

Radiopharmacy stock / release computer systems

Veenstra Instruments

PART OF  **COMECERGROUP**

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**Radiopharmacy
Management
software
System**



Software system

- Started in the early 1980's as the Isotope Bookkeeping Computer (IBC) in combination with a Dose Calibrator.
- Today we use the 7th generation.



Software design



How the customer explained it



How the project leader understood it



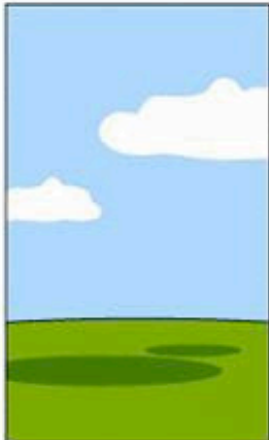
How the analyst designed it



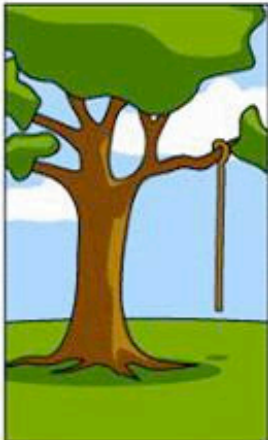
How the programmer wrote it



How the business consultant described it



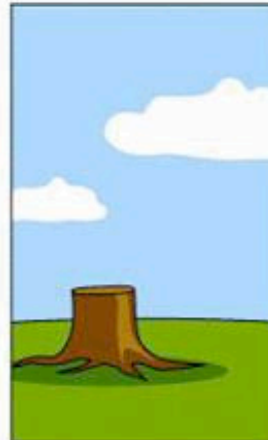
How the project was documented



What operations installed



How the customer was billed



How it was supported



What the customer really needed



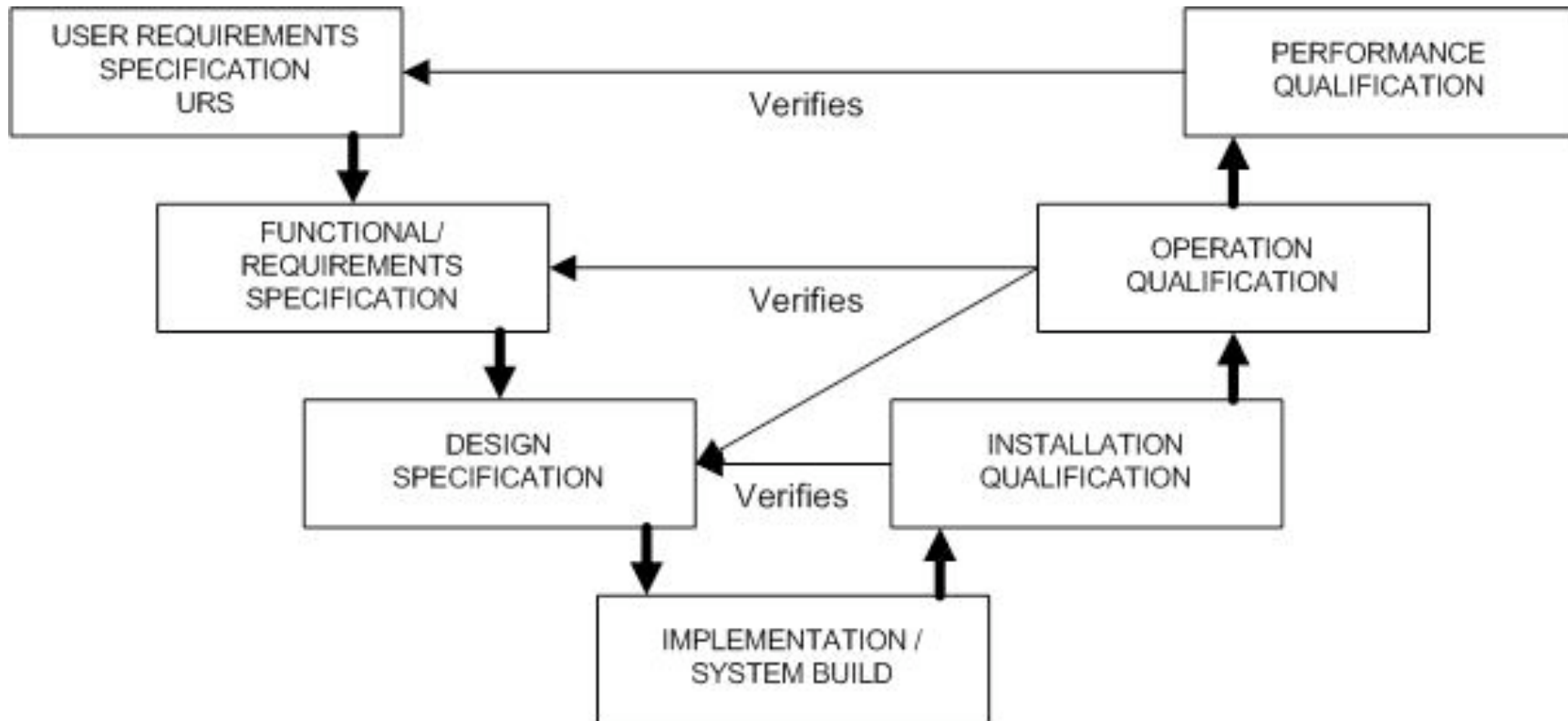
Software design

- GAMP:

Good Automated Manufacturing Practice



GAMP V-model



Validated software

- Supplier statement (certificate) that the software is developed and designed according the GAMP V-model and meets the functional requirement specifications.
