Building the Quality System

The document system

Prof. Dr. F. Vanstapel, MD PhD
Laboratoriumgeneeskunde
UZ-KULeuven

Teaching goals

Teaching Goals

- Understand the standards
- Understand the need to apply
    - good programming practices
    - good communication practices
- Learn about technical platforms

Part 1/4 : Understanding the standards

cited from ISO 15189:2003

4.3 Document control

4.3.1 The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation.
A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period.
These controlled documents may be maintained on any appropriate medium — including, or not, paper. National, regional and local regulations concerning document retention could apply.

control = actions to ascertain future proper use

archived : for future auditing & recall for retrograde corrective actions, etc.

4.2.1 Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel.
The management shall ensure that the documents are understood and implemented.

acknowledgement

document identification system

cited from
ISO 15189:2003 4.3.3 Document identification

4.3.3 All documents relevant to the quality management system shall be uniquely identified, to include

a) title
b) edition or current revision date, or revision number
c) number of pages (where applicable)
d) authority for issue
e) source identification

→ has to be recognizably identified as
part of the active quality system documentation

content - & communication control system 1/3

cited from
ISO15189:2003 4.3.2 Document control

Procedures shall be adopted to ensure that
a) all documents issued to personnel are reviewed and approved by authorized personnel prior to issue
b) a list identifies the current valid revisions and their distribution
c) only currently authorized versions are available for active use at relevant locations

content - & communication control system 2/3

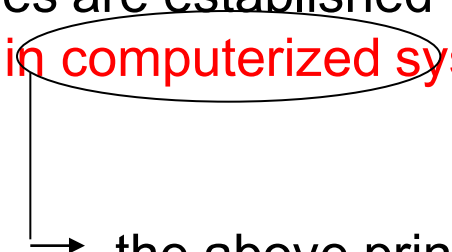
cited from
ISO15189:2003 4.3.2 Document control

d) documents are periodically reviewed, revised when necessary, and approved by authorized personnel
e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use
f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use
g) if the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined, while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable

content - & communication control system 3/3

cited from
ISO15189:2003 4.3.2 Document control

h) procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled



→ the above principles have to be realized

Part 2/4 : Document control
Operational definition

Document control : Operational definition 1/4

What is the purpose of
written procedures, instructions, forms, records ?

Quality =
effective (save) and efficient use of time, money, resources
by systemizing processes :

- nothing important is left out
- no waste steps are introduced
- business in done in an orderly, structured way
- everyone is clear about who is **responsible**
  for doing what, when, how, where
- organize continuity & chain of custody

→ while writing / revising the documents

controlled distribution ←

Document control : Operational definition 2/4

Process control
adjust the level of document control to
the requirements of the process served by the document system

	purpose →	process control
instructions	lean – fail proof who, what, when, how, where	lean instructions target users
logs	create & share knowledge act upon facts	define subject matter continuously expand database continuously register actions
projects	optimize processes	define targets focus & timeliness readjust

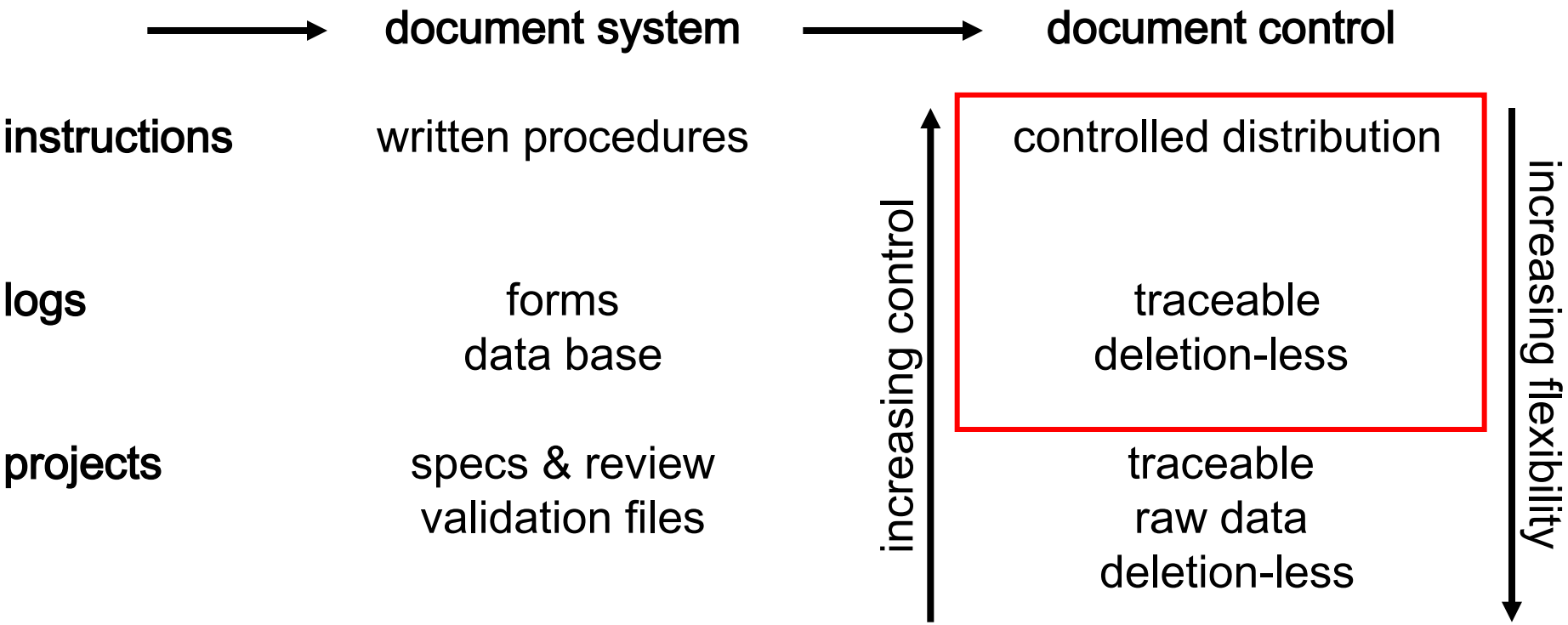
Document control : Operational definition 3/4

