U. S. Department of
Health and Human Services

Center for Devices and
Radiological Health

Medical Device Interoperability: Participants in Safety

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OSEL/**DESE**

FDA Interoperability Workshop

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Interoperability players

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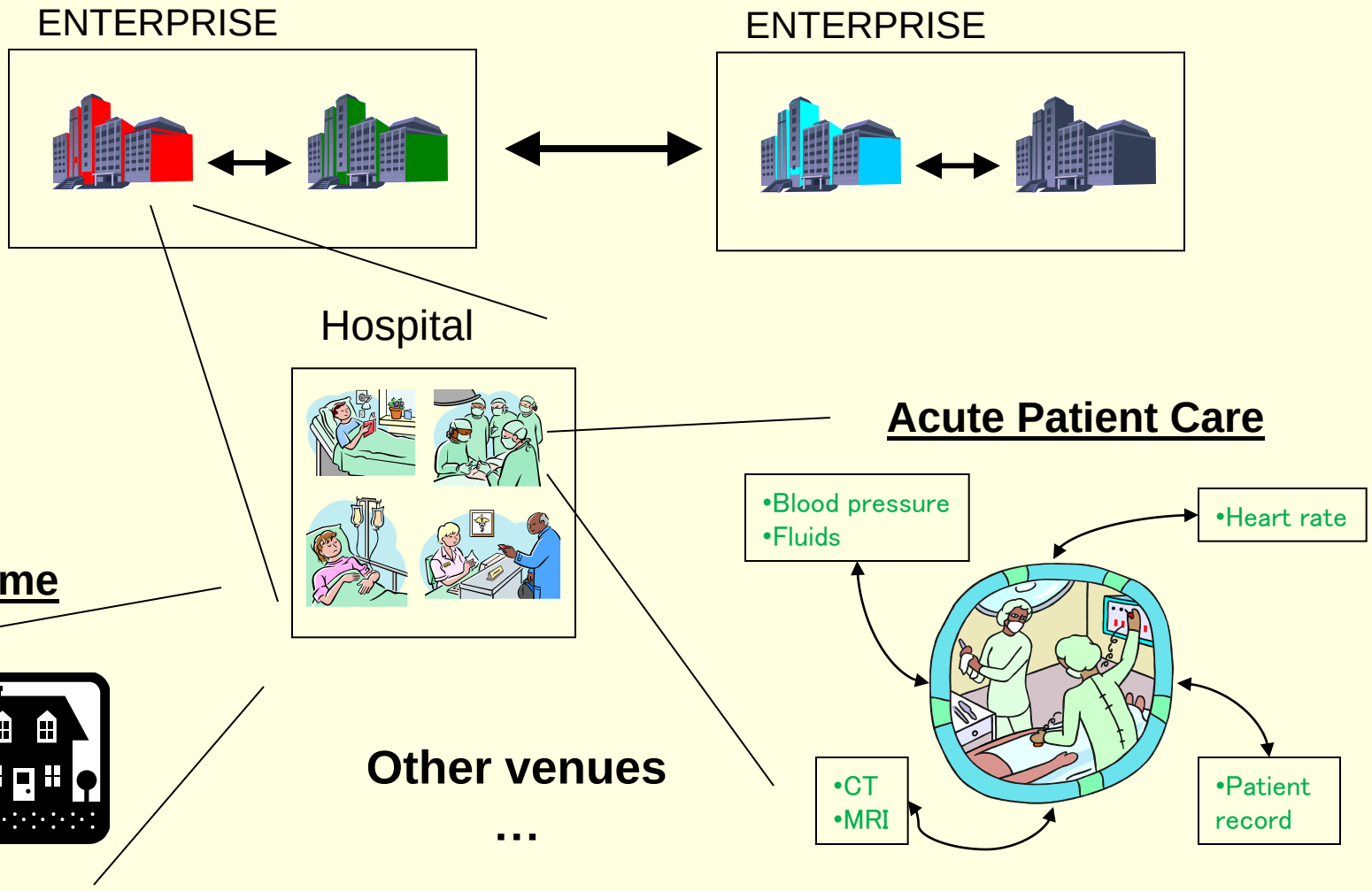

