Setting the Standard for Automation™

ISA-88 Batch Control:
Standard Summary & Update
ISA Tarheel Capital Sept 21, 2010

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Standards
Certification
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Agenda

- **Introduction to ISA-88**
- Batch Processes
- Process Model
- Physical Model
- Equipment Entity Model
- Types of Control
- Recipes
- Modes & States
- Control Activity Model
- Project Execution

Introduction to ISA-88: What is it?

- ISA-88 is a multi-part ANSI standard and the global basis for modern batch control systems
  - Consists of 4 parts (going on 5) and 3 technical reports
    - Parts 1-4 adopted internationally as IEC-61512
  - Part 1 defines a flexible modular framework for batch control
    - Emphasizes good practice for design and operation of flexible batch plants and use with any combination of manual and automated equipment control
    - Part 1 is explicitly intended for people using, specifying, or implementing batch control or related software products
  - Other parts detail specific aspects, mainly of interest to developers
  - "ISA-88" now refers to both the standard (was S88) and the committee (was SP88)

Introduction to ISA-88: What did it fix?

- ISA-88 committee was chartered in 1988 to address the following
  - A universal model for batch control did not exist
  - Difficulty communicating requirements
  - Difficulty integrating solutions from different vendors
  - Comprehensive implementation was not practical with available tools
- These problems were directly addressed in
  - ANSI/ISA-88.00.01-1995, Batch Control – Part 1: Models and Terminology
  - ANSI/ISA-88.00.02-2001, Batch Control – Part 2: Data Structures and Guidelines for Language
  - IEC 1131-3: 1993, Programmable controllers – Part 3: Programming languages

Introduction to ISA-88: What else does it include?

- Other parts of ISA-88
  - ANSI/ISA-88.00.03-2003, Batch Control – Part 3: General and Site Recipe Models and Representation
  - ANSI/ISA-88.00.04-2006, Batch Control – Part 4: Batch Production Records
- Associated technical reports
  - ISA-TR88.0.03-1996, Possible Recipe Procedure Presentation Formats
  - ISA-TR88.00.02-2008, Machine and Unit States: An Implementation Example of ISA-88
  - ISA-TR-88.95.01-2008, Using ISA-88 and ISA-95 Together

Introduction to ISA-88: What's happening now?

- Ongoing work to improve ISA-88
  - Part 1 update to be published about Q1 2011
    - Much clearer organization and explanations to facilitate understanding, address most misconceptions, and elaborate on accepted interpretations
    - Includes general guidelines for compliance that apply to software, specifications, and implementation
    - Coordinated IEC effort to continue after receipt of approved ISA version
  - ANSI/ISA-88.00.05, Batch Control – Part 5: Modular Equipment Control
    - Defines a structured approach for allocation and control of equipment resources

Introduction to ISA-88: Why should you know about it?

- Use of ISA-88 good practice facilitates both implementation and operation, but requires understanding beyond how to use a "compliant" software package
  - ISA88's terminology and model hierarchies are vendor-neutral and essential knowledge for communicating requirements.
    - Vendor-specific extensions or terminology should be excluded from platform-independent functional requirements
  - ISA88 defines an integrated approach with multiple implementation options and interpretations to fit different needs
    - Vendor recommendations may be polarized biased on a particular philosophy used in their product design
  - Must understand ISA88 models and functions that are not visible to users to fully grasp software and develop compliant specifications

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Batch Processes: Definition

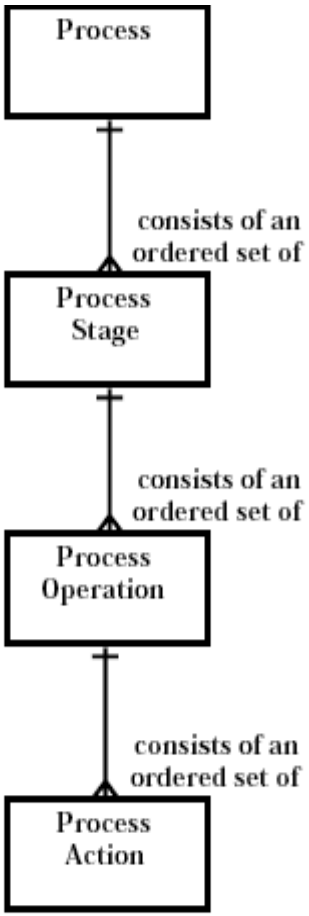
- ISA-88 defines **Batch Process** as “a process that leads to the production of finite quantities of material by subjecting quantities of input materials to an ordered set of processing activities over a finite period of time using one or more pieces of equipment”
- ISA-88 defines **Batch Control** as “control activities and functions that direct batch processes”

