

ICE-PAC

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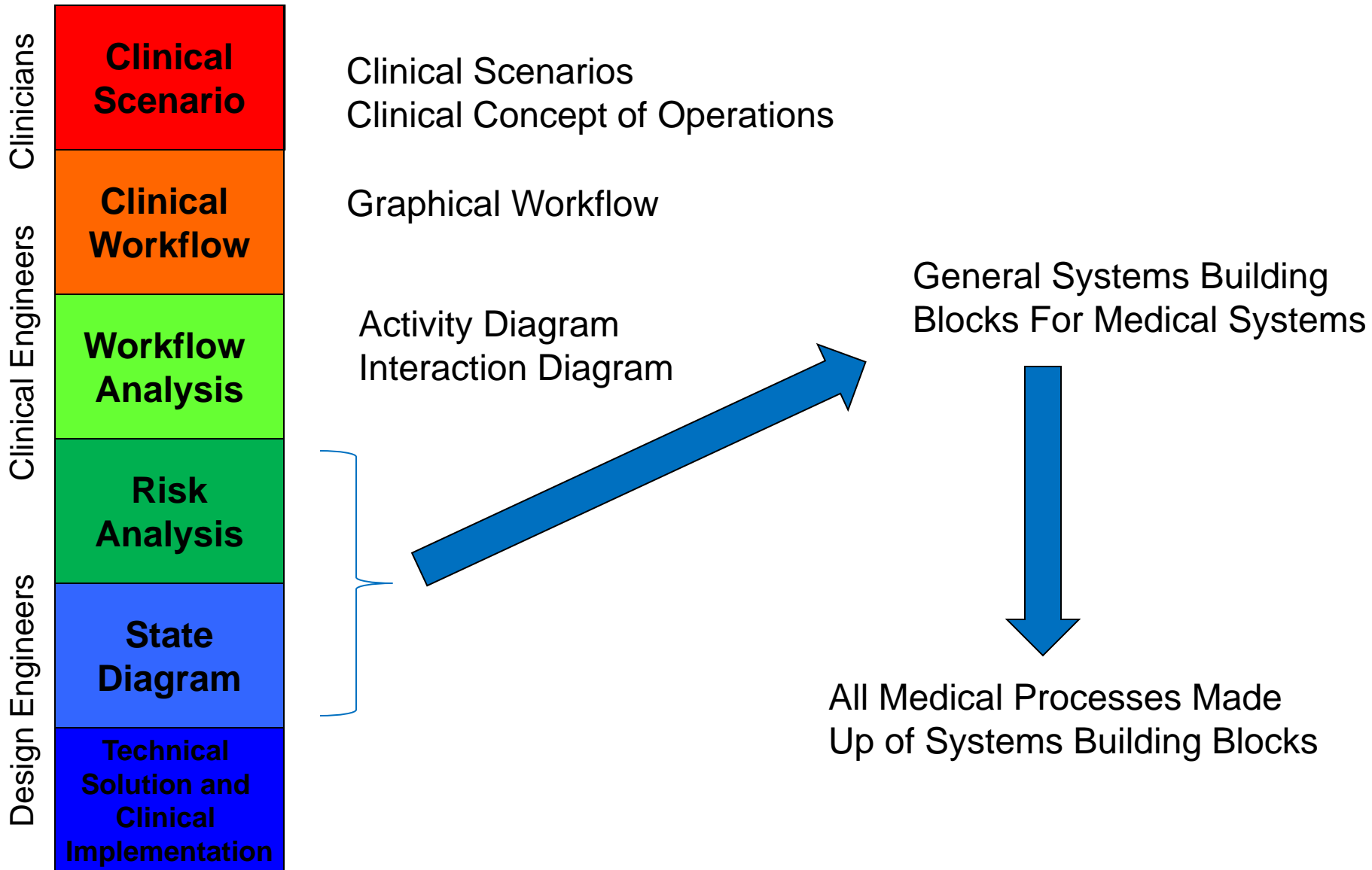
- ICE-PAC is a joint working group between
ASTM:

Device in the Integrated the Clinical Environment
Standard (ICE) and IHE PCD in order to analyze
existing standards (IEEE 11073 and ASTM
F29.21)

