfy its customer
by meeting customer requirements*

*control over operation to prevent any
non-conformance or defective process*

*by following a certain international
standards*



'the' Brand

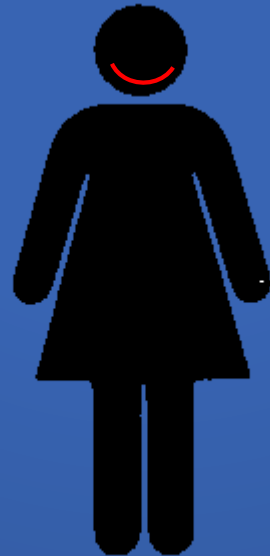
*strive to satisfy its customer
by meeting customer requirements*

*control over operation to prevent any
non-conformance or defective process*

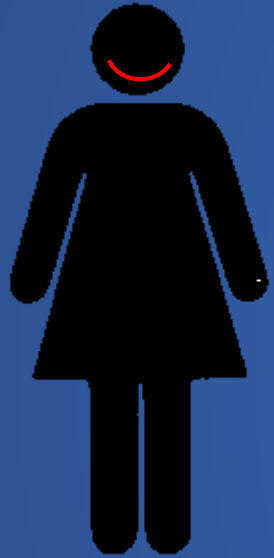
by its own standards



which company is
perceived as more reliable?



the opinion.



**WHICH COMPANY
WILL SHE CHOOSE?**

$$Q = \frac{\text{productivity} + \text{customer satisfaction}}{\text{cost}}$$

$$Q = P = MS$$

profit *market share*

Q = sustainability

**the benefit of a systemic process
is to create consistency**

who'd wants an occasional success?
who'd wants an occasional
world class products?

**in order to sustain our business
and win the market**

**we need our processes to consistently
creating world class products**



HOW TO IMPLEMENT ISO 9001 *successfully*



commitment **consistency**
proactively looking for improvement
focus on **problem solving**
create a **realistic solution**
evaluate system and documentation



inside ISO 9001

THE 8 CLAUSES

1. Scope; 2. Reference; 3. Terms and Definitions

4. Quality Management System

- 4.1 General Requirements
- 4.2 Documentative Requirements

5. Management Responsibility

- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
- 5.5 Responsibility, authority and communication
- 5.6 Management review

6. Resource Management

- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work environment

7 Product Realization

- 7.1 Planning
- 7.2 Customer related process
- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring equipment

8. Measurement, analysis, and improvement

- 8.1 General
- 8.2 Monitoring measurement
- 8.3 Control of nonconforming products
- 8.4 Analysis of data
- 8.5 Improvement



oops,
did I just give you
headache?

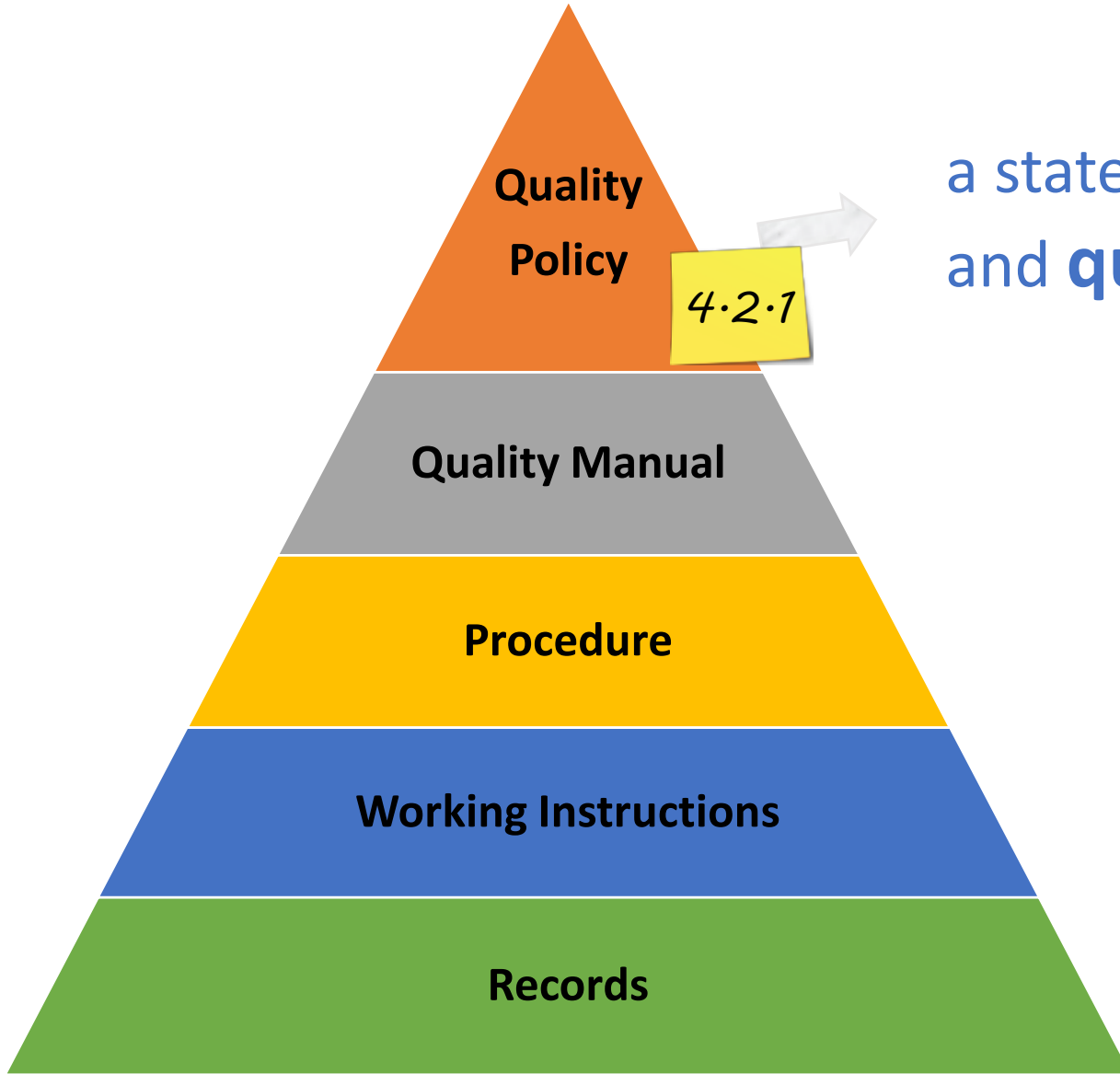
*No worries!
just follow the post-it notes!*