Batch Processes: Characteristics

- Manufacturing processes may be classified as
  - Continuous process – creates a continuous flow of bulk material
  - Batch process – creates finite quantities of bulk material
  - Discrete process – creates finite quantities of parts
- Batch process characteristics
  - Batch processes are discontinuous and seldom fully automated
  - Procedures for a variety of products, exception conditions, and cleaning requirements must typically be accommodated
  - Flexible facilities offer a variety of paths through the equipment
  - Batch processing is common in highly regulated industries with extensive validation and data collection requirements

Process Model: 2010 Version

1995 Original



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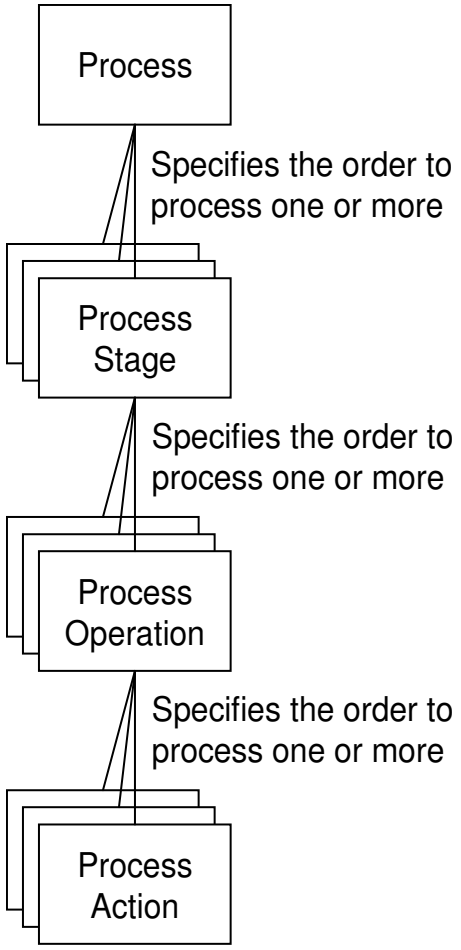

Process Model: Level Definitions

- **Process Model:** “a hierarchical model which illustrates the subdivision of a batch process”
- **Process:** “a sequence of chemical, physical, or biological activities for the conversion, transport, or storage of material or energy”

  EXAMPLE – The production of PVC by polymerization of VCM

- **Process Stage:** “a part of a process that usually operates independently from other process stages and that usually results in a planned sequence of chemical or physical changes in the material being processed”

  EXAMPLES - Typical process stages in the PVC process might be: Polymerize, Recover VCM, Dry PVC

Process Model: Level Definitions

- **Process Operation:** “a major processing task that usually results in a chemical or physical change in the material being processed and that is defined without consideration of the actual target equipment configuration”

  EXAMPLES - Typical process operations for the polymerization of VCM into PVC process stage might be: Prepare Reactor, Charge, React

- **Process Action:** “a minor processing task that may be combined with other minor processing activities to make up a process operation”

  EXAMPLES - Typical process actions for the react process operation might be: Add Catalyst, Add VCM, Heat

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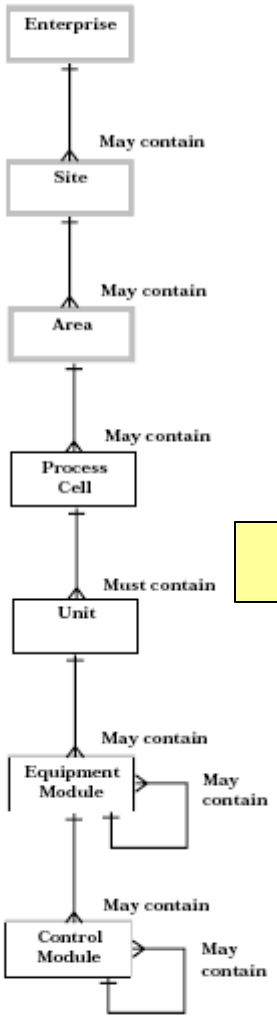
Physical Model: 2010 Version