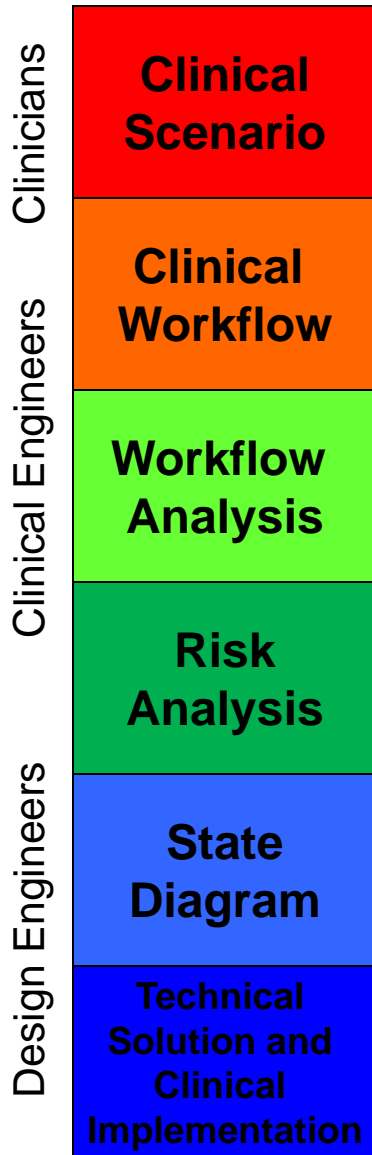
to explore standards gaps and profile roadmap
gaps.

- To produce requirements for across the different
standards at a systems level
- Identify hazards where clinical practice meets
engineering systems