- Also every change in functionality meets these requirements.



Validated software

- Risk based approach because it is impossible to verify everything.
- According EU GMP: “... *an justification (certificate) of suppliers of automated systems can be taken in account.*”



Radiopharmacy

- According EU GMP: *“Software users need to identify which validation activities are needed to proof that the critical aspects of the processes in the radiopharmacy can be handled.”*



Radiopharmacy

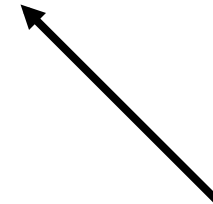
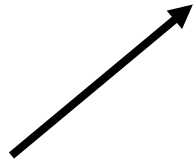
- According EU GMP: “A *risk-assessment policy needs to be performed to identify the range and size of the validation.*”



Radiopharmacy



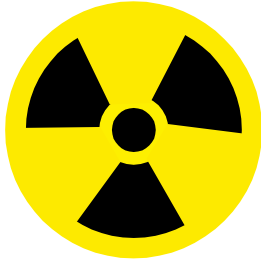
Radiation safety
guidelines



Pharmaceutical
guidelines



Radiopharmacy



- Shielding
- Measuring
- Monitoring
- Registration

Radiation
Regulation



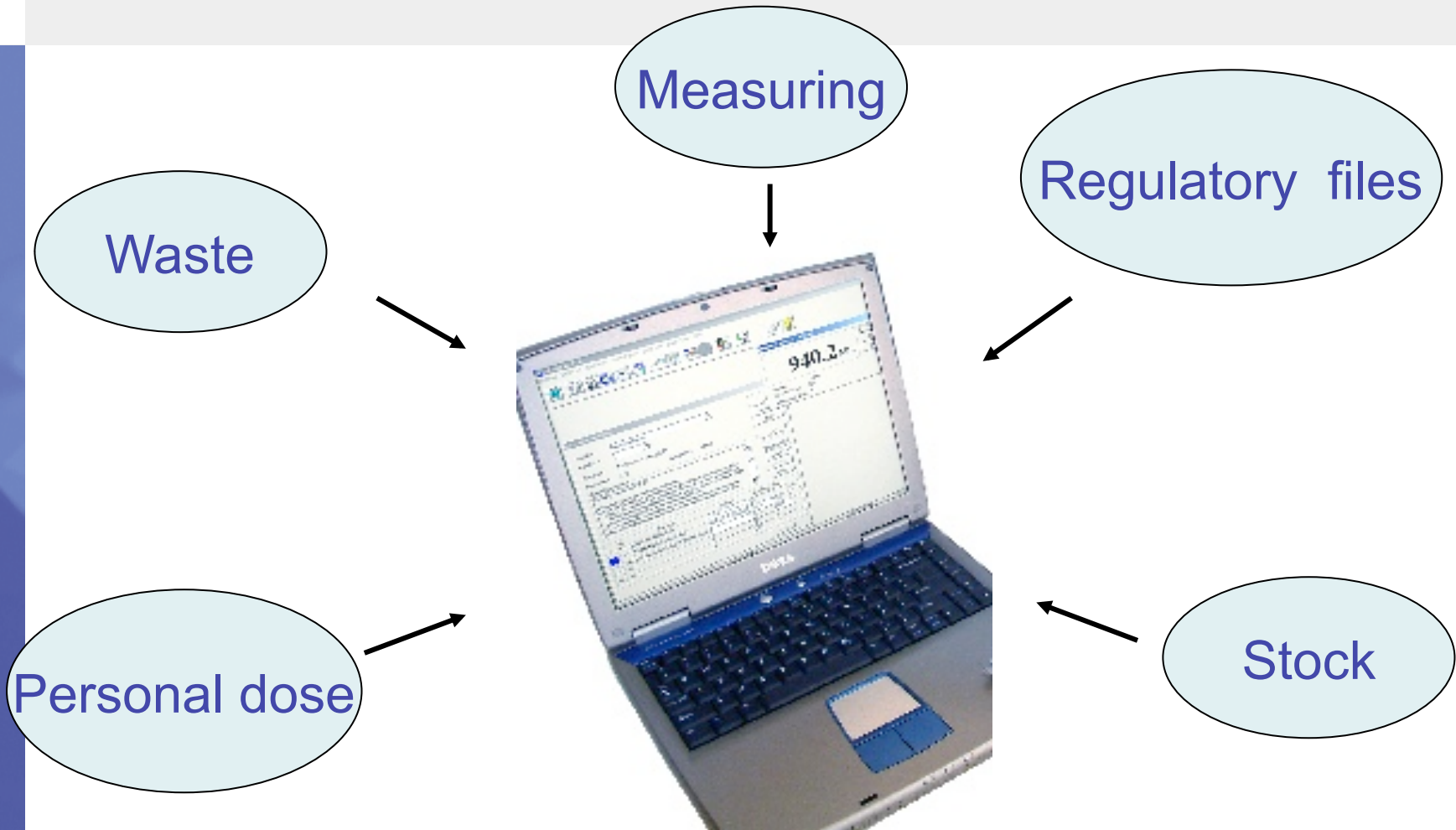
- Sterility
- Quality
- Control
- Registration