1995 Original



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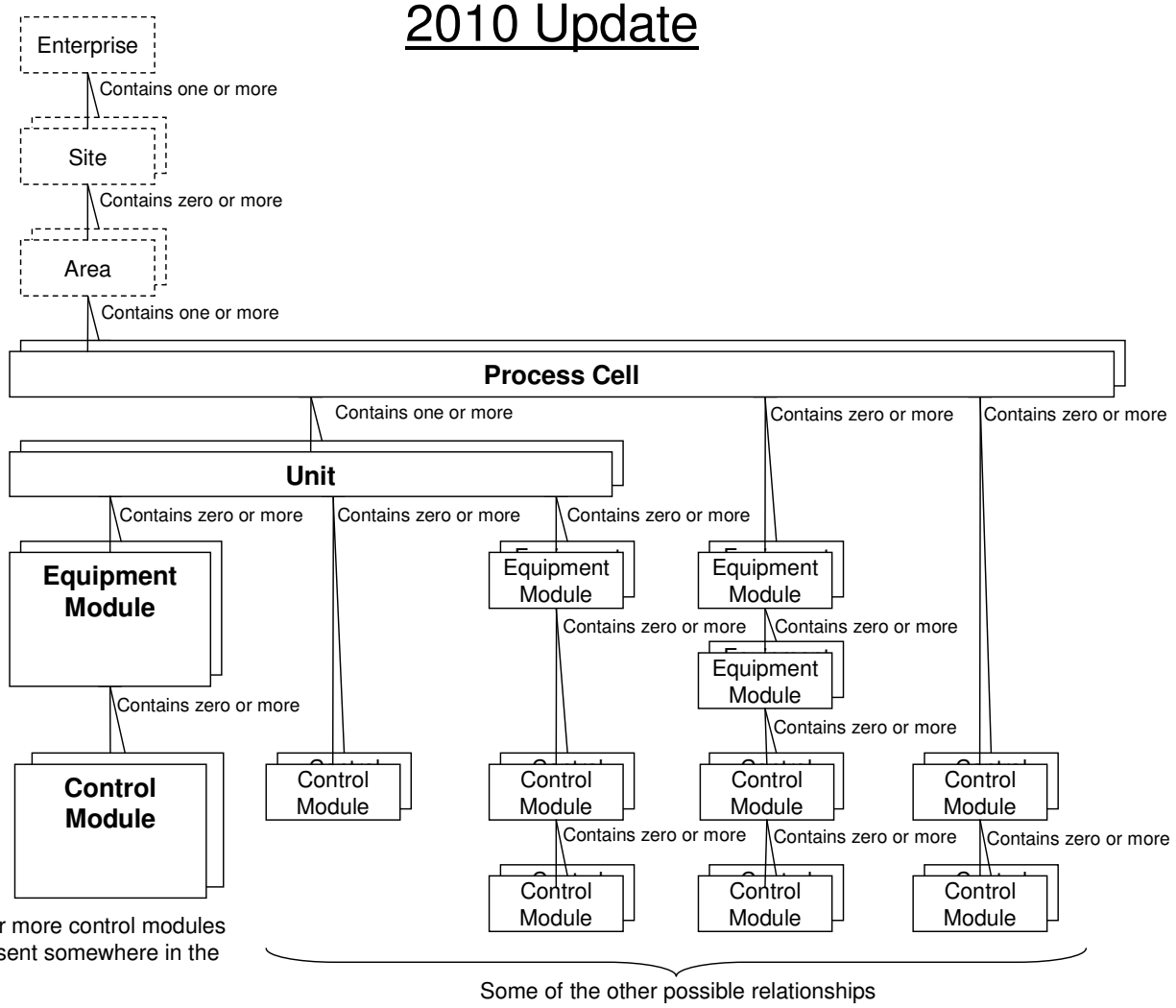


Note: One or more control modules must be present somewhere in the process cell.