Methodology



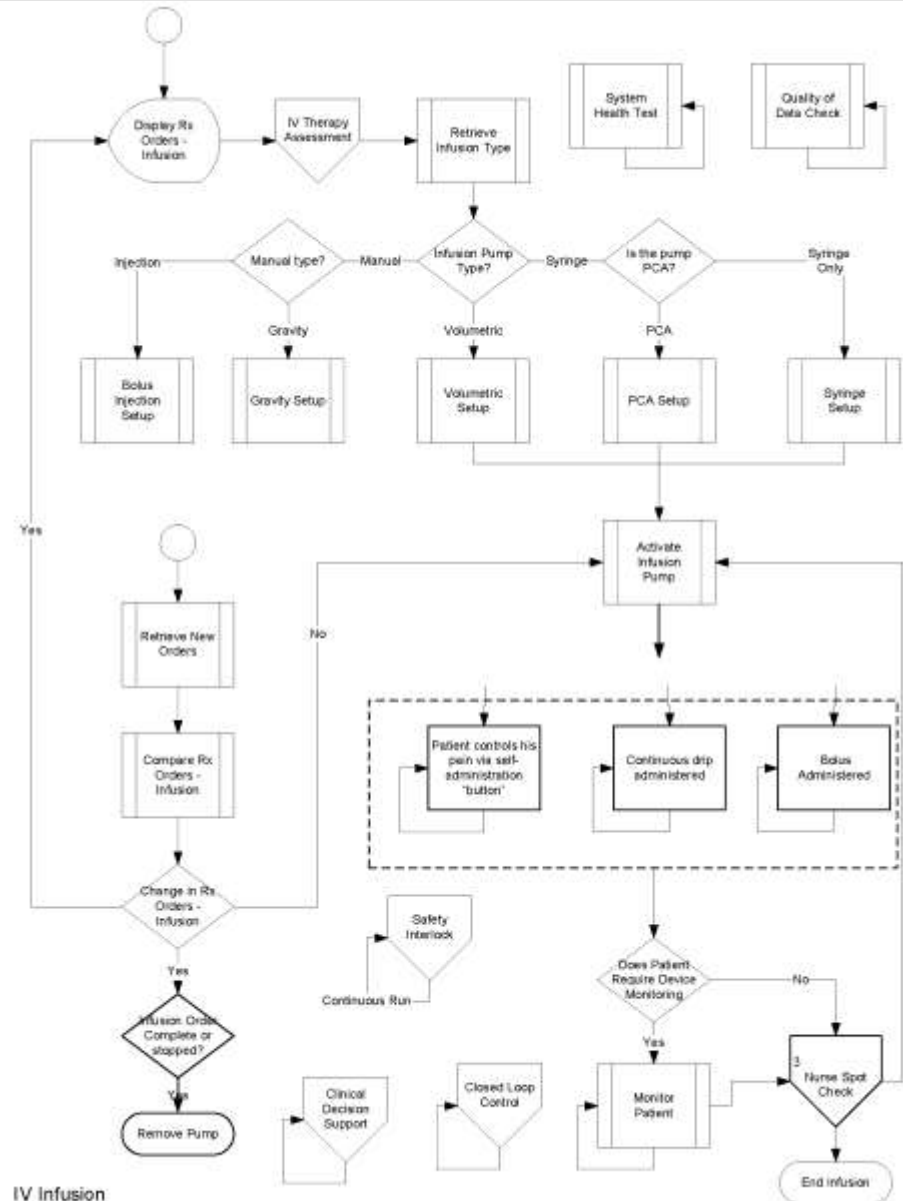
Requirements



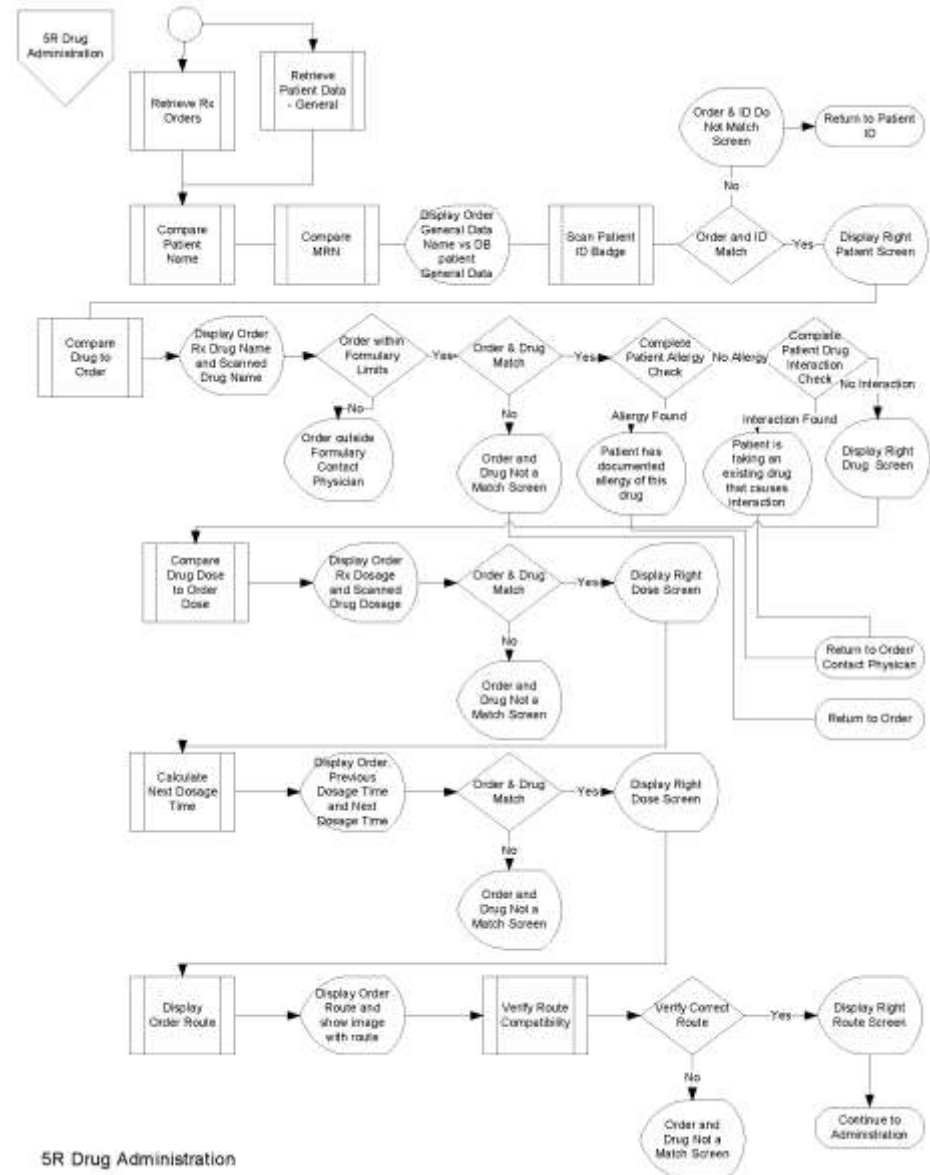
- Gathering Requirements from Clinical System
- Providing Traceability of System Requirements
- Provide Systems Level Risk Analysis
- Provides Traceability to Mitigating Risk
- Designing for the System, not modifying the system causing unintended consequences
- General Building Blocks and Interactions between the blocks are key to Safety
- If General Building Blocks make up Specific Systems then Systems are safe

