Documents And Records Control System Based On ISO 15189:2022

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کارگاه آموزشی سیستم مدیریت کیفیت در آزمایشگاه های تشخیص پزشکی بر مبنای ISO 15189:2022

سنندج

۳۱ مرداد و ۱ شهریور ۱۴۰۳

Challenges

- Deficiency in training
- Lack of improvement plan
- We do not understand the current situation
- Absence of road pattern

8.3 Control Of Management System Documents

- **8.3.1 General**
- **The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.**

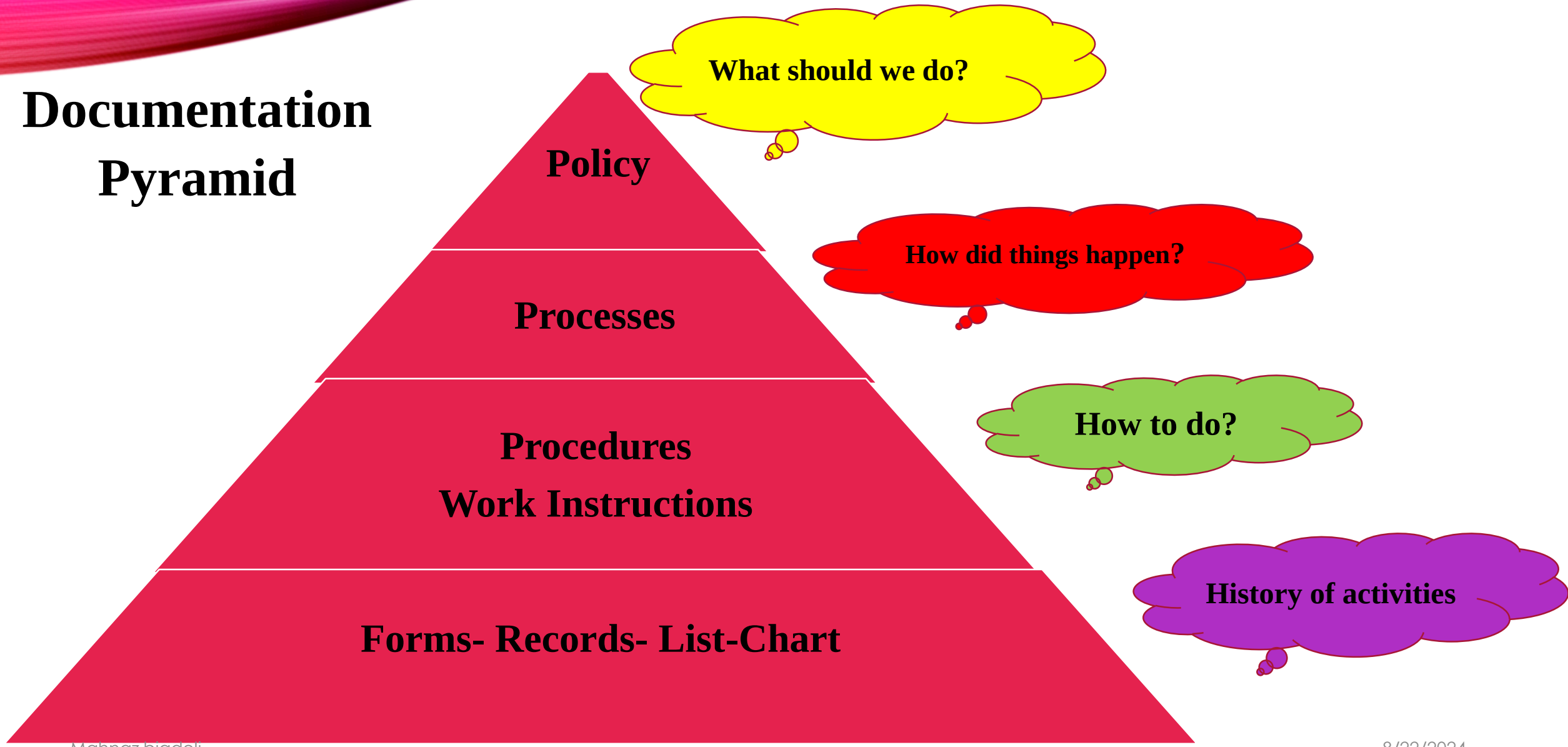
Internal documents

External documents

Documents

Records

Documentation Pyramid



8.3.2 Control Of Documents

- The laboratory shall ensure that:
- a) documents are **uniquely identified;**
- b) documents are approved for adequacy before issue by **authorized personnel who have the expertise**and competence to determine adequacy;
- c) documents are **periodically reviewed** and updated as necessary;
- d) **relevant versions** of applicable documents are **available** at points of use and, where necessary, their
- **distribution** is controlled;
- e) changes and the **current revision status of documents are identified;**

8.3.2 Control Of Documents

- f) documents are protected from **unauthorized changes and any deletion or removal;**
- g) documents are protected from **unauthorized access;**
- h) the unintended use of **obsolete documents is prevented**, and suitable identification is applied to them if they are retained for any purpose;
- i) at least one paper or electronic copy of each obsolete controlled **document is retained for a specified**time period or in accordance with applicable specified requirements.