Process control
adjust the level of document control to
the requirements of the process served by the document system

	→ process control	→ document system
instructions	lean procedures target users	written procedures
logs	define subject matter continuously expand database register actions	commented forms data base
projects	define targets focus & timeliness readjust	specs progress reports validation files management review

Document control : Operational definition 4/4

Process control
adjust the level of document control to
the requirements of the process served by the document system



Part 3/4 : Document Control in Practice

The document system

Authoring

Publication - Issuing

Maintenance

The first document

Before all others : write the document control system

1. Define :
    - authoring
        - = the process owner
    - verification
        - = stamp docs as part of the quality system
        - = all conditions are met to go to the next step
    - authorization
        - = synchronize publication, issuing & enactment
2. Instruct users on issuing procedure
    - characteristics of active documents
    - notification & verification of notification
    - revision history
3. Define technicalities of rendering and issuing process

Part 3/4 : Document Control in Practice

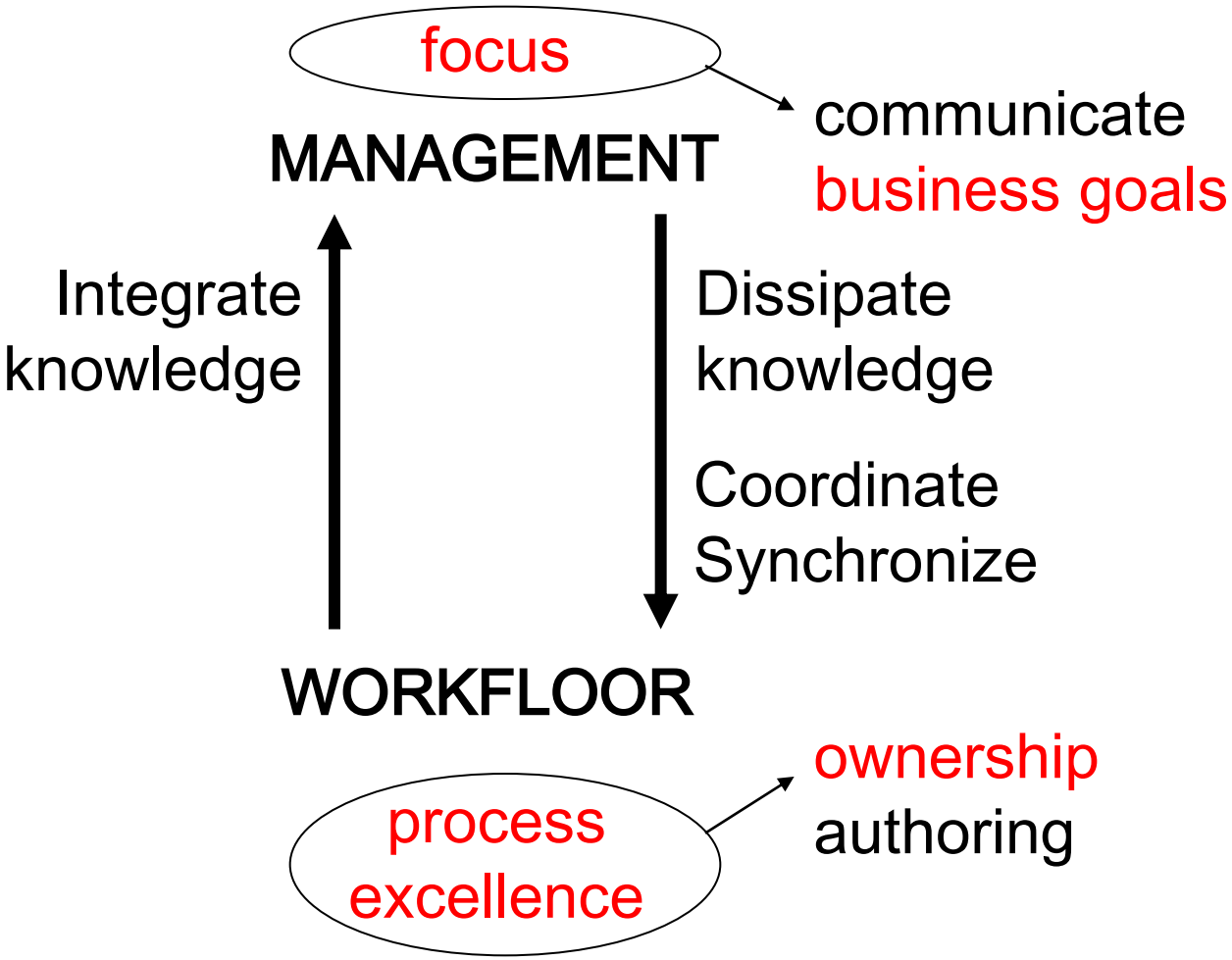
The document system

Authoring

Publication - Issuing

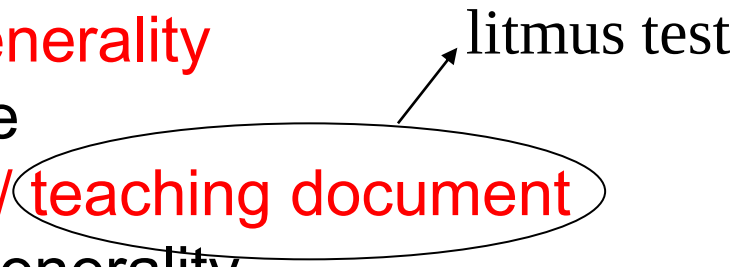
Maintenance

The role of the hierarchical system



Drafting a document

1. Define : scope / targets / timeline / process-manager
2. Buy-in from stakeholders / process owners
3. Strive for lean fail-proof procedures
   - inventory of current practices
     the why is more important than the how
   - cut what is waste
   - retain what is needed
   - strive for simplicity & generality
   - provide for maintenance
4. Suitability as instruction sets / teaching document
   - universal: simplicity & generality
   - checklist format
     the how is more important than the why
5. **Publish**: No procedure is worst than a deficient procedure.
   Nothing is perfect from the first time, or for ever.



Part 3/4 : Document Control in Practice

The document system
Authoring
Publication - Issuing
Maintenance

Life cycle of a document (1/2)

1. The user has always access to
   the active unadulterated document,
   that is easily recognizable as such
2. Provide for low-threshold feedback-channel for users