Pharmaceutical
Regulation



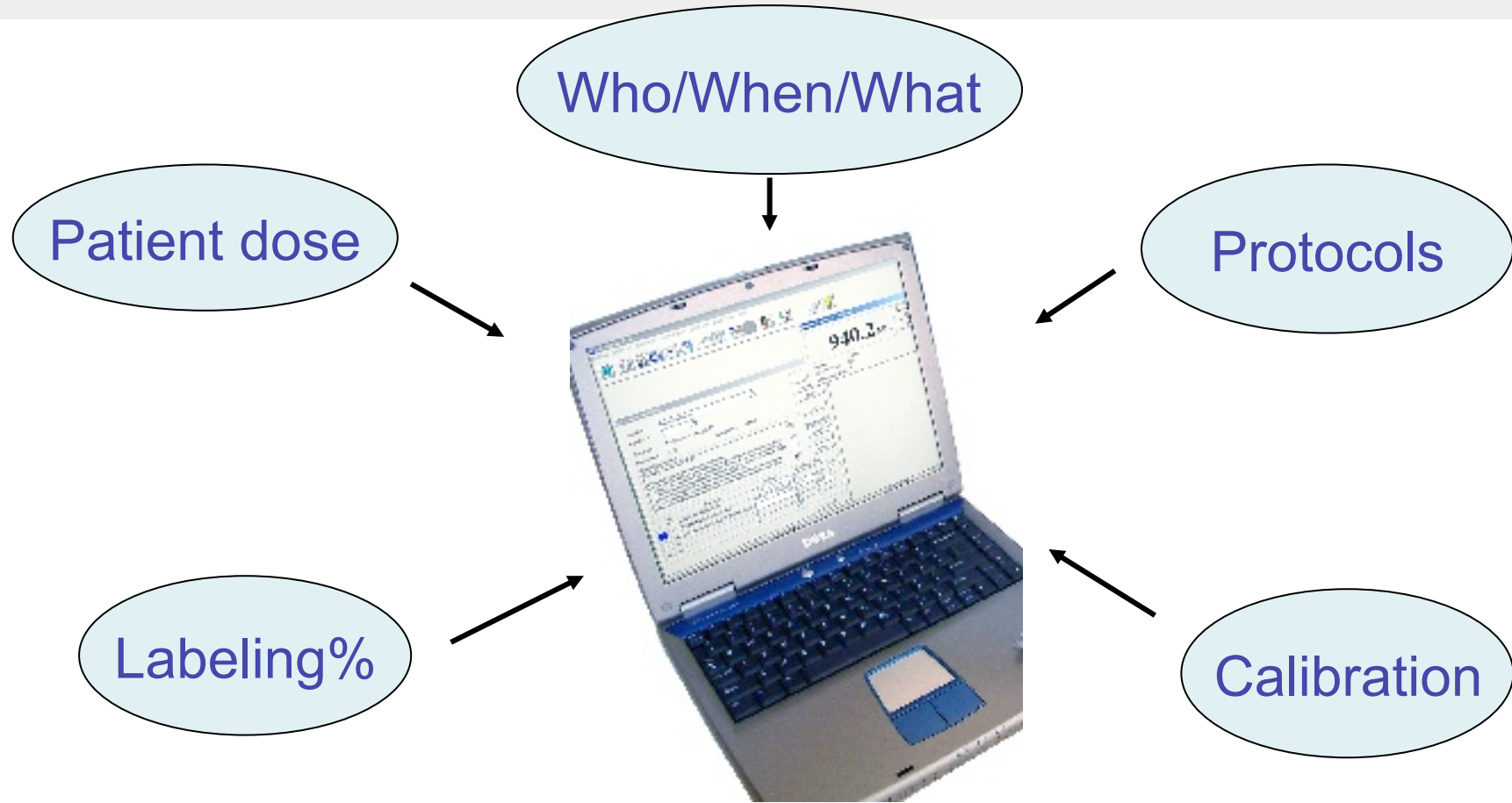


Registration





Registration



Software system

- Modular design to meet the various workflows:
 - Nuclear medicine radiopharmacy
 - Cyclotron facility
 - Central pharmacy
 - Receiving site