Some of the other possible relationships

Physical Model: Level Definitions

- **Enterprise:** “an organization that coordinates the operation of one or more sites”
- **Site:** “a component of a manufacturing enterprise that is identified by physical, geographical, operational, or logical segmentation within the enterprise”

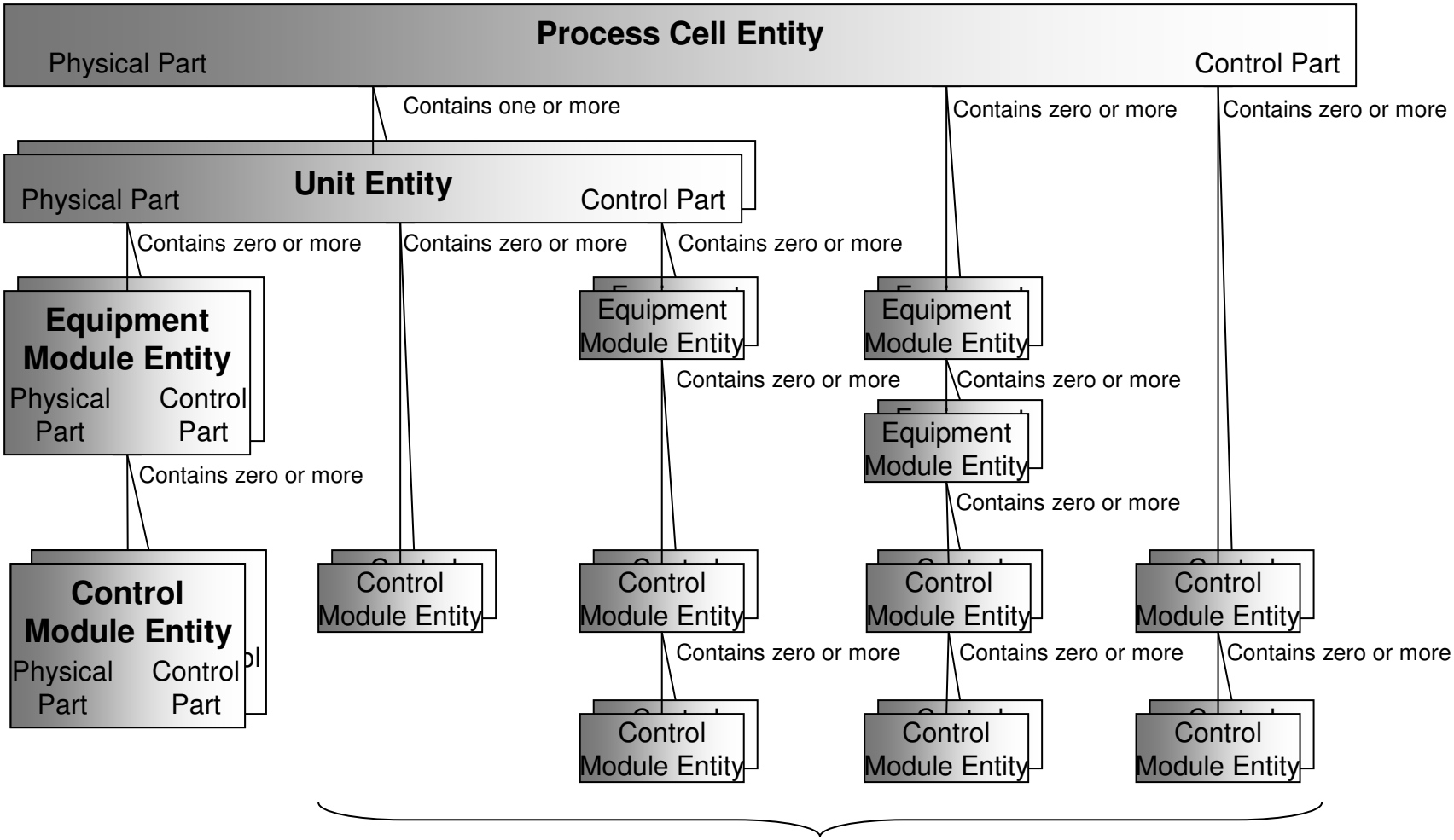
  NOTE - A site may contain areas, process cells, units, equipment modules, and control modules.