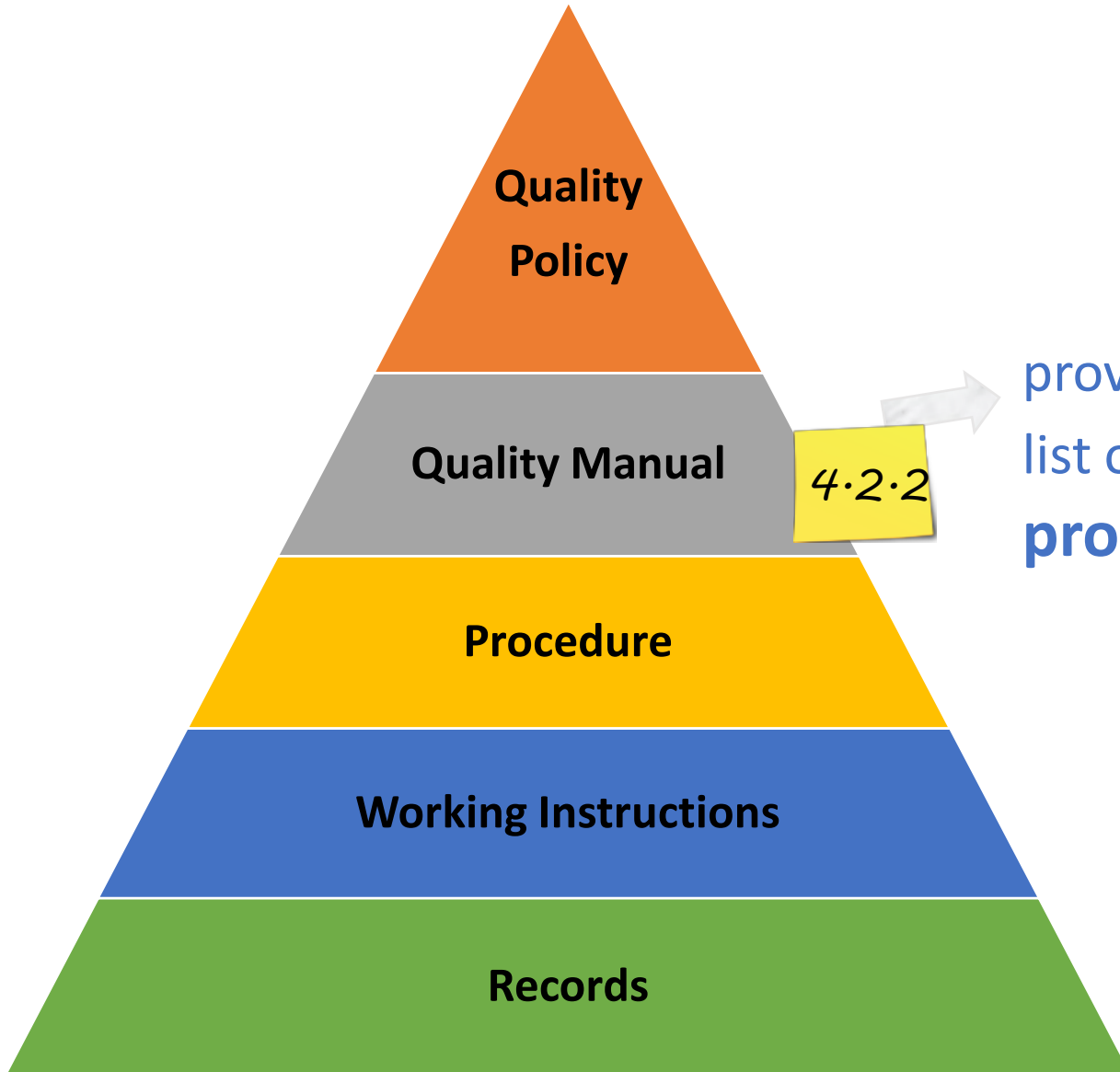


but first,
documentation.

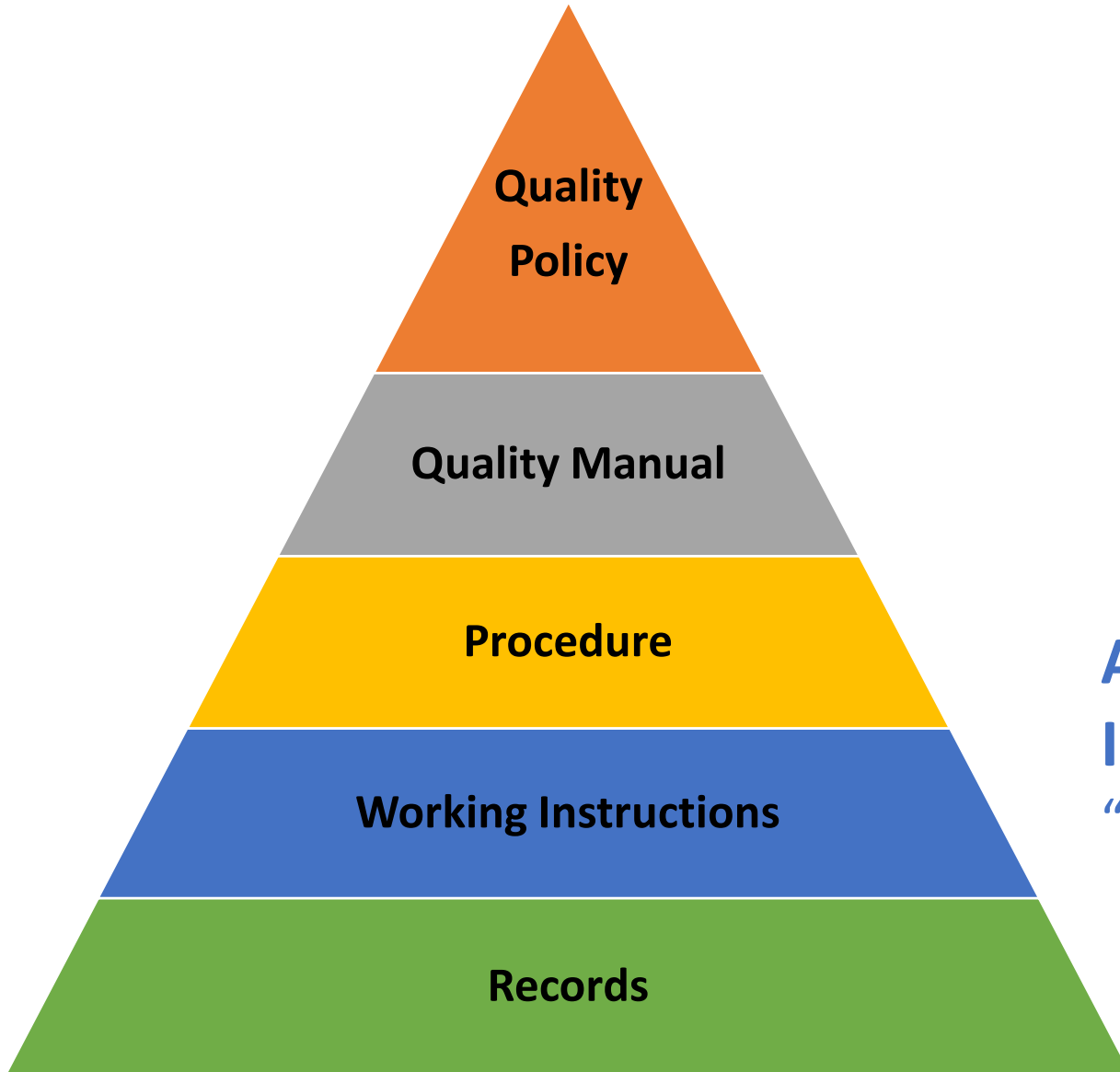
Documentation is the heart of quality management system. You do what you write, and you write what you do.



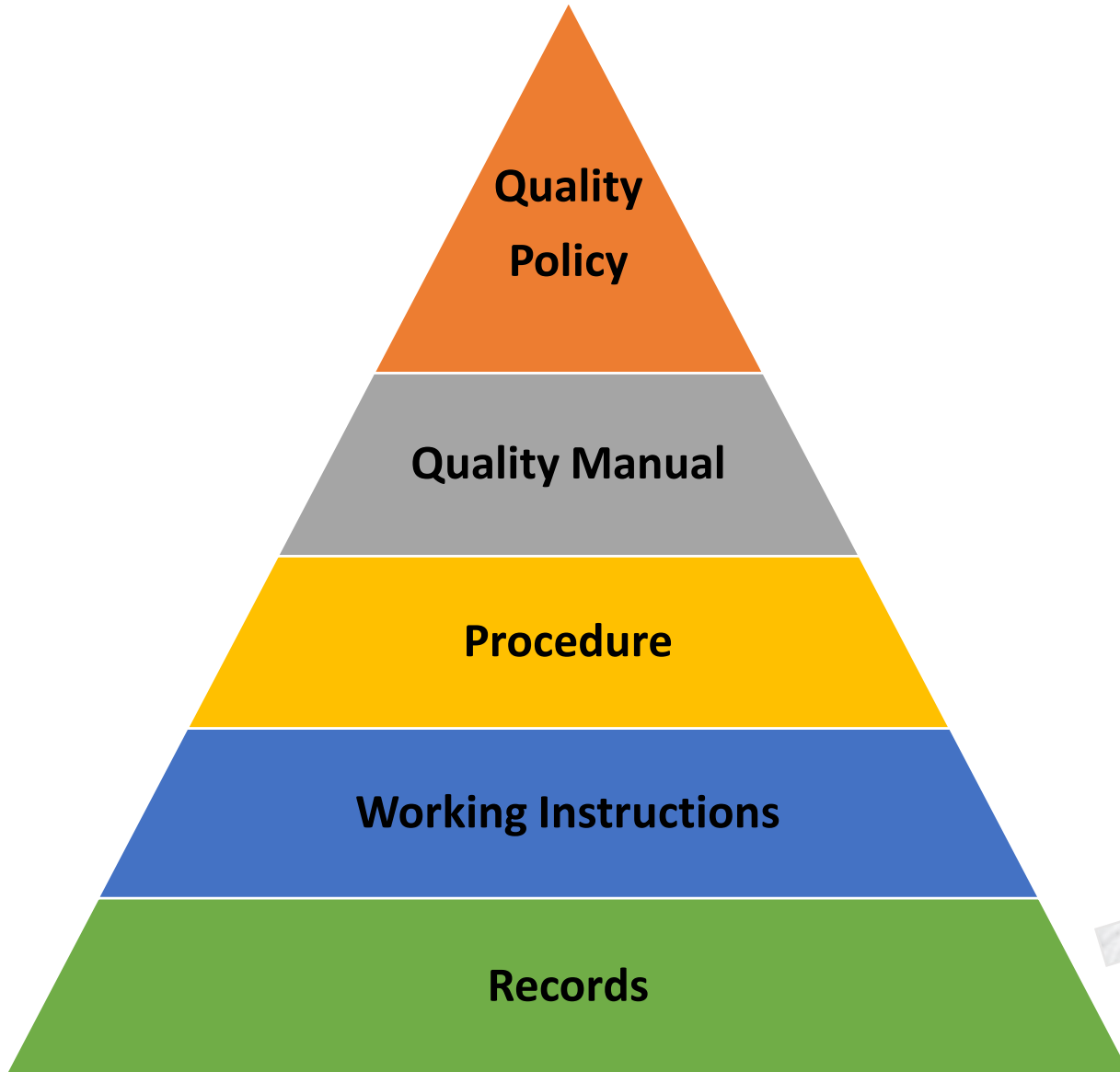
a statement of a **quality policy**
and **quality objectives**