   & for immediate reaction upon feedback
3. If documents under revision are widely accessible,
   then they have to be recognizable as inactive copies
4. All adjustments are aptly & timely processed
   by a hierarchical system, in order to
   - preserve unity of purpose
   - integrate & dissipate knowledge
   - preserve control of the process of authoring & issuing

Life cycle of a document (2/2)

5. Significant revisions with impact on the modus operandi
   - replace the active document
   - summarize change in the revision history
   - mark significant changes in the body
   - notify user
6. Documents are timely (e.g. yearly) systematically revised
   - accuracy
   - efficacy & efficiency
7. Control the process of rendering and issuing of documents by means of an appropriate technical checklist

DO's

1. Provide for a procedure for urgent adjustments of instruction sets
2. Users & process owners are directly responsible for the content & the adherence to their instruction sets
3. The quality system has to guard unity of purpose & focus
4. Have a (technical) procedure for rendering and issuing

DONT'S

1. The (hierarchical) quality system should never step in for the process owners
2. Never create the impression that instruction sets are non-committal intermediate documents of a project

Part 3/4: Document Control in Practice

Summary

SUMMARY (1/2)

GOOD PROGRAMMING PRACTICES

1. Be particular about definitions
   a definition = a propedeutic tool
2. Separate
   why = validation file
   who, where and when = organisation
   what and how = standard operation procedure (SOP)
3. Programme modularly
   one module = one act
4. Clean code
   - say it only once
   - don’t embed variants but call the general procedure
   - keep track of all calling functions

SUMMARY (2/2)

GOOD COMMUNICATION PRACTICES

1. Be particular about definitions
   a definition = a comprehensive general instruction
2. Reduce communication noise :
   why = validation file
   who, where and when = organisation
   what and how = standard operation procedure (SOP)
3. Reduce communication noise :
   one module = one act = one bite-size instruction
   say it only once = one general procedure to memorize
   say it without variants = instructions are not non-committal
   use structured instruction sets =
   don’t ask reader to make an interpreted summary
   as much and no more detail than needed