- **Area:** “a component of a manufacturing site that is identified by physical, geographical, operational, or logical segmentation within the site”

  NOTE — An area may contain process cells, units, equipment modules, and control modules.

  – Enterprise, Site, and Area levels are not used in ISA-88, except respectively as the organizational levels at which General and Site Recipes exist and for consistency with ISA-95 Enterprise-Control System Integration.

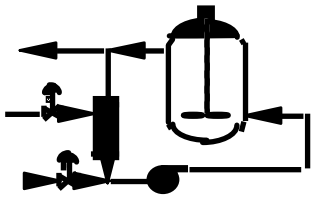
Equipment Entity Model: 2010 Version



Note: One or more control module entities must be present somewhere in the process cell entity.

Equipment Entity Model: Core Concept

- **Equipment Entity:** "a collection of physical processing and control equipment and equipment control grouped together to perform a certain control function or set of control functions"
- **Equipment Control (product-independent):** "the equipment-specific functionality that provides the actual control capability for an equipment entity, including procedural, basic, and coordination control"



Physical Equipment

Equipment Entity

Behaviors

Basic control
Procedural control
Coordination control

Equipment Control

Equipment Entity Model: Control Modules

- **Equipment Entity Model:** "a hierarchical model to logically organize the physical assets used in a batch process in combination with the control present at each level"
- **Control Module:** "the lowest level grouping of equipment in the physical model that can carry out basic control"

  "NOTE 1 — This term applies to both the physical equipment and the equipment entity."

  "NOTE 2 — The control module level may not be omitted from the physical model."

  "NOTE 3 – The control module level contain the interfaces to the physical equipment."

  – A Control Module that contains another Control Module may be referred to as a Compound Control Module, but this is not considered an additional level in the model.

- Examples are a sensor, block valve, regulating loop, or multi-valve header

Equipment Entity Model: Equipment Modules

- **Equipment Module:** "a functional group of equipment that can carry out a finite number of specific minor processing activities"

  "NOTE 1 — An equipment module is typically centered around a piece of process equipment (a weigh tank, a process heater, a scrubber, etc.). This term applies to both the physical equipment and the equipment entity."

  "NOTE 2 — Examples of minor process activities are dosing and weighing."

  "NOTE 3 – Two types of equipment modules are identified: recipe-aware equipment modules and generic equipment modules."

  An Equipment Module that contains another Equipment Module may be referred to as a Compound Equipment Module, but this is not considered an additional level in the model.

- Equipment modules may be engineered around processing equipment such as a heating/cooling system, an agitator, or auxiliary equipment such as a dosing system

Equipment Entity Model: Common Resources

- **Common Resource:** “a resource that can provide services to one or more requesters”

  “NOTE — Common resources are identified as either exclusive-use resources or shared-use resources.”

  – Common resources are usually either Control Modules or Equipment Modules.

- **Exclusive-use Resource:** “a common resource that only one user can use at any given time”

  – EXAMPLE: A shared weigh tank that can be used by only one reactor at a time is an example of an exclusive-use resource.

- **Shared-use Resource:** “a common resource that can be used by more than one user at a time”

  – EXAMPLE: A process heater and a raw material distribution system which are capable of serving more than one unit at a time are examples of shared-use resources.

Equipment Entity Model: Units

- **Unit:** “a collection of associated equipment modules and/or control modules that can carry out one or more major processing activities”

  “NOTE - Examples of major processing activities are react, crystallize, and make a solution.”

  – **A Unit may only operate on one batch at a time.**

  – The unit level may not be omitted from the equipment entity model.

  – A Unit may directly contain Control Modules and Equipment Modules.

  – A Unit may also request the services of other Units or of Common Resources that are directly contained within the same Process Cell.

- It is usually centered on a relatively independent major piece of processing equipment, such as a mixing tank or reactor.

Equipment Entity Model: Process Cells

- **Process Cell:** “a logical grouping of equipment that includes the equipment required for production of one or more batches”

  “NOTE — This term applies to both the physical equipment and the equipment entity.”

  – **Train:** “a collection of one or more units and associated lower level equipment groupings *within a Process Cell* that has the ability to be used to make a batch of material”

  – Further processing outside of the Process Cell requires execution of a separate recipe in another Process Cell.