General Overview Workflow of All Infusion Therapies

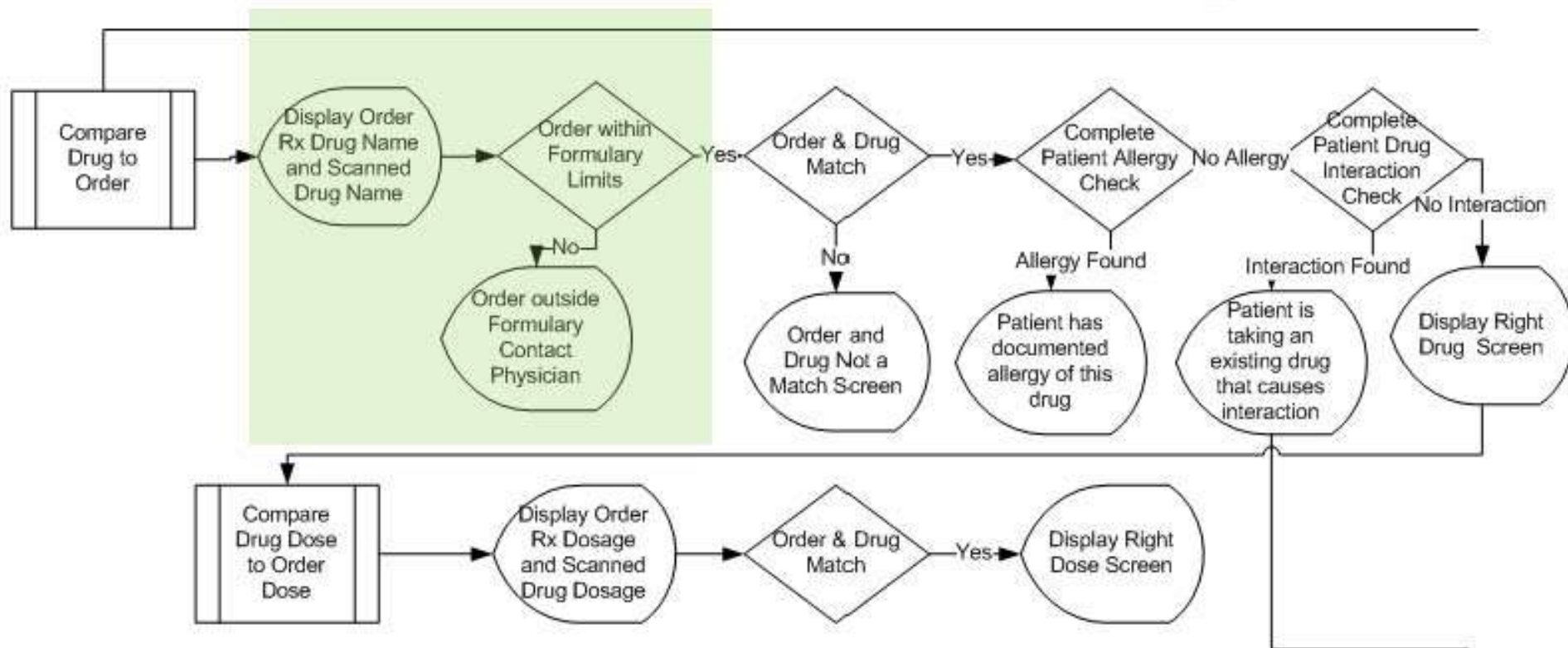
Each Box is has at
least one additional
drilled down
page



Example of the 5R's of Infusion Delivery



Smart Pump Technology



Current Findings

- Contextual Data is required for intelligent systems. This includes:
 - Device characteristics
 - accuracy,
 - Precision
 - Source/source characteristics
 - Quality of Data
 - communication quality
 - Data quality
 - Patient History