DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# AN OVERVIEW OF SOFTWARE DEVELOPMENT MODELS – BASICS
# HOW TO MANAGE CHANGES FOR SAMD IN THE DEVELOPMENT LIFECYCLE


**Tony Yip**

*Manager of Quality Assurance & Regulatory Affairs, Elekta Far East Region*

*BEng, MSc (Comp. Sci.), CISA,*
*IRCA Registered QMS Principal Auditor*


**AHWP 2015 Annual Meeting**

*Bangkok, 4 Nov 2015*

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

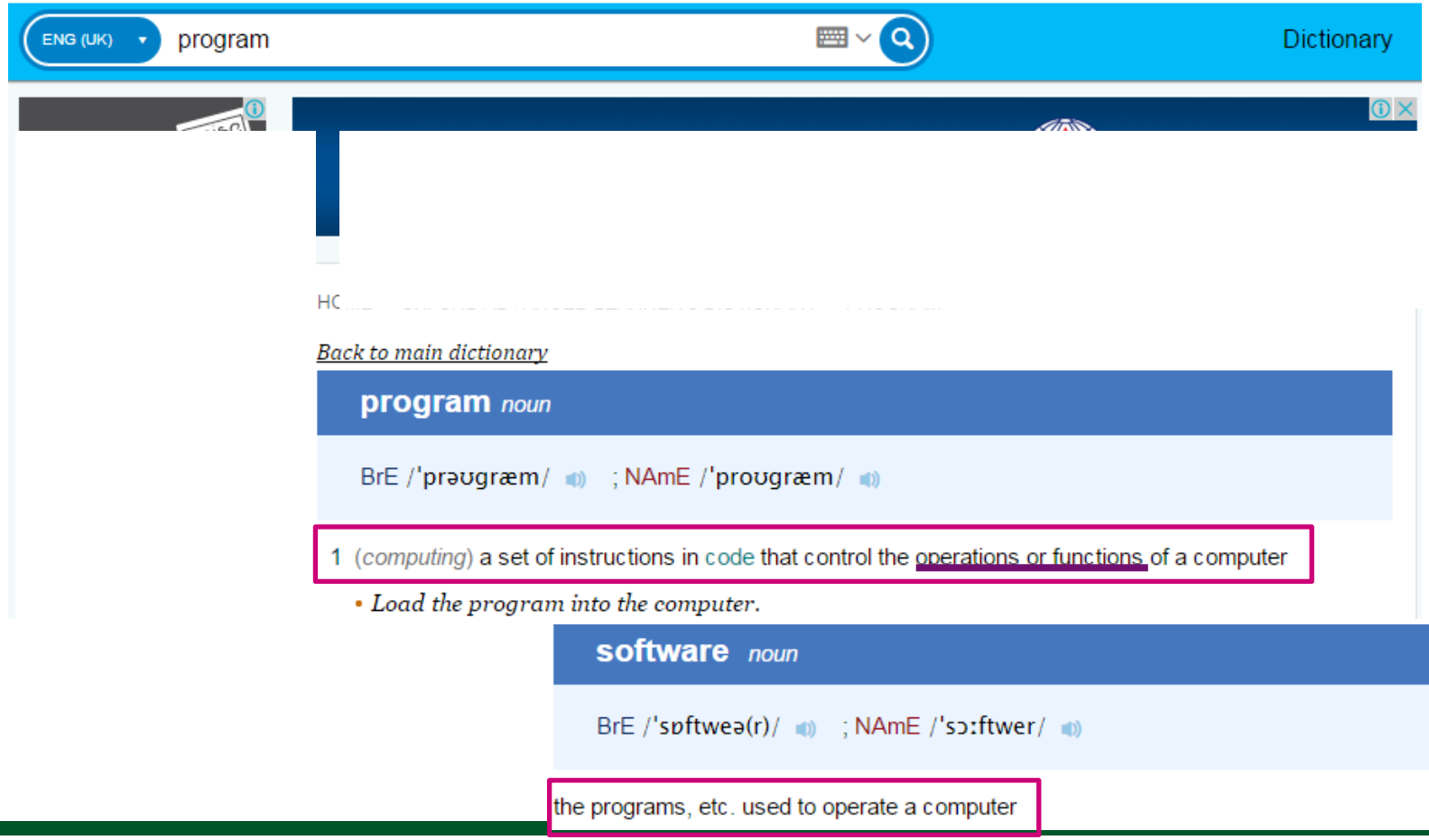
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# WHAT IS SOFTWARE

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# WHAT OXFORD DICTIONARY SAID