  – A Process Cell must contain at least one Unit, but it may also directly contain Equipment Modules and Control Modules, generally as Common Resources.

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Basic Control: Definition & Usage

- **Basic Control:** "the control dedicated to establishing and maintaining a specific state or behavior of equipment and process"

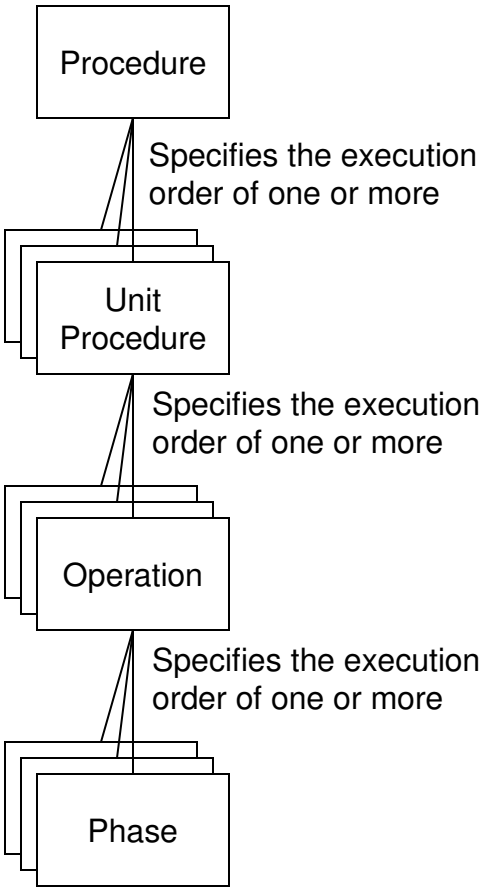
  "NOTE — Basic control may include regulatory control, interlocking, monitoring, exception handling, and discrete or sequential control necessary for establishing or maintaining a specific state or behavior."

  – Control Modules perform Basic Control and may directly control equipment.

  – Higher level equipment entities may perform Basic Control, but it is preferred that they do so only through Control Modules that they contain or reference.

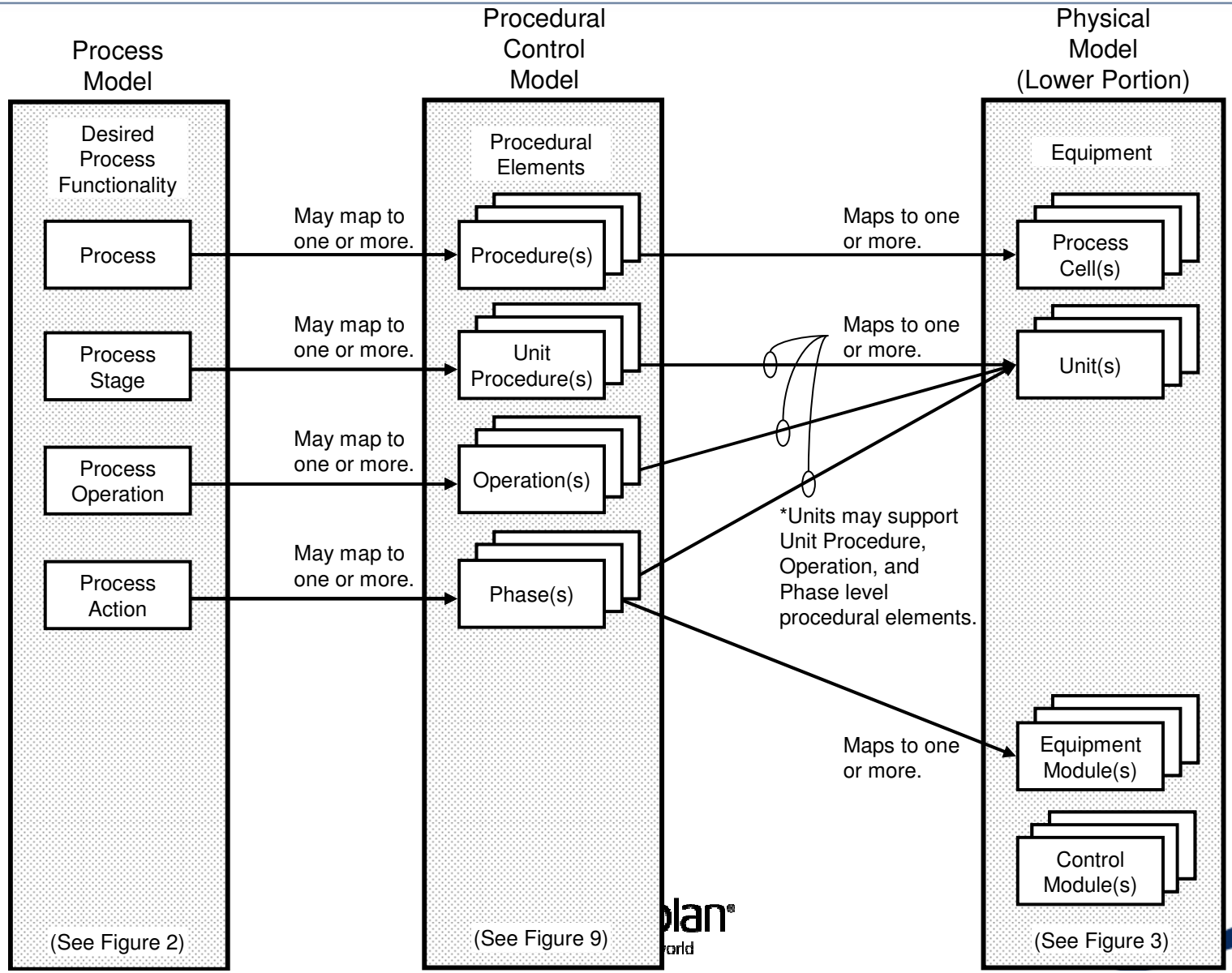
  – Higher level equipment entities may not control equipment except through Control Modules.