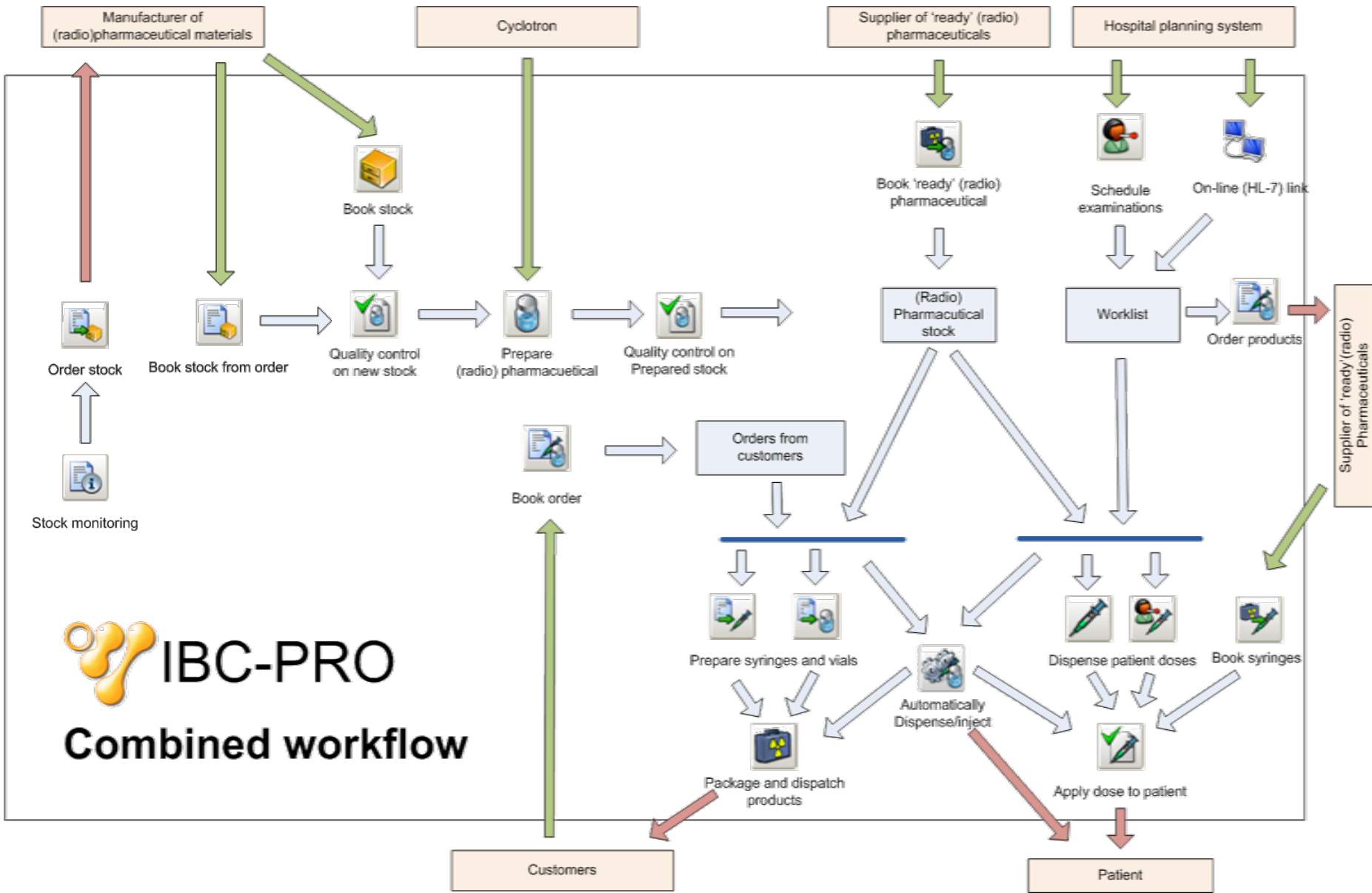


Modular design

	IBC-PRO	IBC-Protocol	IBC-OC Pharmaca	IBC-Barcode	IBC-Pharmacy	IBC-Syringe check	IBC-Waste	IBC-Purchase	IBC-Receive	IBC-Delivery	IBC-Room assignment	IBC-Test	IBC-LINK (HL-7)
NM Radiopharmacy	Required	Required	Recommended	Recommended	Optional	Recommended	Recommended	Recommended	Optional	Optional	Optional	Recommended	Recommended
Cyclotron facility	Required	Required	Recommended	Recommended	Optional	Optional	Recommended	Recommended	Unnecessary	Optional	Optional	Recommended	Recommended
Central pharmacy	Required	Required	Recommended	Recommended	Optional	Optional	Recommended	Recommended	Unnecessary	Required	Optional	Recommended	Recommended
Receiving site	Required	Unnecessary	Unnecessary	Optional	Optional	Recommended	Recommended	Unnecessary	Required	Unnecessary	Optional	Optional	Recommended

Required	Recommended	Optional	Unnecessary
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 **IBC-PRO**
Combined workflow

NM Radiopharmacy

- Database functionality
- User management
- Patient management
- Stock management
- Patient dose preparation and administering
- Waste management



Database functionality

- Registration
- Definitions must be approved and are provided with an audit trail
- The action is blocked when exceeding the limits (dose, volume)
- Label manager
- Report generator



User management

- Every user needs a user name & password and a set of privileges



Patient management

- Link to the RIS/PACS system
- Automatic patient- & examination data import
- Approval of the dose



Stock management

- Active- and non-active stock
- Booked in or in-house prepared
- Printing labels
- Identification via barcode scanning
- Mandatory pharmaca quality control tests including Molybdenum breakthrough%
- Purchase order management



Batch preparations

- User definable protocols to meet current routine (Standard Operating Procedure)
- In-process control tasks
- Suitable for both standard Technetium preparations and the more difficult ones like blood cell labeling



Measurement

