U. S. Department of
Health and Human Services

Center for Devices and
Radiological Health

HCSS / CPS Strategic Priorities

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The Challenge

Center for Devices and Radiological Health

- Devices have evolved from analog to digital
- Devices are transmitting data on networks
- Devices are aggregating data
- Devices will be sharing data
- Devices will be **interoperating**
- Devices will be systems of systems
- Devices will be omni-present
- Devices will challenge current concepts – biological
  - Software is now ubiquitous in medical devices
  - Software complexity in devices is increasing

FDA Strategic Priorities in HCSS

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- Formal methods based design
  - Device software/system safety modeling
  - Component composition
  - System/software certification/assured verification
  - Forensic analysis
  - Engineering tool foundations
- Cyber physical systems
  - Integration of computer and information-centric physical and engineered systems
- Architecture, platform, middleware, resource management
  - Interoperable Plug and Play devices
  - Vigilance and trending systems
- Component-based foundations for accelerated design and verifiable system integration

FDA Strategic Priorities in HCSS (cont'd)

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- Infrastructure for Medical Device Integration & Interoperation
- Model based development
- Component based design frameworks
- Patient modeling & simulation
- Adaptive patient-specific algorithm
- Requirements & metrics for certifiable assurance & safety

The Strategy

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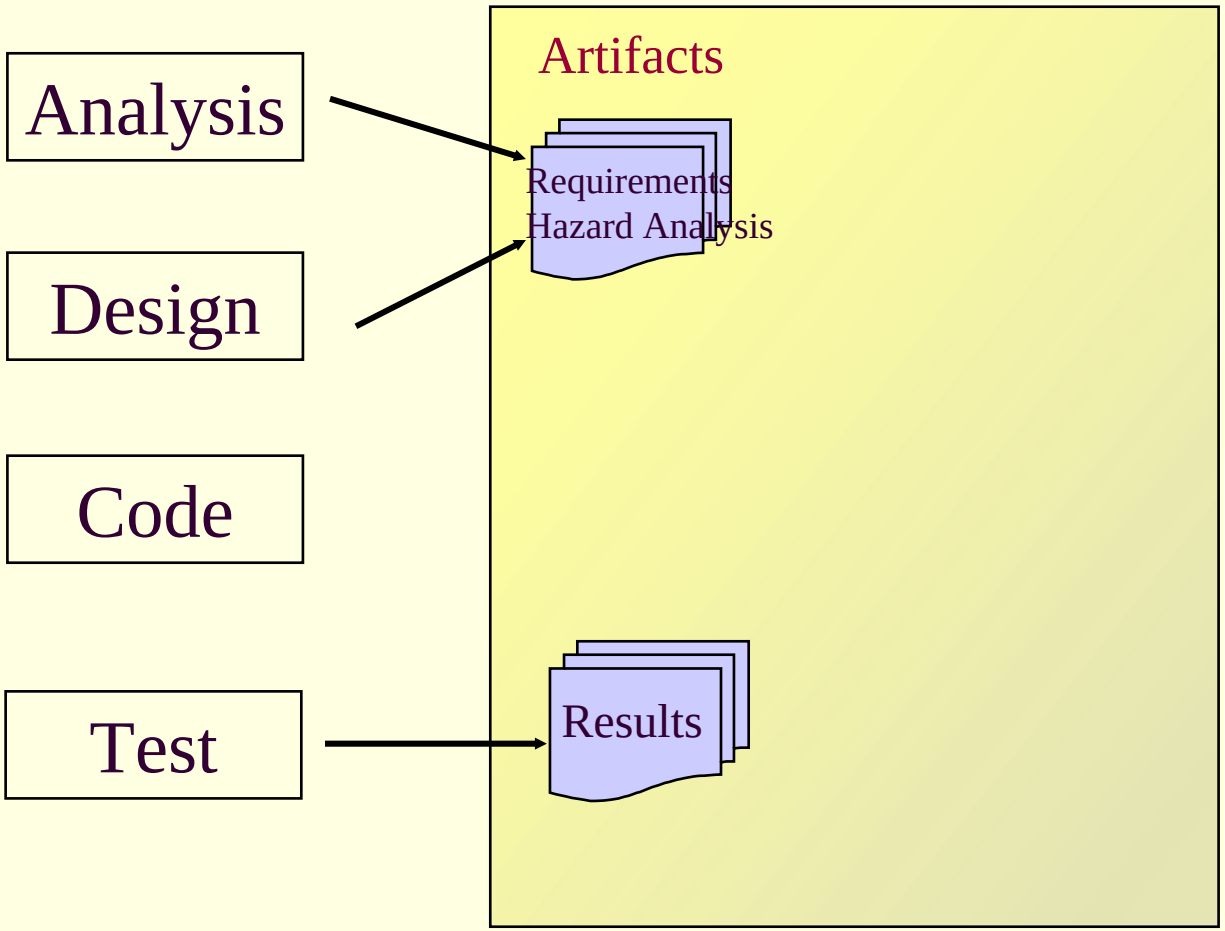
Software Development Lifecycle Process