Oxford Dictionaries
Language matters




COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

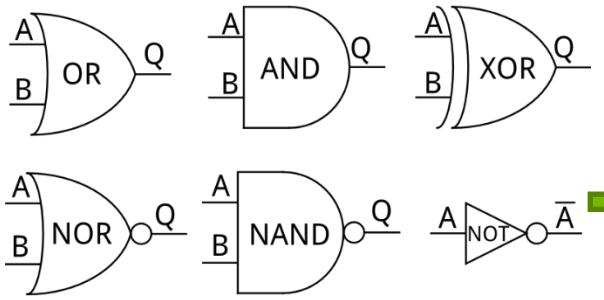
# IEC 62304 DEFINED…

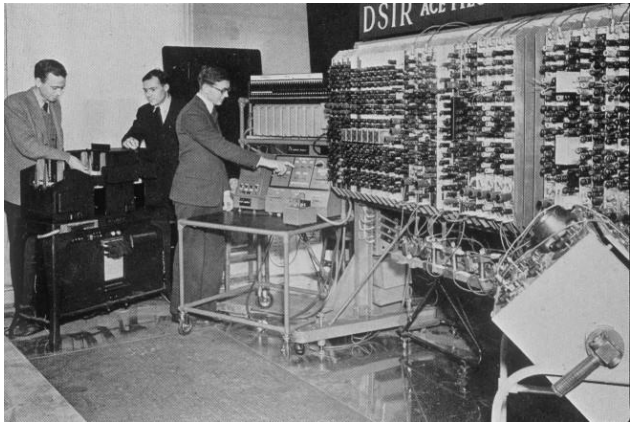

- Set of computer programs, procedures, and possibly associated documentation and data
- Integrated collection of Software Items organized to accomplish a specific function or set of functions
- Any identifiable part of computer program
- Software item that is not subdivided into other items

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

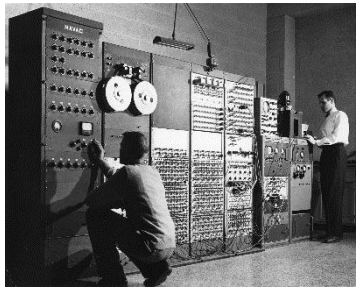
# SOFTWARE EVOLVEMENT

## Logic Gates -> Programmable Logic Controller (PLC) -> Computing Systems -> Software




Turing Machine, 1937
(Filmed as "The Imitation Game")



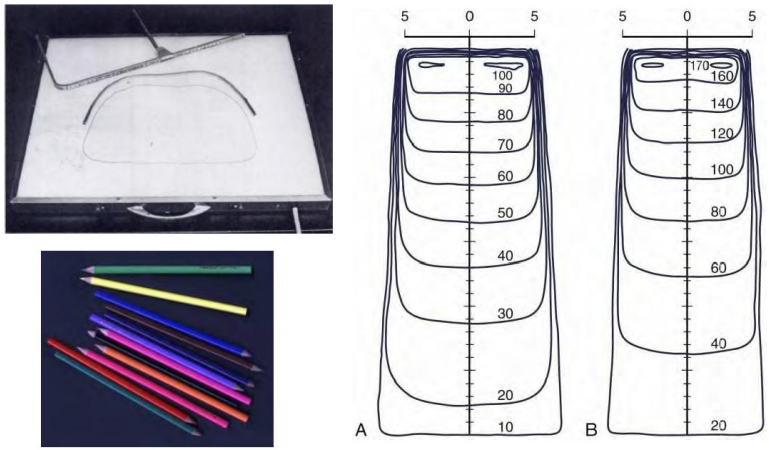
IBM SSEC, 1948

After many years of development…

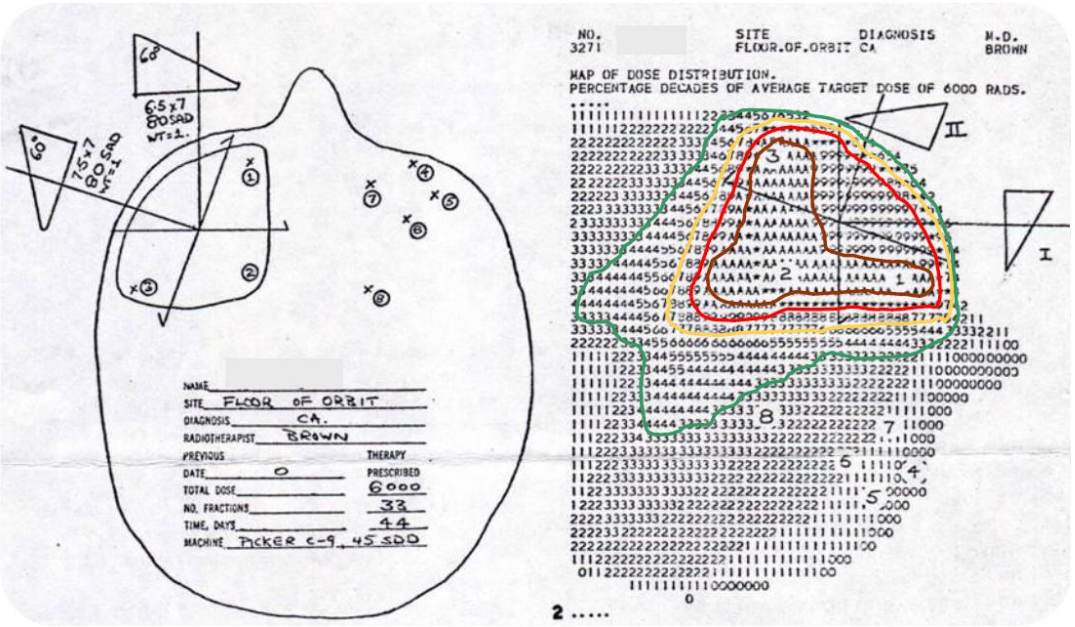
Extended reading: http://plato.stanford.edu/entries/computing-history/
Image credit: http://d3l9bzfuzkm13y.cloudfront.net/wp-content/uploads/2015/02/Designed-by-Alan-Turing-the-original-Bombe-computer-took-the-form-of-emulating-several-hundred-Enigma-rotors-2-655x438.jpg ; https://cdn.sparkfun.com/assets/3/4/7/5/e/51e5c089ce395f8d16000000.png ; https://tctechcrunch2011.files.wordpress.com/2012/06/app-store-icon.png ; http://www.androidcentral.com/sites/androidcentral.com/files/styles/large/public/topic_images/2014/topic_google_play.png?itok=MrXJ4PqV