provide **scope** of the system and **exclusion**,
list of **procedures**, and description of
process interactions



A good procedure and working Instruction are those with clear “What”, “Why”, “When”, “Where”, “Who”, and “How.”

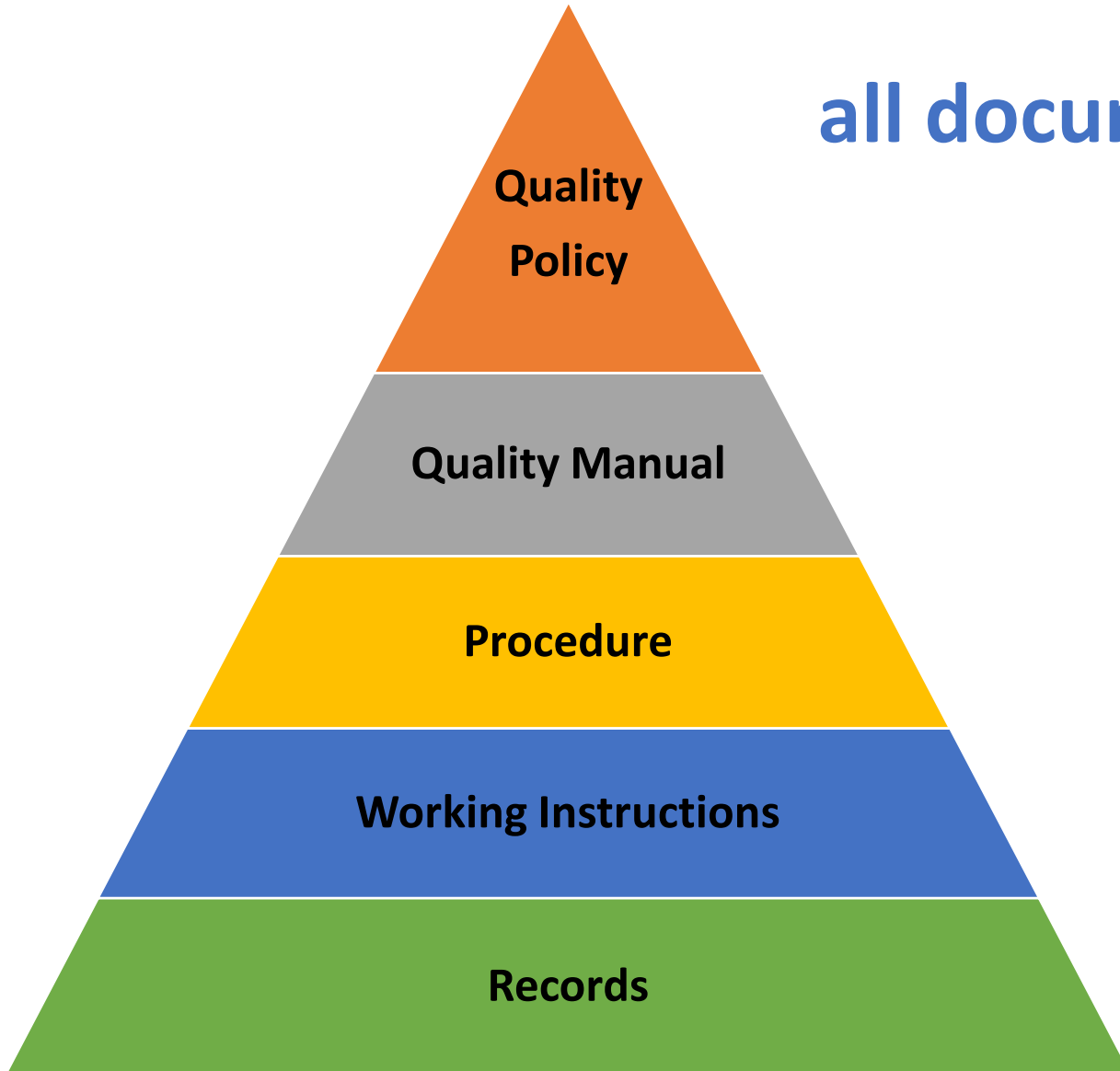


Records are **Evidence!**

Any documented evidence to a process. It doesn't have to be in a form of a *form* (:D), it could be anything that could prove what actually happen. Including photograph.

all document should be controlled!

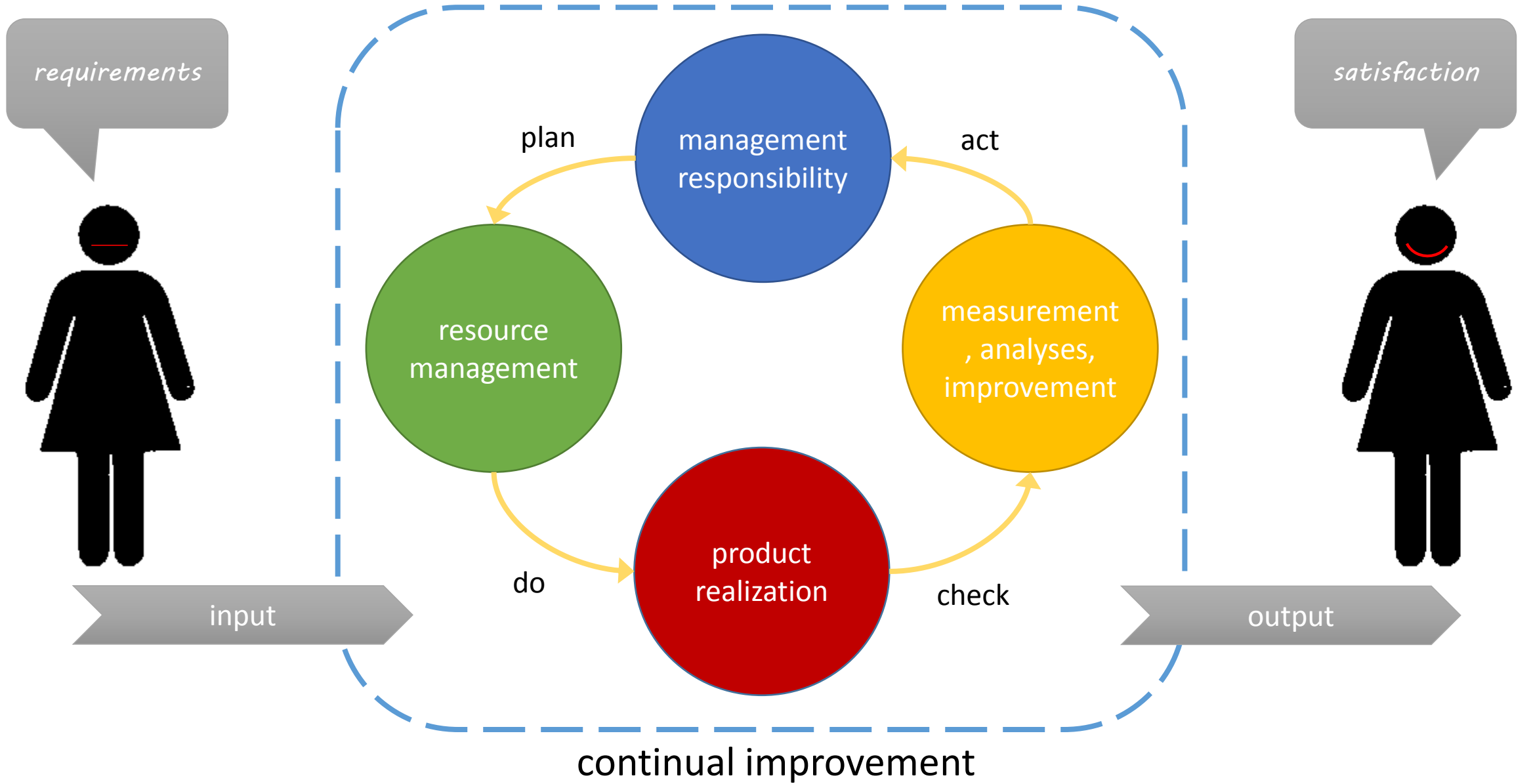
4.2.3



two of the most
important principles are
process approach and continual
improvement