architectures & devices

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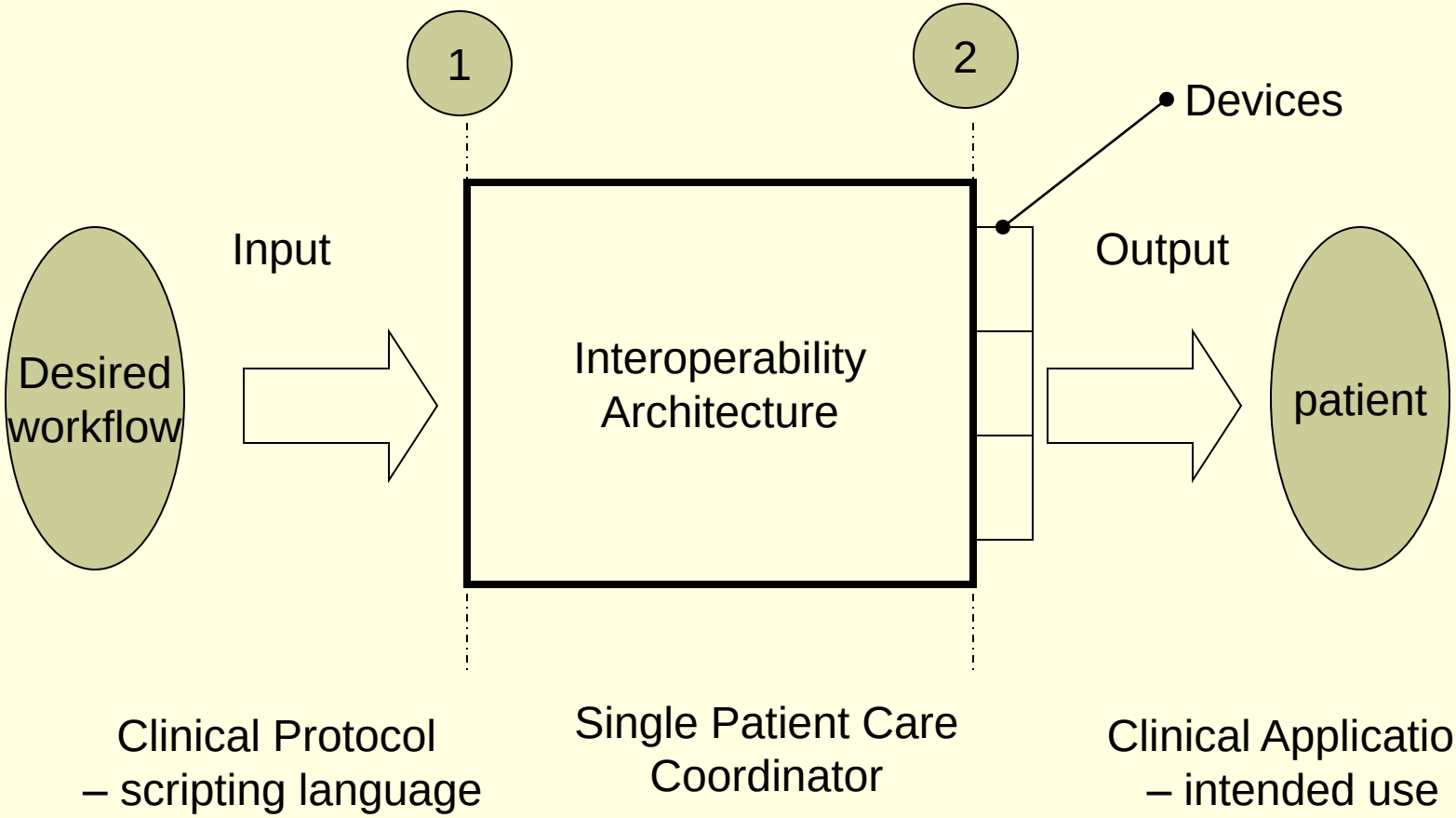

Types of behaviors in interoperable systems:

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- Data aggregation
  - Data collection (one way) from devices into electronic health record (EHR)
- Data exchange
  - enable smart interlocks (turn off laser when not pointing at patient, pause patient controlled analgesia infusion)
- Instrument control
  - enable autonomous control (artificial pancreas)

Example actors & actions

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Operation	Device
Configure	PCA pump
Pull latest drug library	HIS
Get weight and allergy information	Program infusion
Enable safety monitoring	Pulse oximeter
Enable reporting and alarming	Network controller

Hazard analysis and safety information

External Generalization/ Specialization Relationship	Internal Generalization/ Specialization Relationship	Process Traceability (Specific)	Hazardous Scenarios	Clinical or Technical (C or T, other)
Order Entry		Physician Selects Drug Orders	Physician Inputs Wrong Order Information in Order Entry System	C
Order Entry		Physician Selects Drug Orders	Order Entry System Not Online	T
Order Entry		Physician Selects Drug Orders	Hospital Network not available	T
		Register Controller with Network	**ICE Manager Failure**	T
		Register Controller with Network	Incorrect ID of Controller	T
	Medical Device or Third Party Cause	Register Devices with Controller	Medical device data not available due to communication failure	T

Leverage other industries and technologies

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- Understand what their challenges were and what they were trying to accomplish
- Understand the hazardous scenarios, failure modes & mechanisms, and risk control techniques (process & product based)
- Assess the applicability to medical device interoperability scenarios

Stakeholders

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- Clinical users
  - Responsible parties – hospitals, clinic operators, physician offices
- Technology providers – e.g. middleware layers
- Technology maintainers
- Specification developers (e.g. Standards bodies)
- Regulators
- Payors

Standards – just a sample

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- ISO, IEC
  - ISO 14971
  - IEC 60601-1-xx, -2-xx
  - IEC 80001, -xx
  - ISO/IEC 80601-2-xx
- ASTM
  - F2971
- ISO/IEEE
  - 11073

Profiles

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- IHE
- Continua

Assurance paradigms

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- Clearance/approval
- Directives, Notified Bodies
- Certifications

IEC 80001 -

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- Application of risk management for IT-networks incorporating medical devices
- supervision, operation, installation and maintenance
- **3.6 Other providers of information technology**
  - Other providers of information technology may provide:
  - a) infrastructure components;
  - b) infrastructure services;
  - c) client devices not being MEDICAL DEVICES;
  - d) servers;
  - e) application software; or
  - f) middleware

IEC 80001

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- Examples of supplementary information:
  - a) test strategies and test acceptance criteria;
  - b) disclosure of failure modes;
  - c) system reliability statistics;
  - d) safety cases; and
  - e) performance.