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# RADIATION THERAPY 1960'S



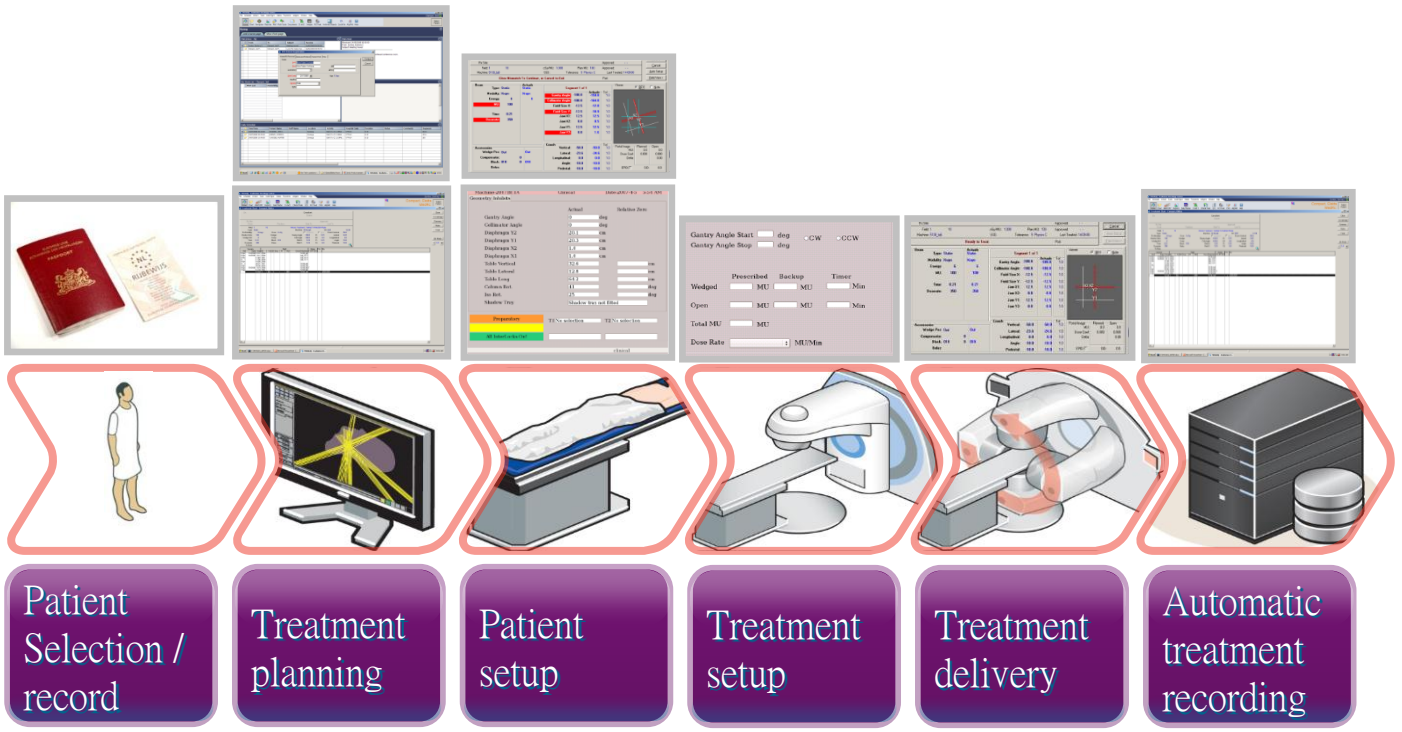

1960' s Treatment Planning Tools




1960' s Treatment Planning Service - by Memorial Hospital and M.D. Anderson, USA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# RADIATION THERAPY NOWADAYS



DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SOFTWARE ENGINEERING

## Manufacturer ⇔ Developer

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

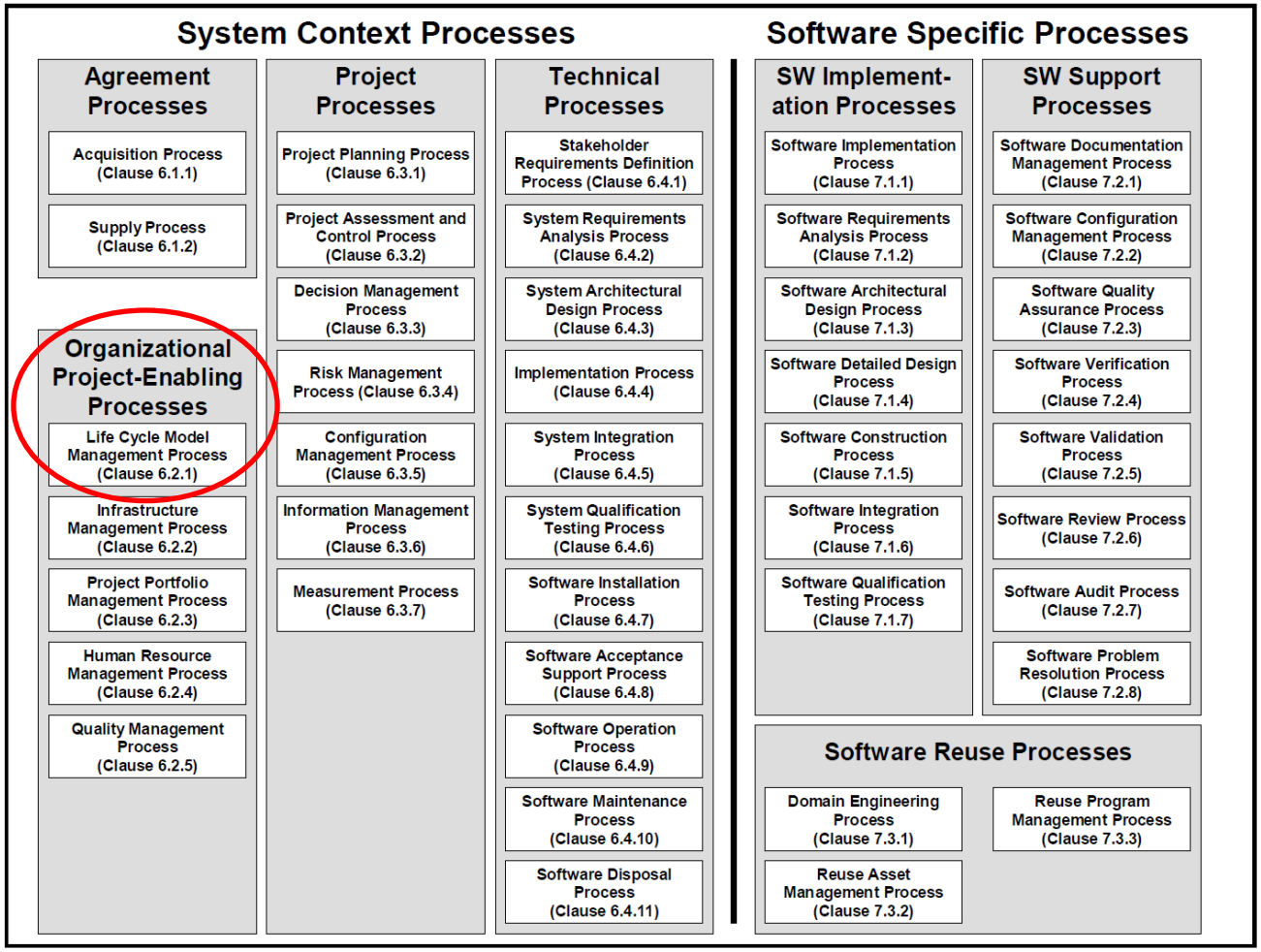
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SOME REFERENCE TO START

- ISO 15288: System and Software Engineering – System Life Cycle Processes (Not specific for Medical Device)
- ISO 12207: System and Software Engineering – Software Life Cycle Processes (Not specific for Medical Device)
- ISO/IEC TR 19759: Software Engineering – Guide to the software engineering body of knowledge (SWEBOK) (Not specific for Medical Device)
- Medical Device SaMD SDLC – IEC 62304
- Health Software SDLC – IEC 82304 (coming)

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SYSTEM & SOFTWARE LIFE CYCLE PROCESS




ISO/IEC 12207:2008

**Figure 1 — Life Cycle Process groups**

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# LIFE CYCLE MODEL

- ✓ Framework of processes and activities concerned with the life cycle that may be organized into stages, which also acts as a common reference for communication and understanding

ISO/IEC 12207 Definition

- ❖ Life Cycle Model does not specify what document needs to be generated in different stages, but process & activity standard like IEC 62304, ISO/IEC 15288, ISO/IEC 12207 does

# IEC 62304

Introduction Section:

- This standard does not prescribe a specific life cycle model. The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this standard onto that model.