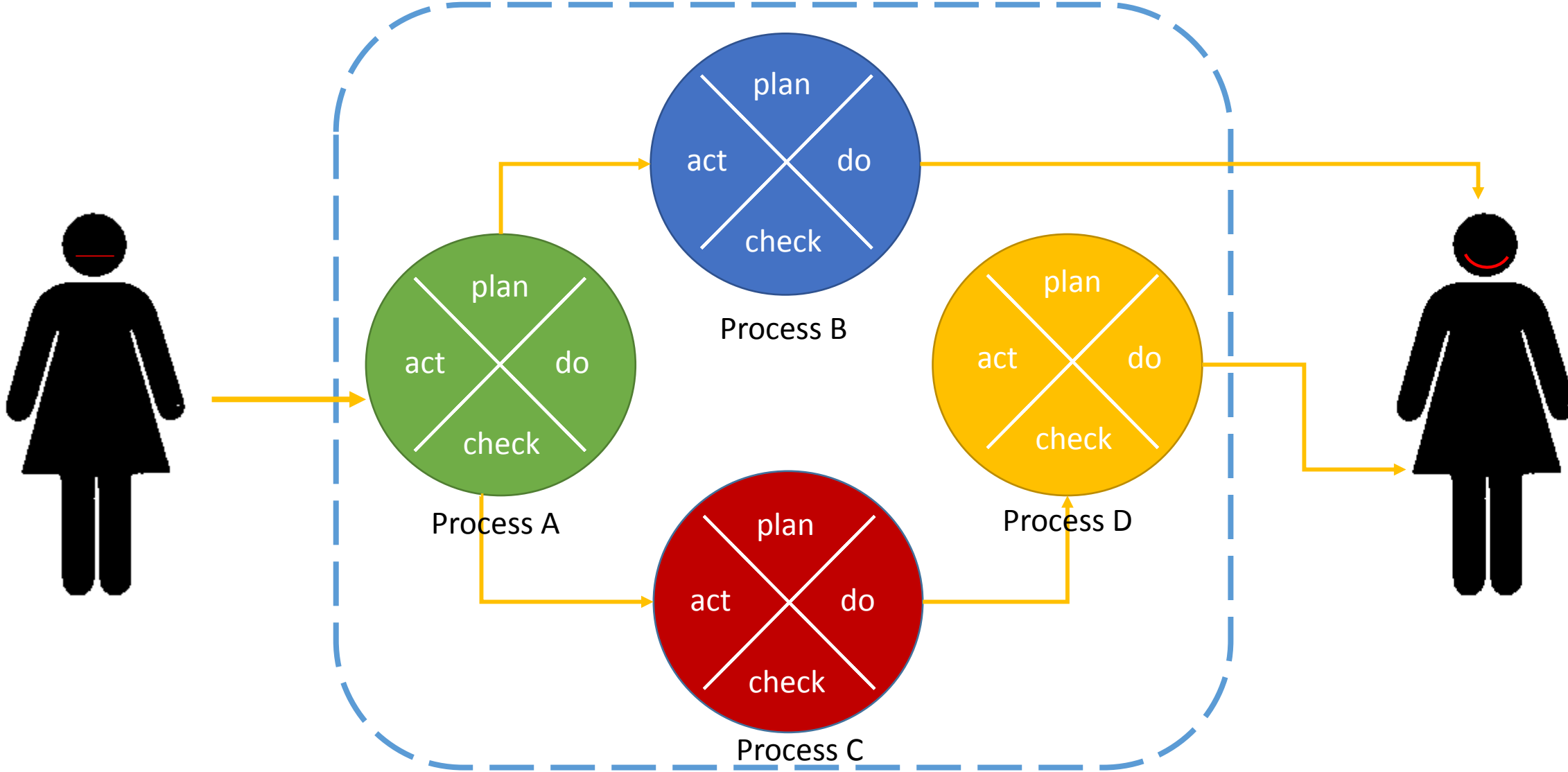
Continual improvement is a set of recurring activities that an organization carries out in order to enhance its ability to meet requirements.

Continual Improvements can be achieved by
carrying out audits, self-assessments,
management reviews, and benchmarking
projects



process approach is a management strategy. It means that they **manage the processes** that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes **together**.

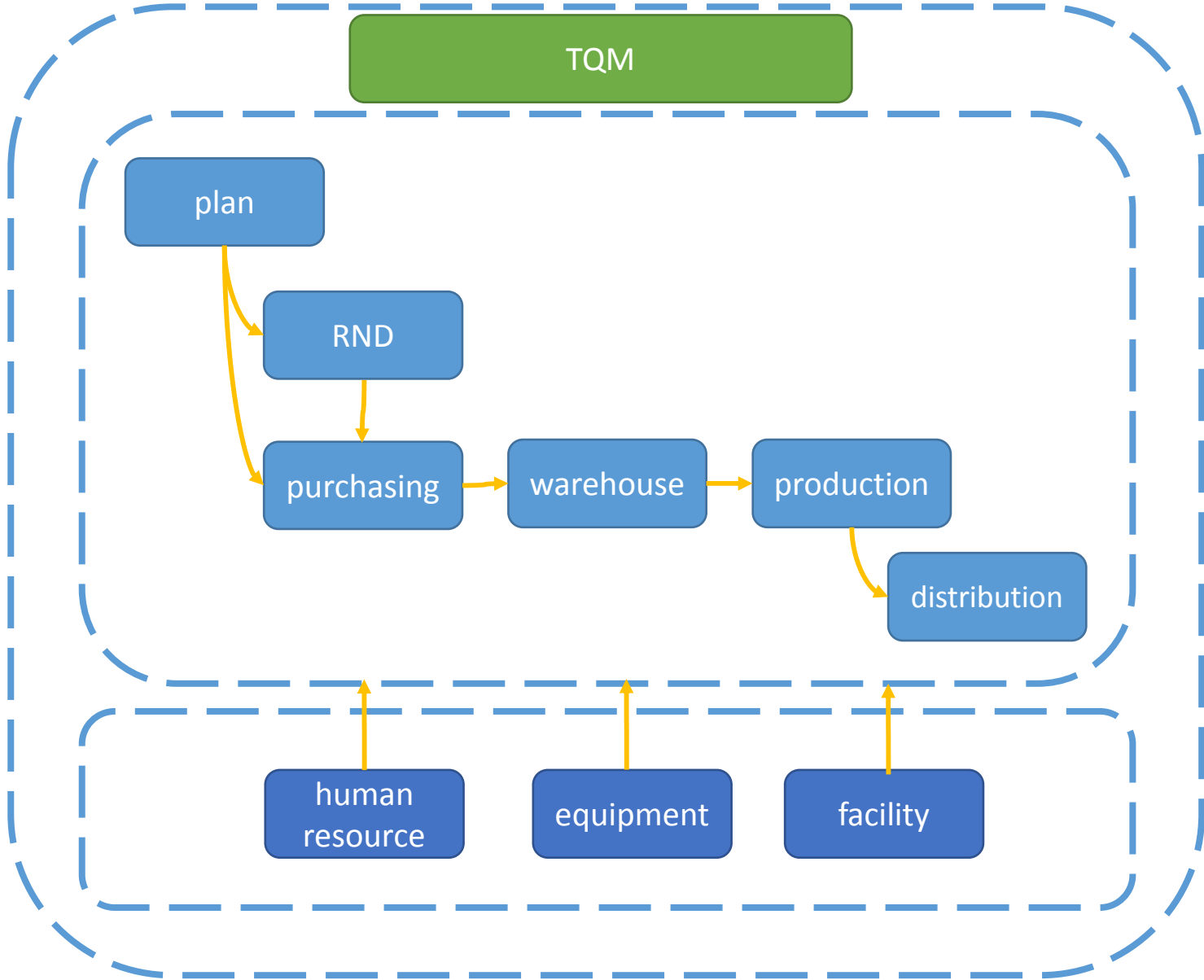
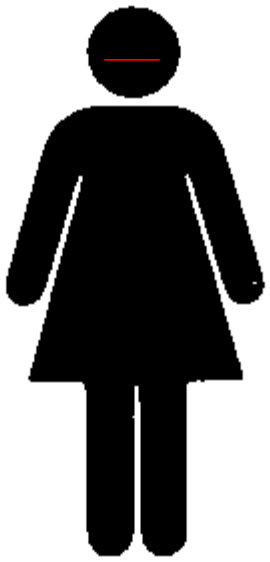
process approach (wholeness)