The Importance Of Documentation

- The main pillars of the quality management standard
- Determining the correct framework for activities
- Providing the possibility of transferring and circulating information
- foundation for audit, review and continuous improvement
- Ability to analyze activities, processes

8.4 Control Of Records

- **8.4.1 Creation of records**
- The laboratory shall **establish and retain legible records** to demonstrate fulfilment of the requirements of this document.
- Records shall be created at the **time each activity that affects the quality** of an examination is performed.
- NOTE Records can be in any form or type of medium.

8.4.2 Amendment Of Records

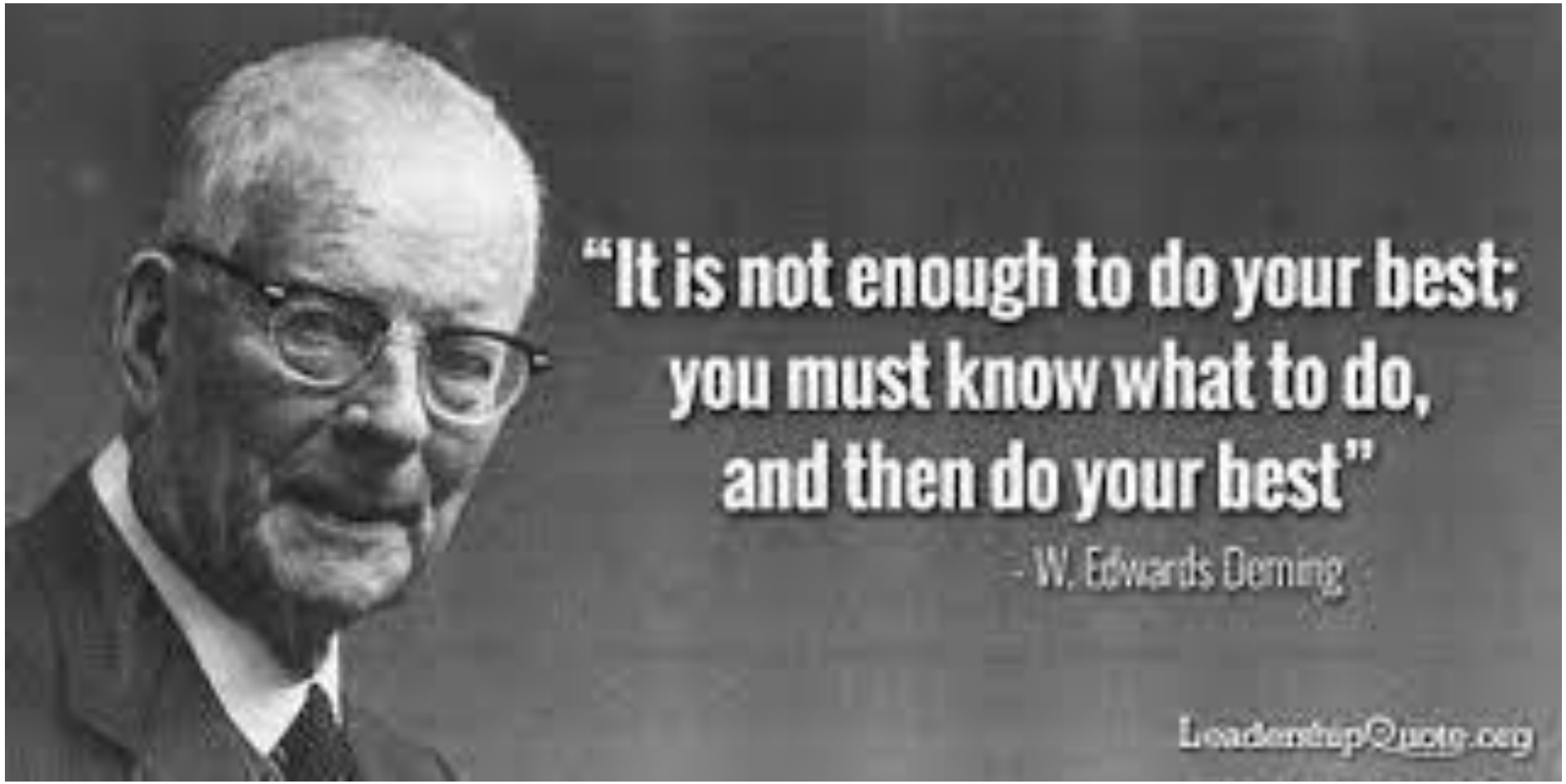
- The laboratory shall ensure that amendments to **records can be traced to previous versions** or to original observations. Both the original and amended data and files shall be kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.

8.4.3 Retention Of Records

- a) The laboratory shall implement the procedures needed for the **identification, storage, protection**

from unauthorized access and changes, **back-up**, **archive**, **retrieval**, **retention time**, and **disposal** of its records.

- b) The **retention times** for records shall be specified.
- NOTE 1 In addition to requirements, retention times can be chosen based on identified risks.
- c) Reported examination results shall be retrievable for as long as necessary or as required.
- d) All records shall be **accessible** throughout the entire retention period, legible in whichever medium
- the laboratory keeps records, and available for laboratory management review (see 8.9).
- NOTE 2 **Legal liability** concerns regarding certain types of procedures (e.g. histology examinations, geneticexaminations, pediatric examinations) can require the retention of certain records for much longer times than for other records.


"It is not enough to do your best;
you must know what to do,
and then do your best"
- W. Edwards Deming
LeadershipQuote.org