Annex B

**Table B.1 – Development (model) strategies as defined in ISO/IEC 12207**

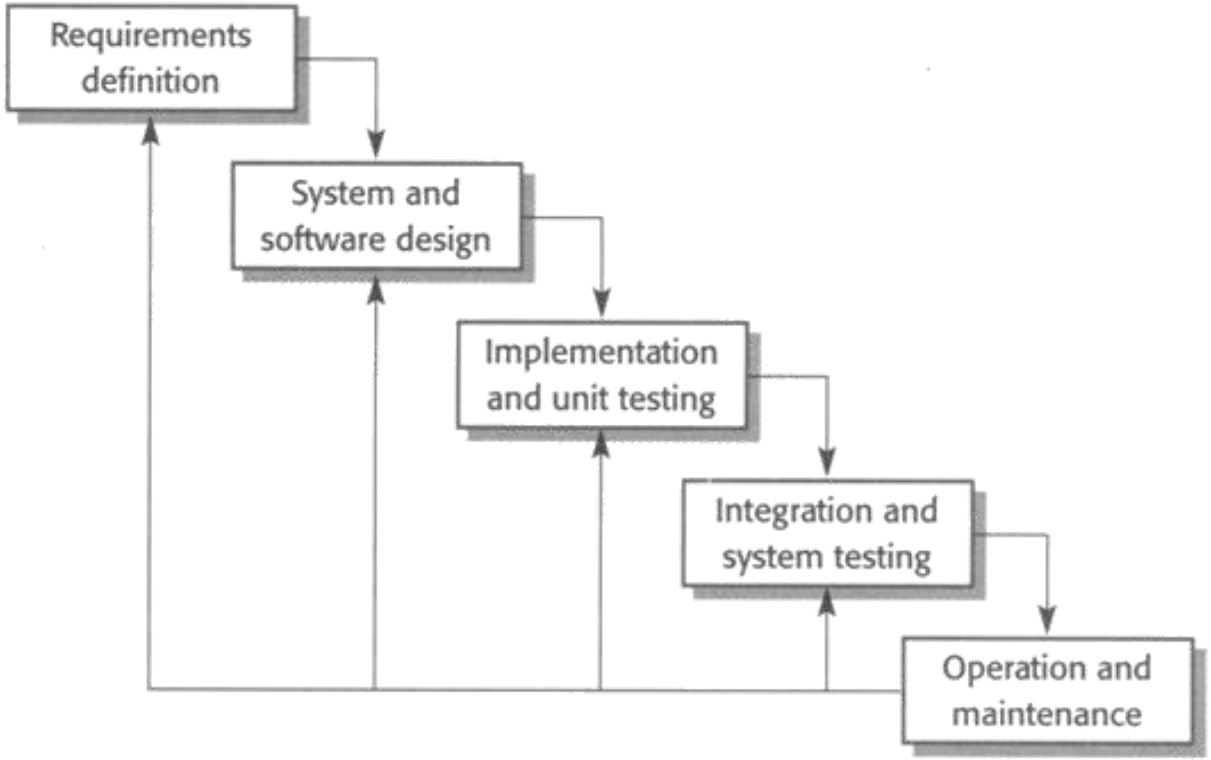
| Development Strategy | Define all requirements first? | Multiple development cycles? | Distribute interim software? |
|---|---|---|---|
| Waterfall (Once-through) | yes | no | no |
| Incremental (Preplanned product improvement) | yes | yes | maybe |
| Evolutionary | no | yes | yes |

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SOFTWARE DEVELOPMENT LIFE CYCLE (SDLC) - MODELS

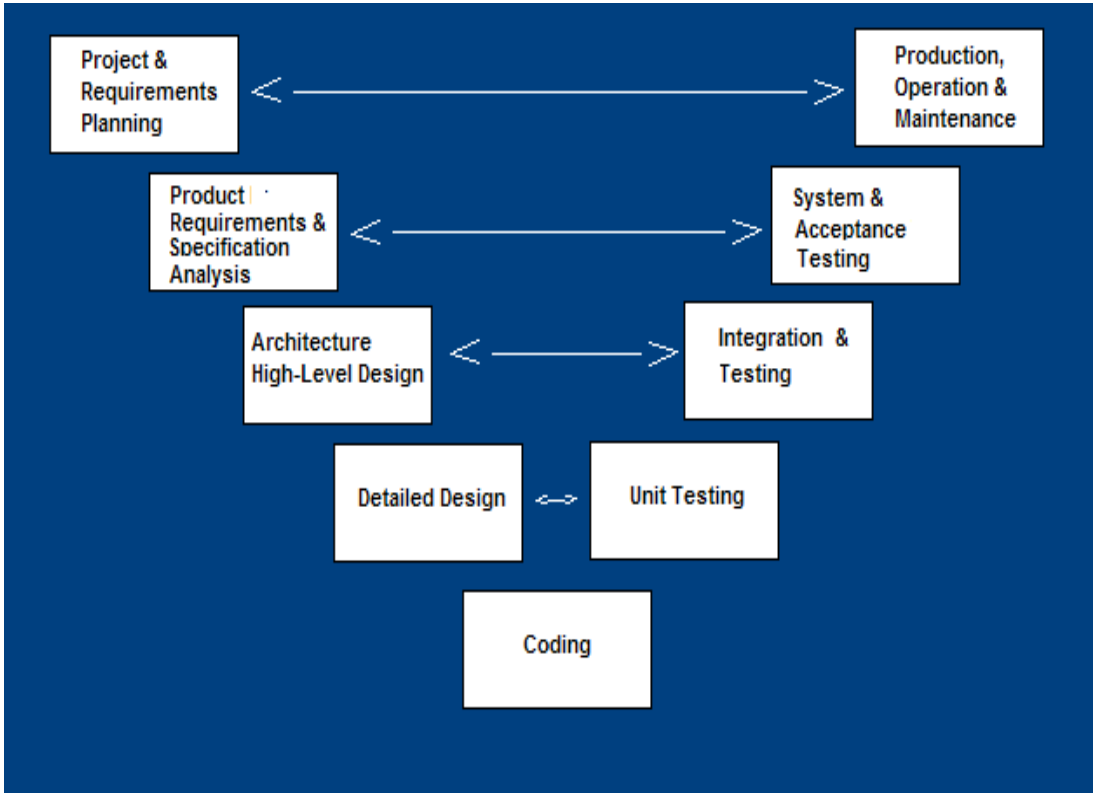
1. Waterfall
    i. V-shaped
2. Incremental Development
3. Evolutionary development
4. Other: Spiral Model, Traditional SDLC etc