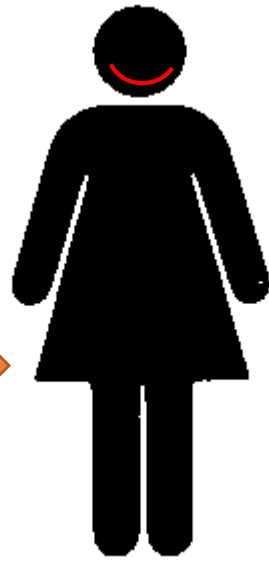
let's simulate it

common process

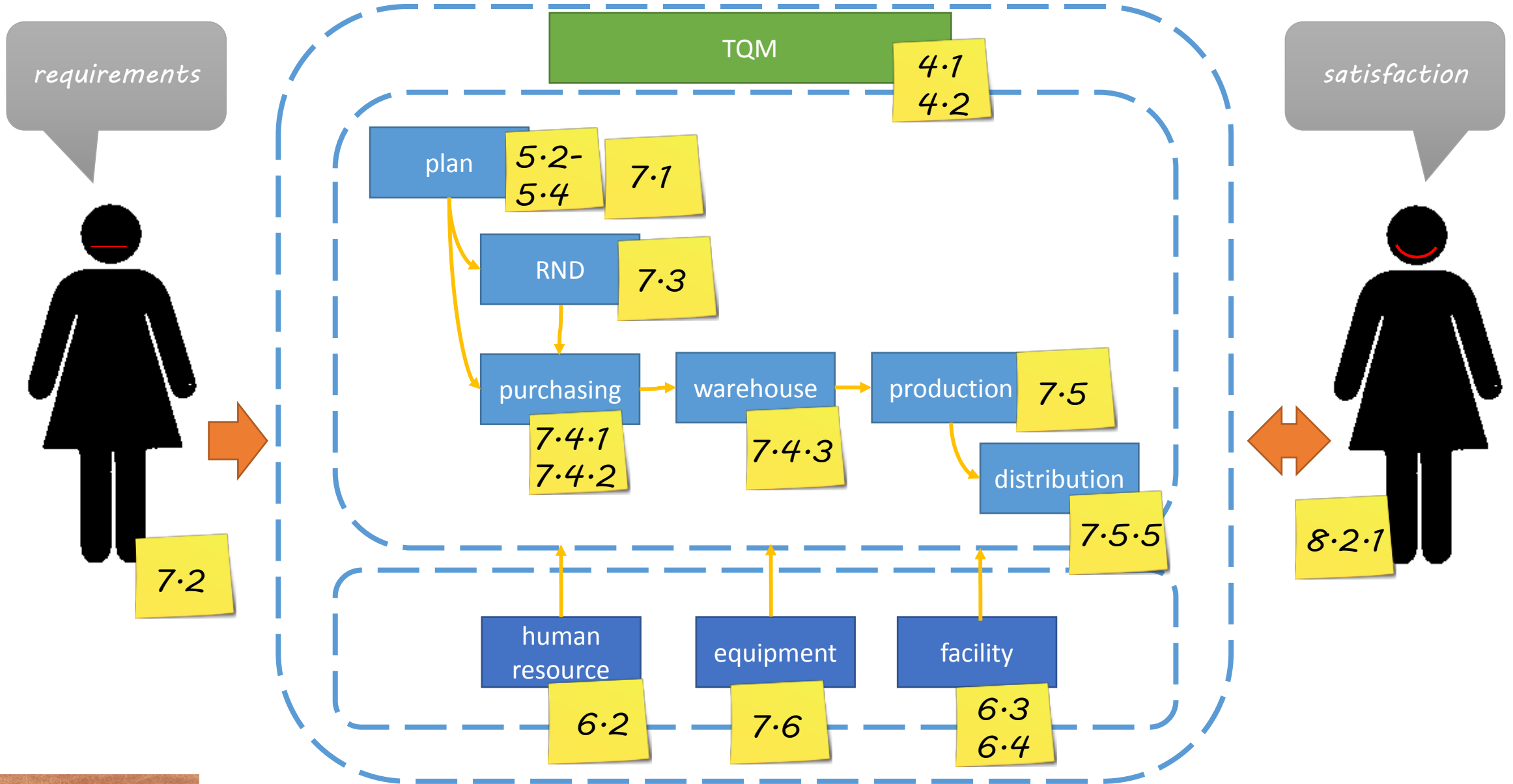
requirements



satisfaction



common process



**as an internal auditor
your first task is simple**

to memorize all the clauses

**sadly, you will not remember any of it
(without exercise)**

ONE

**search the document for
mandatory procedures**

HINT

there are 6 of them

TWO

**search the document for
mandatory records**

HINT

there are 21 of them



*it's probably best
to drink some coffee
before we explode
now...*

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interpretation of

QMS ISO 9001:2008

(for a beginner auditor, part 2)



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before we begin, lets agree on

5 common definitions

based on ISO 19011:2011

audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

audit criteria

set of policies, procedures or requirements used as a reference against which audit evidence is compared

audit evidence

Records, statements of fact or other information which are relevant to the audit criteria and verifiable

audit findings

results of the evaluation of the collected audit evidence against audit criteria

audit conclusion

Outcome of an audit, after consideration of the audit objectives and all audit findings.

INTERNAL AUDIT 101



INTERNAL AUDIT 101

8.2.2



audit type.

first party audits



awesome garment



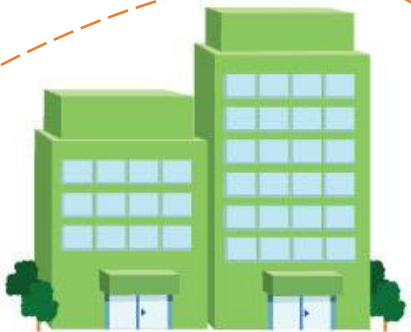
SHAFCO



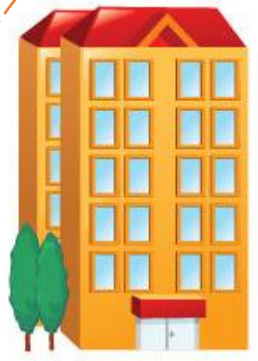
Certification Body

audit type.

second party audits



awesome garment



SHAFCO



Certification Body

audit type.



awesome garment



SHAFCO

third party audits



Certification Body

audit principles.



this is Anton, he's an appointed internal auditor.