- Automatic isotope selection
- Mandatory Dose Calibrator quality control tests necessary to prove the reliability, stability and accuracy of the read-out
- Other brand Dose Calibrators can be connected



Patient dose preparation

- Work list including half life time correction
- Barcode scanning to make sure the correct pharmacoin is used
- Printing a label



Patient dose preparation

- Use of dose calculation methods for the calculation of paediatric doses like EANM Dosage card
- Syringe dispenser communication



Patient dose administering

- Barcode scanning for identification of patient and/or syringe
- Automatic calculation of the injected patient dose according to the actual injection time



Patient dose administering

- Any remaining remnant activity in the syringe can be measured and will be subtracted from the calculated injected dose
- Registers the amount of activity that is really injected into the patient



Waste management

- Active and non-active waste
- Requirement to show the total in-house activity of stock and waste
- Cleans up the actual stock at the end of the day



Reports

- Daily overviews with who/when/what
- Digital approval
- Aim: paper free radiopharmacy but reports can be printed and exported to other file formats



Test environment

- To prevent that software- and hardware updates and upgrades will be tested in the production environment



Cyclotron facility

- Extended production protocol definitions
- Vial dispenser communication



Central pharmacy

- Management of the complete order administration for a Central pharmacy: from booking in orders up to dispatching the orders to clients
- Automatic printing of the official transport documents for the carrier and the client



Receiving site

- Order management of ready made pharmaca received from a Central pharmacy
- After receiving the doses must be booked into the system



Display

- 17" LCD monitor mounted in Laminar flow cabinet or isolator
- Touch screen possible

In combination with a fanless mini-PC especially for use in clean rooms



Thank you