# WATERFALL MODEL




The "once-through" strategy, also called "waterfall", consists of performing the development PROCESS a single time. Simplistically: determine customer needs, define requirements, design the SYSTEM, implement the system, test, fix and deliver.

# V-SHAPE SDLC MODEL

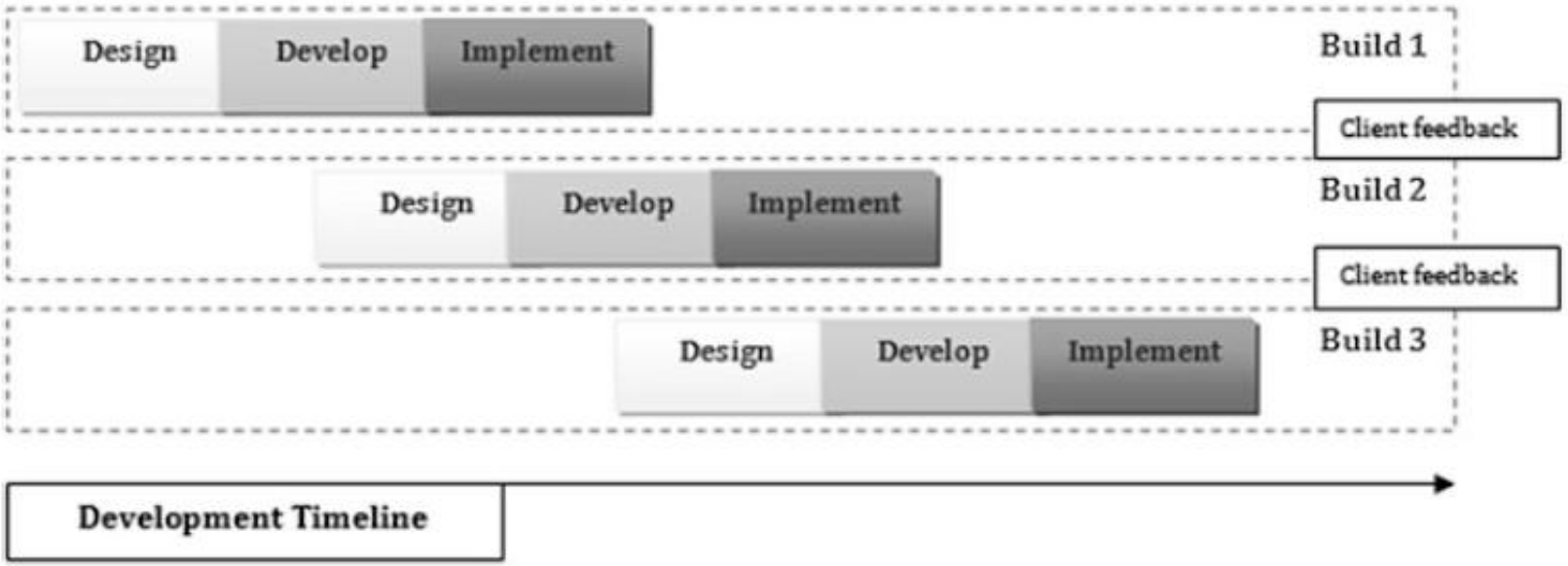



- A variant of the Waterfall that emphasizes the verification and validation of the product.
- Testing of the product is planned **in parallel** with a corresponding phase of development