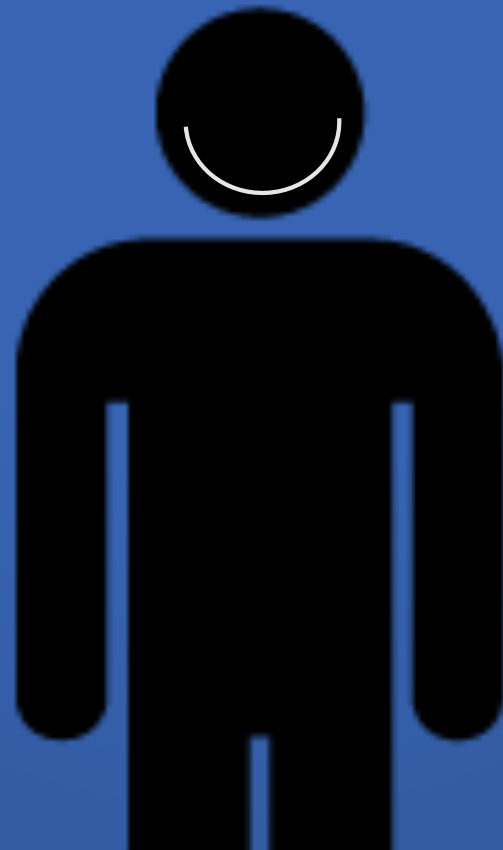
*He was chosen because he act and work with **integrity**.*

*He was never let his emotion gets in the way. His reports was **fair**.
Truthful, accurate, objective, clear, and complete.*

*He tries to be **professional** in every task handed to him, and
treat them with **confidentiality**.*

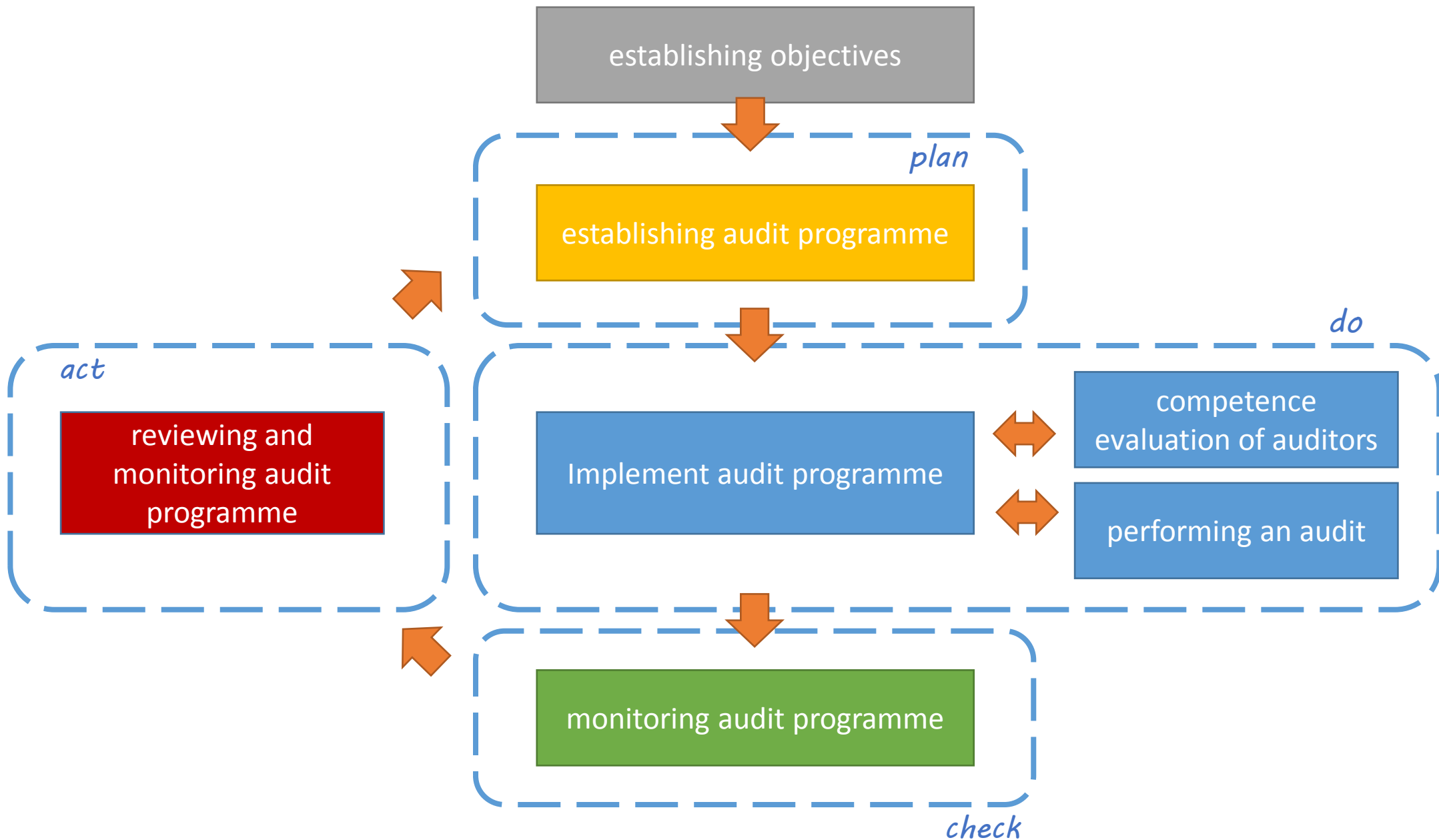
*He shows **independency** towards others influence.
And he speaks by **data**.*

*he's single by the way.
Anyone?*

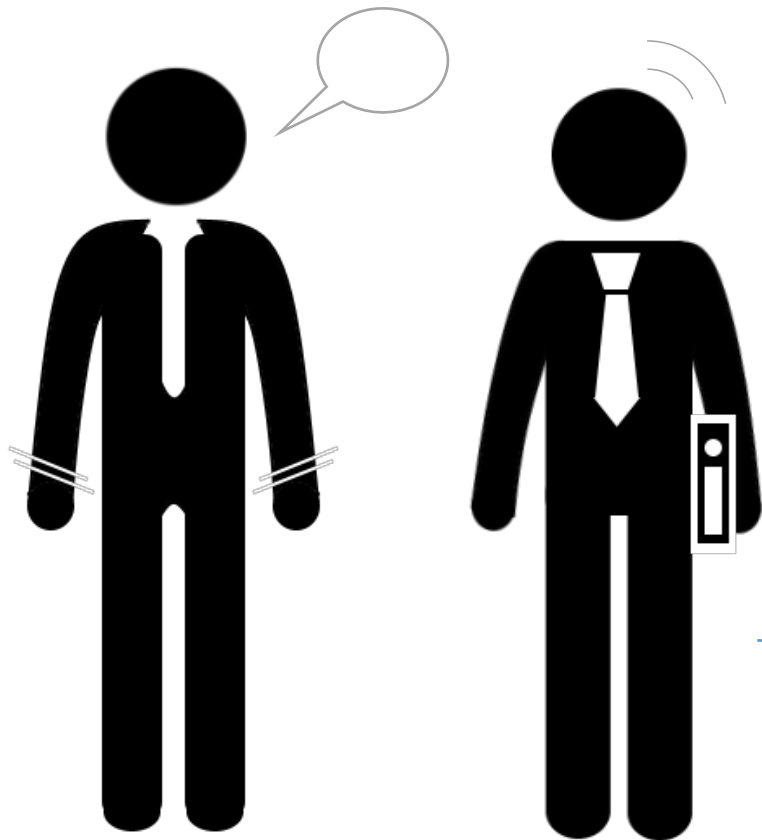




MANAGING AUDIT PROGRAMME



audit objectives are top down by Top Management
and should be inline with management system policy
and objectives



*this is Harry,
he's the Management Representative/Lead Auditor*

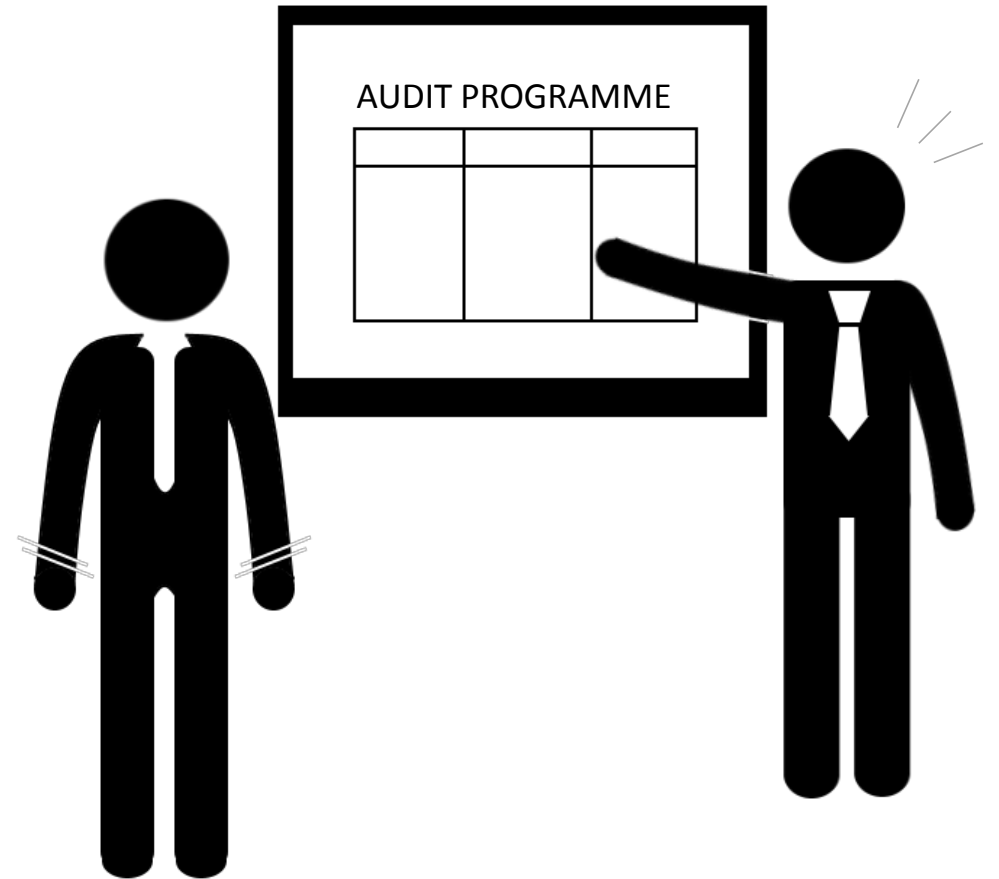
planning is essential.