Part 4/4 : Document Control & IT

Automation projects

1. Inventory
   - requirements
   - current procedures
2. Simplify & Standardize
3. After implementing step 2
   - evaluate : automation possible ?
     - suitability of available technologies ?
     - cost-effective ?
     - costs : implementation
       - maintenance
       - future portability
     - costs of quality failure :
       - garbage information
       - & waste processes

Automation projects

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Requirements of an IT platform

cited from
ISO15189:2003 4.3.2 Document control

h) **procedures** are established to describe how changes to documents maintained in computerized systems are to be made and controlled

1. The IT platform is **embedded in procedures**

2. **Suitability for purpose = primary issue**
   Looks & Feels are secondary issues

Requirements of an IT platform

Must Have

- Control over issuing of authorized and unauthorized copies
- Imprint authorization status
- Accommodate a multitude of different documents (xls, doc, …)
- Requires minimal IT skills
- Server stability

Should Have

- Produce clean code
- Link management
- Site crawler
- Facilities for end-user feedback about procedures
  (with immediate notification of significant person)
- Facilities for notification of users
  (and confirmation of that notification)

Requirements of an IT platform

Could Have

- Various degrees of structured text management
- Query external data bases (e.g. LIS)
- Inventory (table of contents) of procedures
  - & recall of items for revision
- Facilities for rendering (optimized) printouts

Won't have

- Shall not burden end-user with irrelevant info

Automation projects

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     - **suitability of available technologies ?**
     - cost-effective ?
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html : hypertext markup language

Primitive language for rendering content on a screen
- Meta-element collects “declarations” about the document
- Embedded escape codes interpreted by “browser”
- Layout controlled through tables, frames & style sheets
- Include statements allow for reuse of one-time modular elements

Links, applets, cgi statements, etc.
Standard in evolution & meanwhile surpassed
- applications ahead of standardization
- industry does not adhere to standards and GPP

wiki : (acronym without meaning)

Dialect of html (variant syntax)
Flat database model
Allows input and revisions by end-users
suitable for information sharing (& project follow-up)
for issuing instructions you need to
separate authorized versions from unauthorized comments

xhtml : extended html

All pros and cons of html
+ structured text

Modular
- Classes – Objects – Properties
- Cascading style sheets
- Database oriented
- Flat text is assigned to objects in a database

Text rendering is programmed
- objects can be reused

cms : content management system

Usually a WYSIWYG (what you see is what you get) xhtml editor
Portability issue : differences in storage of objects and their properties :
- objects with embedded meta-elements in a depository
- versus pre-defined (relational) database fields

ems : enterprise management system

Database model extended to multiple applications

Flexibility *versus* Standardisation

Unstructered Documents

☺ Increasing Flexibility

☺ Increasing *ad-hoc* Adaptability

html
wiki

xhtml

cms
ems

☹ Decreasing Flexibility

Increased Standardisation ☺

Structered Documents

Content Organisation

Directories
Subsites

Database

html
wiki

xhtml

cms
ems

Global

Detailed

(= more laborious & error-prone)

Access Control
Work Flow Control

Workflow Organization

2 distinct processes

- End responsibility
  = focus of the business plan,
  coordination within the organization

- Authorization for specific actions (write/read)
  = process owners & users of instructions

Workflow Organization

- separates unauthorized & production versions

- authorization for specific actions (write/read) remains simple

Workflow
is not an IT-issue
but a culture- & management issue

- separates unauthorized & production versions

- defining workflow at the IT-level Is laborious & prone to error
- defining workflow at the IT-level does not guarantee timely execution

Automation projects

1. Inventory
   - requirements
   - current procedures
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3. After implementing step 2
   - evaluate : automation possible ?
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       - costs : implementation
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Costs of Implementation, Maintenance & Porting

☺ Increasing Flexibility
= easy implementation

Increasing *ad-hoc* Adaptability
CAVE : law of diminishing returns ☹

← to unaware end user

html
wiki
xhtml
cms
ems

→

Increased Standardisation
Decreased Portability
☹ = high implementation costs → to IT-department

Decreasing Flexibility
May help guard against
law of diminishing returns
☺

Part 4/4 : Document Control & IT

Summary

SUMMARY

1. Start with being clear about your goals
2. Continue with
   - having procedures
     adjusted to the purpose:
     instructions versus projects
   - simplify & standardize the procedures
3. Choose what is best for you
   - you need to distribute CONTENT:
     - getting content precedes rendering content
     - a document has a lifecycle of revisions
   - your system has to be structured
     - say it only once
     - users can find their way
   - be aware of the lure of bells and whistles
     law of diminishing returns