Content credit: Dr. Kirstie Hawkey, Dalhousie University

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

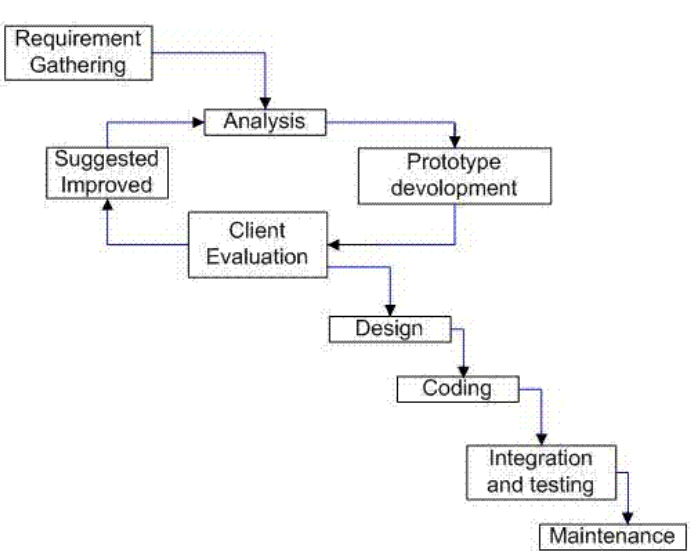
# INCREMENTAL DEVELOPMENT MODEL




The “incremental” strategy determines customer needs and defines the SYSTEM requirements, then performs the rest of the development in a sequence of builds. The first build incorporates part of the planned capabilities, the next build adds more capabilities, and so on, until the SYSTEM is complete.

Image credit: High Level Models and Methodologies for Information Systems, P. Isaias and T. Issa, DOI 10.1007/978-1-4614-9254-2_2, Springer Science+Business Media New York 2015

# EVOLUTIONARY PROTOTYPE MODEL




**Evolutionary Prototyping Model**

The "evolutionary" strategy also develops a SYSTEM in builds but differs from the incremental strategy in acknowledging that the user need is not fully understood and all requirements cannot be defined up front. In this strategy, customer needs and SYSTEM requirements are partially defined up front, then are refined in each succeeding build.