Management Representative should plan programme duration, procedures, and all necessary resources. he/she should also evaluate any potential risk.



get approval.

after all programme has been planned
it's time to face the Board.

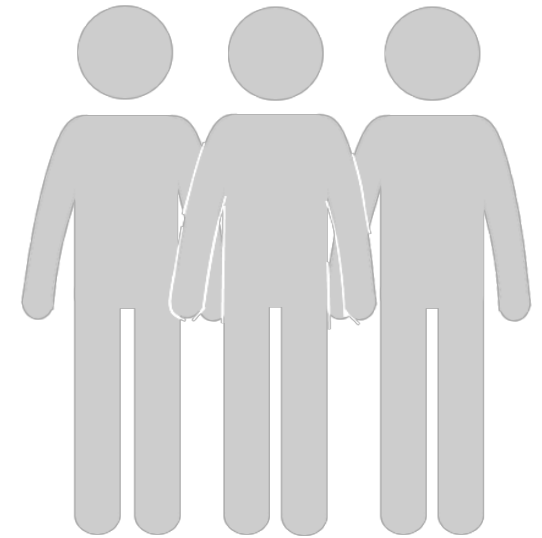


individual audit plan.

a programme consist of several (if not much) individual audit activities. Each of these activities should also be well prepared. Every individual plan should not conflicts the programme plan.



best practice of selecting team.

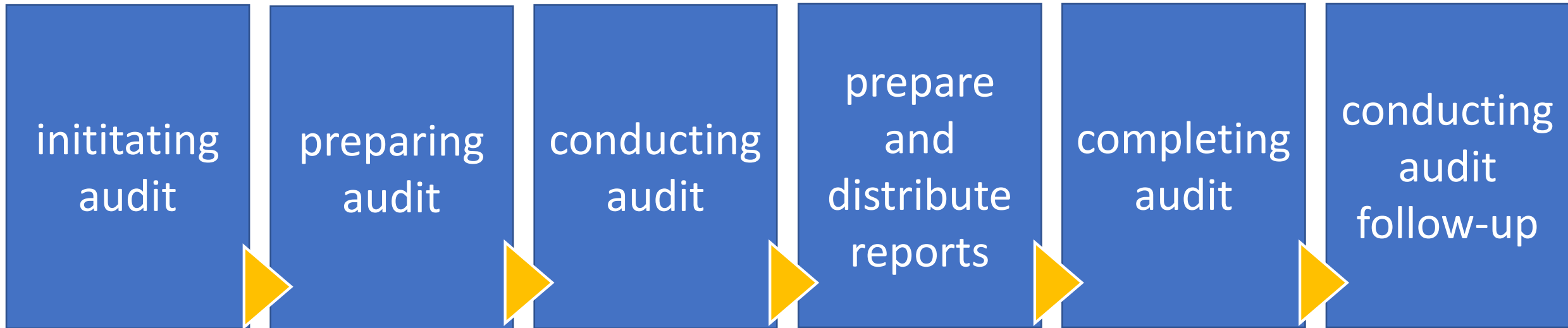


number of people should equal the audit scope, organization structure, and human resources.

Select people from all functions or departments, from staff to senior management.

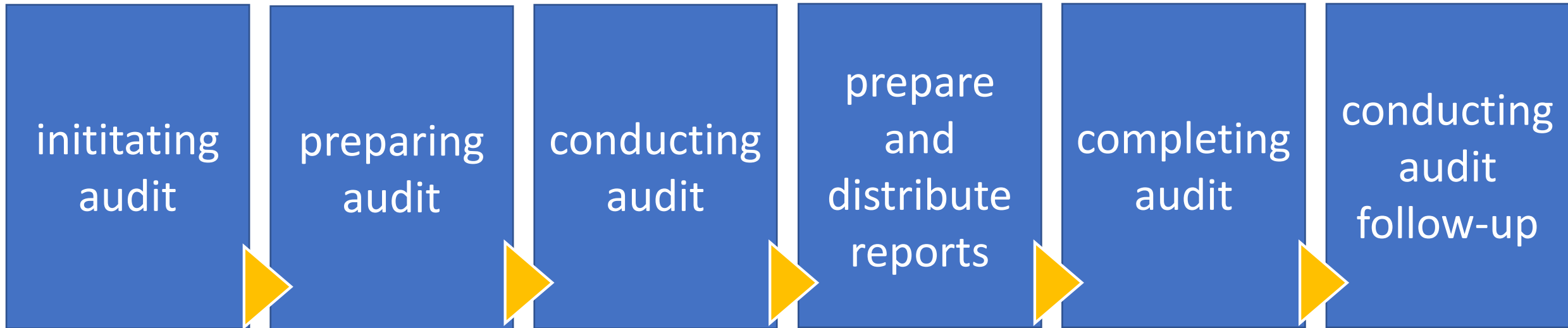
IMPLEMENTING AUDIT PROGRAMME

audit activities



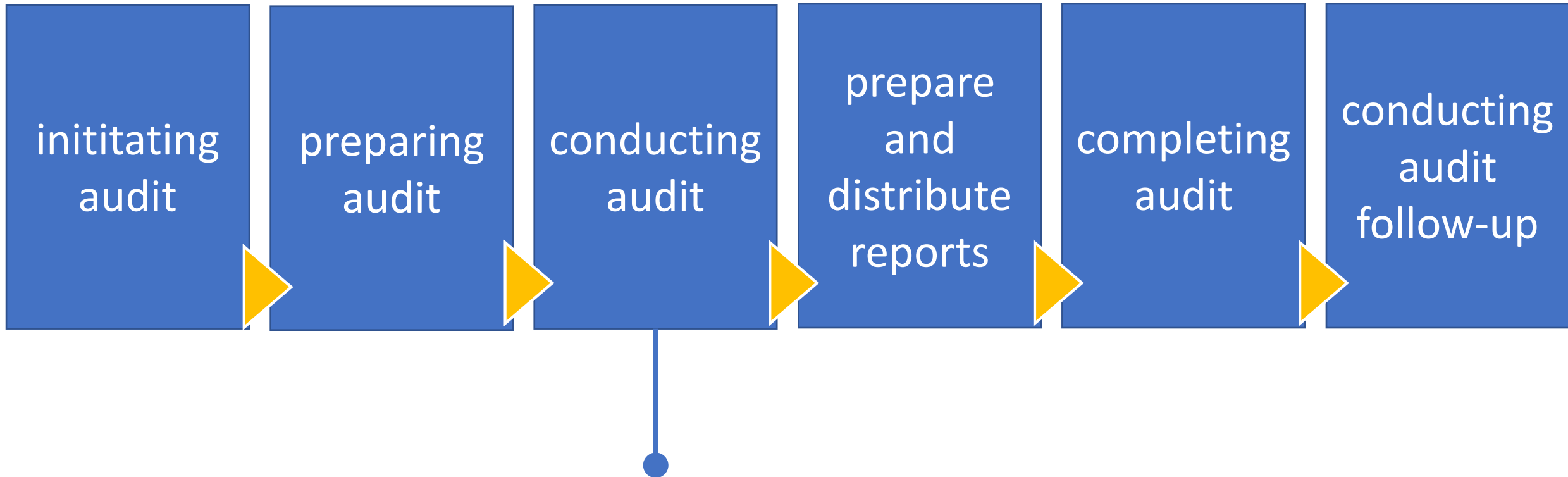
preparation meeting with auditee representative. Agreement on schedule and documents needed.