Manufacturer reporting requirements

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- Any indication of a quality deficiency must be investigated and resolved with the active participation of management[1].
- User and patient complaints must be evaluated in a timely manner, and investigated or reported to FDA as appropriate[2].
- Malfunctions that have caused or contributed to a death or serious injury, or are likely to cause or contribute to a death, must be reported to FDA[3].

[1] Quality System Regulation, §820.100

[2] Quality System Regulation, §820.198

[3] Food, Drug, and Cosmetic Act, §519(a)(1), and §803/804 of regulations

Who actually owns the interoperability safety problem?

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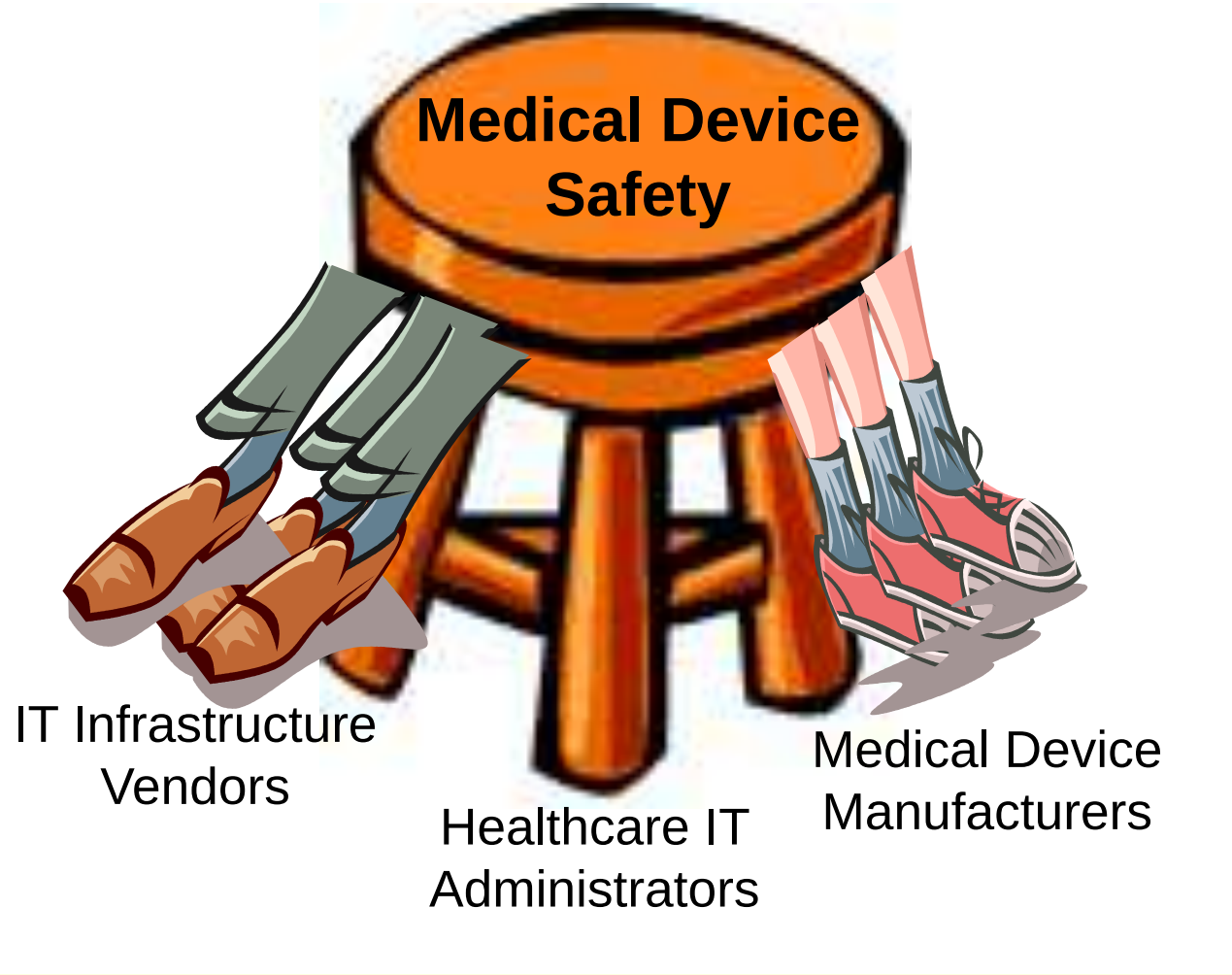

Coming together to solve the problem?

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From this …

Coming together to solve the problem….

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… to this …

END

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