MAY 2020

WK 15 101-265

FRIDAY • APRIL 10

5.10 - Laboratory information management

→ Documented procedure
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to ensure maintaining confidentiality of patient information.

→ Includes management of data & information contained in computer & non-computerized system.

→ Define authority & responsibilites of all personnel who use system, in particular those who.

- access patient data & information
- Enter patient data & examination results
- change patient data or examination results
- authorize release of examination results/ reports

→ The system should be
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Validated by supplier &
Verified functioning by laboratory before introduction,
- Any changes to system authorized, documented & verified before implementation

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→ Validation & Verification include
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- proper functioning of interfaces between LIS & other systems such as with laboratory instrumentation, hospital patient administration system & systems in primary care.
- Documented & documentation that for day to day functioning of system, readily available to authorized users.
- protected from unauthorized access.
- Safeguard against tampering or loss
- operated in environment that complies with supplier specification (or) in case of non computerized system, provides condition which safeguard accuracy of manual recording & transcription.
- maintained in manner that ensures the integrity of data & information & includes recording of system failure & appropriate immediate & corrective action
- In compliance with national or international requirement regarding data protection.