audit activities



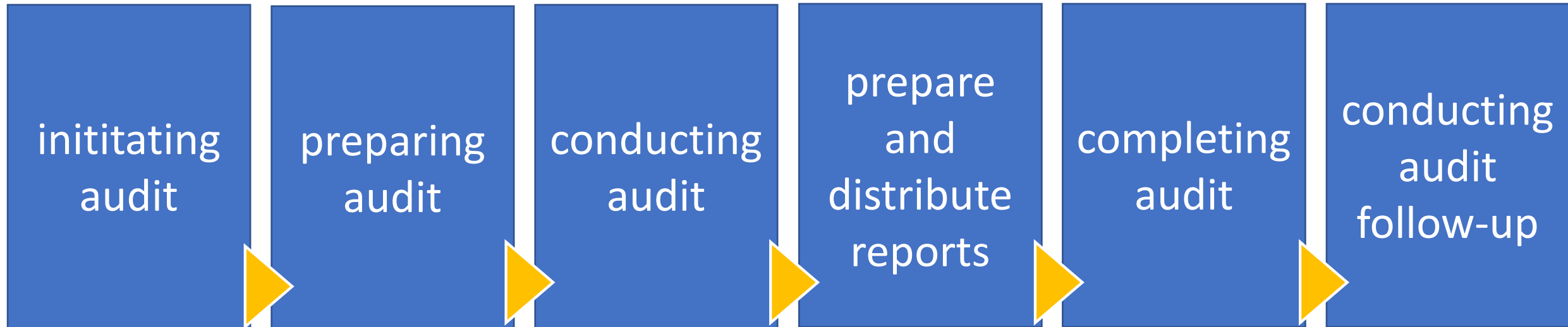
documents review, incl. earlier audit reports. Sampling value.
Auditor assignments. Risk assessment. Audit checklist.

audit activities



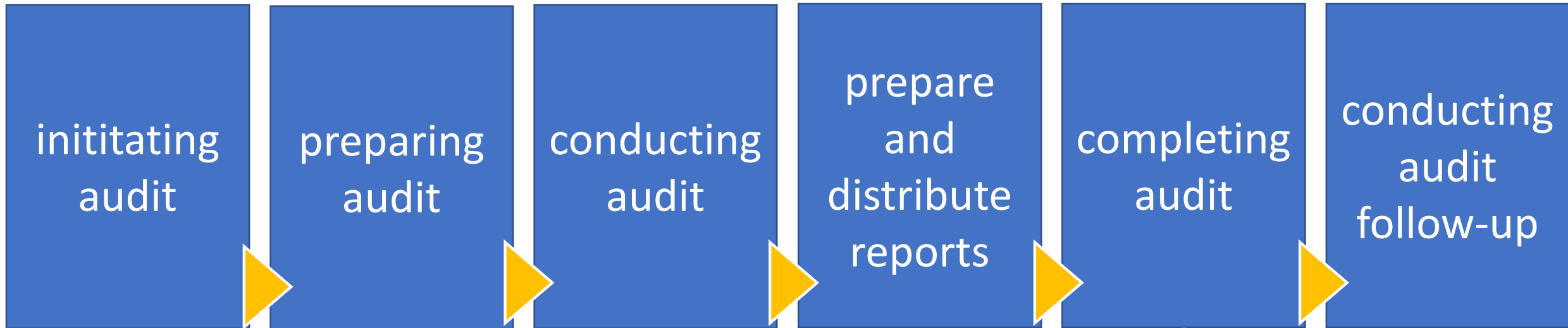
opening meeting. Collecting informations. Gather evidence. Evaluate evidence based on criteria. Determine audit findings. Review, and conclusion.

audit activities



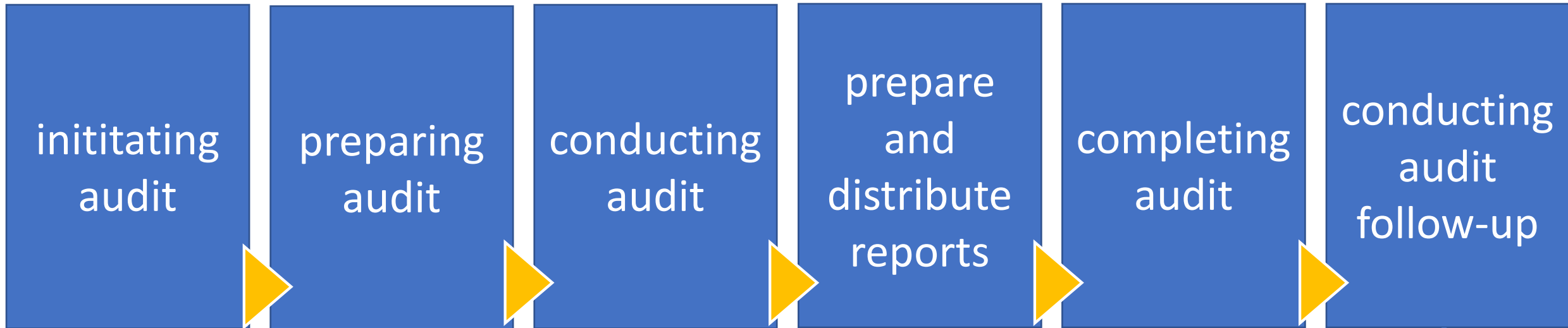
Objective and scope. Audit criteria. Audit members. Schedule. Audit findings. Conclusion. Audit plan. Corrective & preventive actions.

audit activities



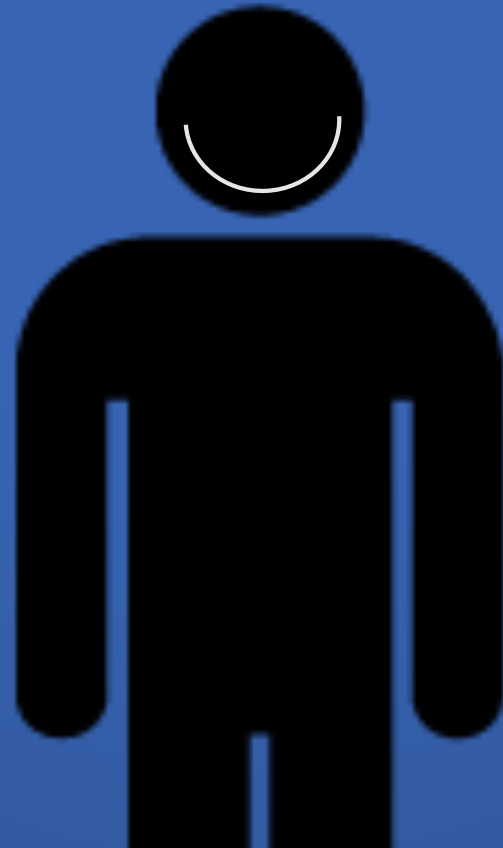
Audit is complete when all programme has been done and declared done by client.

audit activities



Auditee is responsible in taking actions. All actions should have due date. Auditor will verify the actions.

Here's some tips from Anton!



DO!

Default question is open questions, with 5W+1H. If you want to follow the trail, use leading questions. If you want a quick response (or the auditee is just nervous) use closed questions.

DO!

Always check the documents. Documents should be updated, correct, complete, and consistence.

DO!

Audit findings is always one of four brother:

- Conformity*
- Non Conformity*
- Opportunity for Improvement*
- Recommendation*

DO!

You can easily write audit findings by using PLOR system. P = problem, L = location, O = objective evidence, R = reference.

Example:

During the course of the audit in Purchasing dept. we identified Purchase Order number 1234 does not show the price and shipment date. This is not in accordance with Procedure QMS/002, where all Purchase Order must have complete information.

Example:

During the course of the audit in Purchasing dept (L) we identified Purchase Order number 1234 (O) does not show the price and shipment date (P). This is not in accordance with Procedure QMS/002 (R), where all Purchase Order must have complete information.

DON'Ts!

*Don't loose track! Beware of bogged down.
Don't assume. Speak by data.*



Beware of aggressive auditee, nervous auditee, missing people or documents during audits (:D).

*If sample is chosen by auditee, its fishy.
If you are being bullied by auditee, it's fishy.*

References:

Quality Management System ISO 9001:2008 Interpretation & Internal Audit Course, SGS Academy

SNI ISO 9001:2008

SNI ISO 9000:2008

ISO 19011:2011(E)

Pictures from all-free-download.com



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