The Strategy

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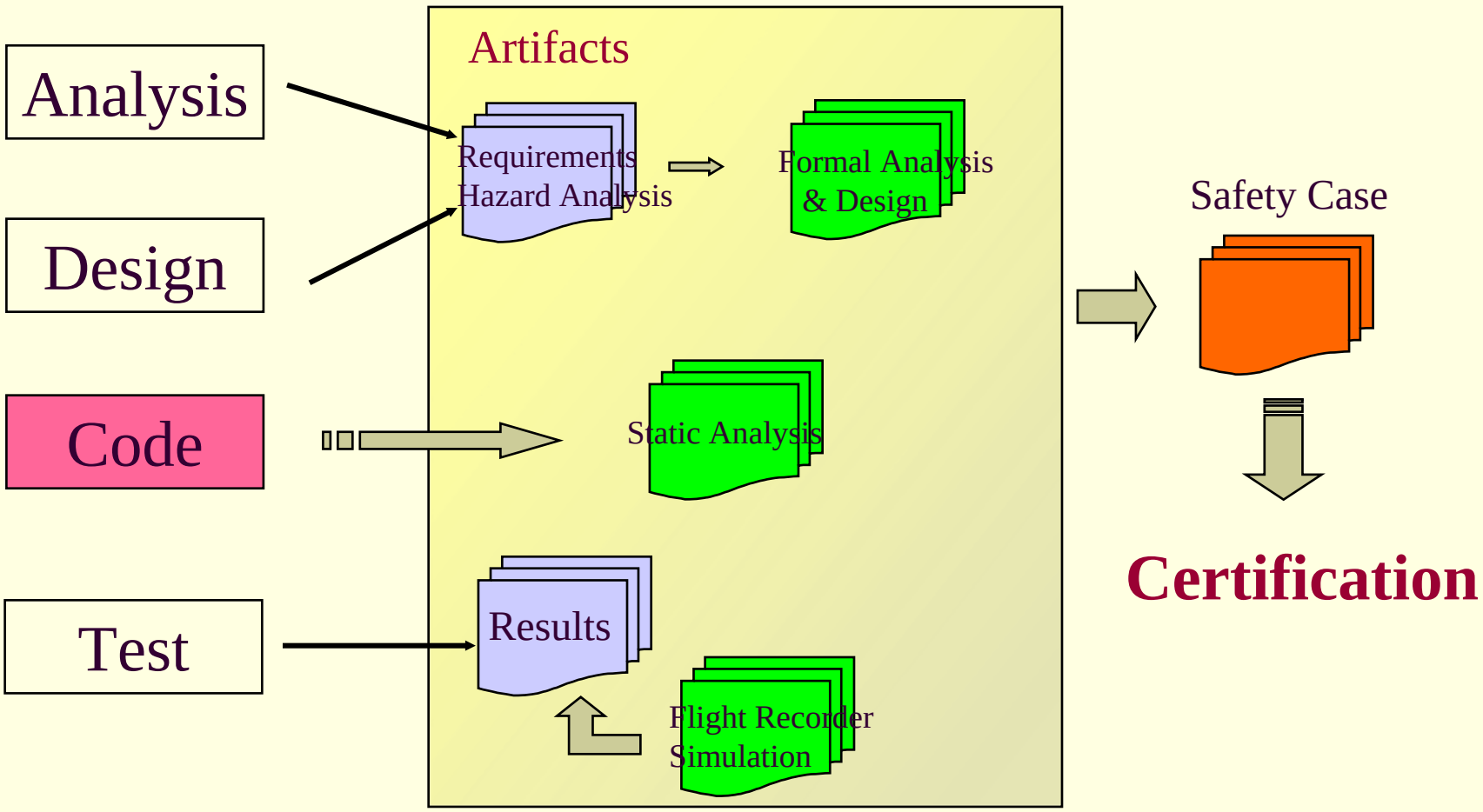

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THE END