Image credit: https://melsatar.files.wordpress.com/2012/03/ev-proto.png

# SPIRAL MODEL

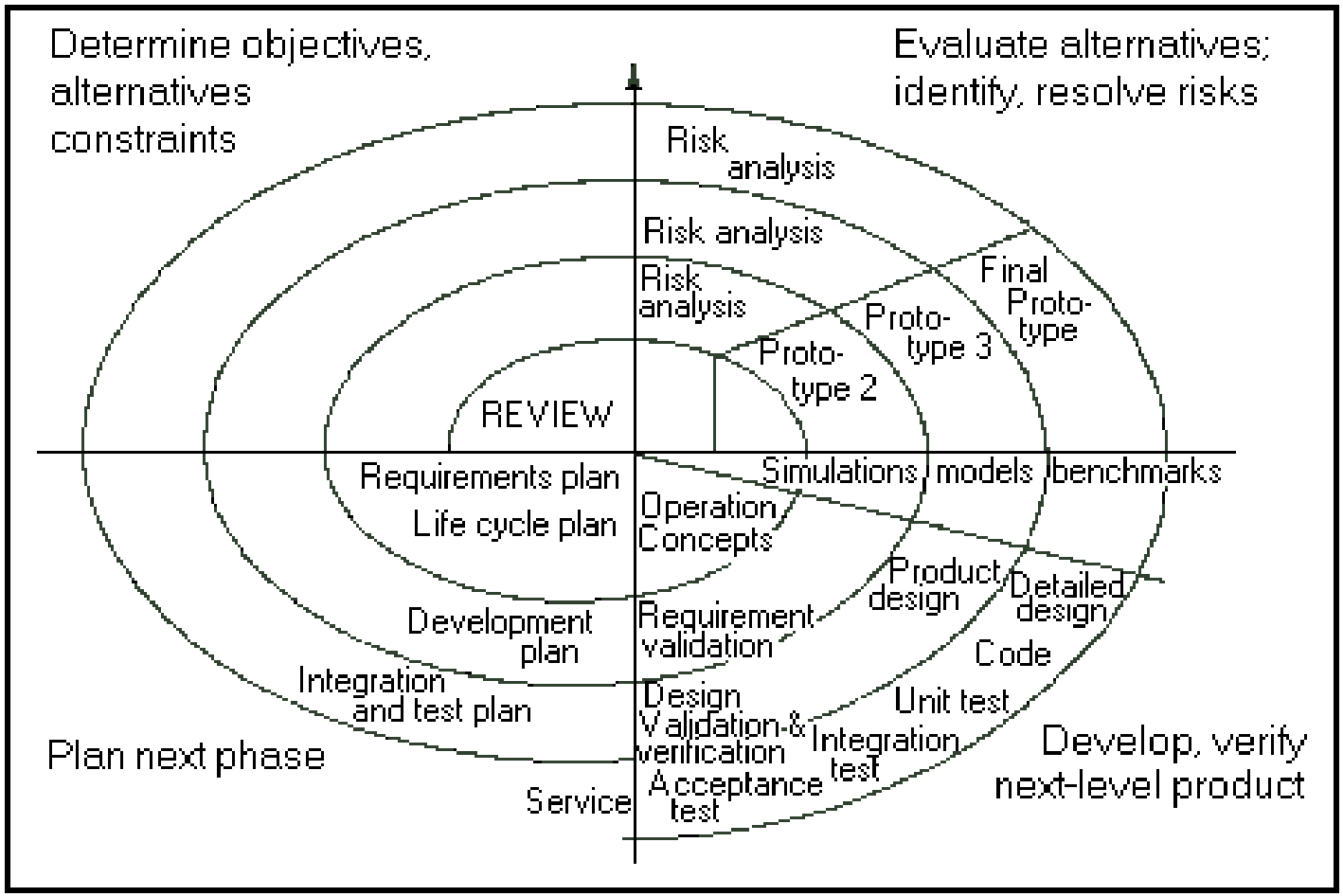



Image credit: IBM

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SOFTWARE ENGINEERING VS TRADITIONAL MD MANUFACTURING

## IMDRF/SaMD WG (PD1)/N23R3: Software as a Medical Device (SaMD): Application of Quality Management System

- ✓ Adopted of SDLC Process & activities into medical device manufacturing QMS



COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

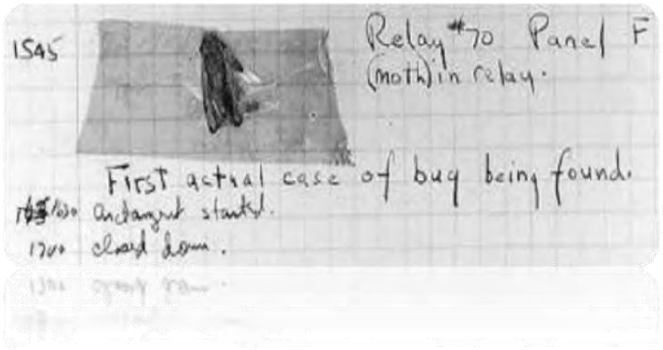
# WHAT IS GENERATED DURING DIFFERENT STAGES OF SOFTWARE DEVELOPMENT

| US FDA Guidance | Related SDLC Stages |
|---|---|
| Level of Concern | Requirement Stage |
| Software Description | Requirement Stage |
| Device Hazard Analysis | Requirement, Design |
| Software Requirement Specifications (SRS) | Requirement Stage |
| Architecture Design Chart | Design Stage |
| Software Design Specification (SDS) | Design Stage |
| Traceability Analysis | Development Stage |
| Software Development Environment Description | Development Stage |
| Verification & Validation Documentation | V&V Stage |
| Revision level History | Deployment Stage |
| Unresolved Anomalies (Bugs or Defects) | Deployment, Maintenance Stage |

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# 1947: FIRST COMPUTER ”BUG”

Engineers working on the Mark II computer at Harvard University found a moth stuck in one of the relays. They taped the insect in their logbook. The words "bug" and "debug" soon became a standard part of the language of computer programmers.



DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# SOFTWARE CHANGE

What can cause a software change:

- ✓ Bug fix
- ✓ New feature
- ✓ Adding fail safe / alarm function to prevent mis-use
- ✓ User Experience Improvement
- ✓ Not really a bug, but minor improvement
- ✓ Adding new Indication for Use
- ✓ Adding Intended Use to existing software

…etc

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# DOCUMENT AFFECTED DURING SOFTWARE CHANGE

- There is no golden rule to confirm what documents will be changed.
- Change is unpredictable as IT environment, technology and user needs change rapidly.
- Some of the regulatory review nowadays cover all/most of the development process & activities documents for particular software, and sometimes even down to code level review.
  - Equivalent to Full Manufacturing Audit/Inspection for particular medical device in traditional medical device manufacturing
  - Imagine the only manufacturing equipment for software developer (manufacturer) are Macbooks or Laptops, working in Coffee shop

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# QUESTION: HOW TO REGULATE THEIR DEVELOPMENT

And new medical device created after few cups of coffee!

Image Credit: https://educationfutures.com/2008/knowmads-in-society-30/

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# QUESTION TO THINK ABOUT: CALCULATOR TO CALCULATOR PROGRAM

1+1=2

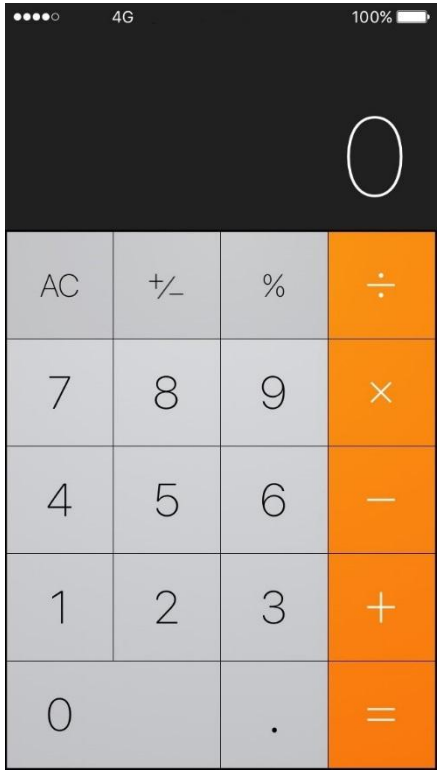




Image credit: http://www.edtechmagazine.com/k12/article/2012/11/calculating-firsts-visual-history-calculators ; http://timerime.com/user_files/50/50011/media/800.jpg?t=1296496689

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Over-Regulate

Under-Regulate

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

# THANK YOU!

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health