Procedural Control Model: Model Definition



- **Procedural (task-oriented) Control:** "the type of control that executes a procedure"
  - **Procedure (definition #1):** "a specification of a sequence of steps, actions or activities with a defined beginning and end that is intended to accomplish a specific objective or task"
- **Procedural Control Model:** "a hierarchical model which depicts the orchestration of procedural elements to carry out process-oriented tasks"
  - **Procedural Element:** "a building block for procedural control that is defined by the procedural control model"
- Functionality at each level of the Procedural Control Model is analogous to the Process Model
  - Procedural Control is not supported in Control Modules

Procedural Control Model:
Mapping to Process Model & Equipment Entities



Procedural Control Model: Level Definitions

- **Procedure (definition #2):** "the highest level procedural element within the procedural control model, which defines the required set of processing activities for a single batch, typically through the initiation, organization, and control of unit procedures"

  "NOTE - Such a procedure may define a process that does not result in the production of product, such as a clean-in-place procedure."

  – This level of procedural control may only execute in a Process Cell

  – Multiple Procedures will generally be active simultaneously in a Process Cell but the initiation of their subordinate procedural elements will be subject to availability of suitable resources (equipment entities)

- **Unit Procedure:** "a strategy for carrying out a major processing task within a unit to accomplish all or part of a process stage typically through the initiation, organization, and control of operations."

  – This level of procedural control may only execute in a Unit

  – No more than one Unit Procedure may be active at a time in a Unit

Procedural Control Model: Level Definitions

- **Operation:** "a procedural element defining an independent processing task to accomplish all or part of a process operation, typically specifying the initiation, organization, and control of phases"
  - This level of procedural control may only execute in a Unit
  - It is possible, but usually not recommended, for more than one Operation to be active at a time in a Unit
- **Phase:** "the lowest level procedural element in the procedural control model that is intended to accomplish all or part of a process action"
  - This level of procedural control may execute in a Unit or in an Equipment Module
  - It is common for multiple Phases to be active simultaneously in a Unit
  - No more than one Phase may be active at a time in an Equipment Module
- The Procedural Model is collapsible, permitting any level(s) of the hierarchy to be omitted except the Procedure level.

Coordination Control: Definition & Usage

- **Coordination Control :** "a type of control that directs, initiates, and/or modifies the execution of procedural control and the utilization of equipment entities"
- This is what manages and interprets batch schedules and recipes, orchestrates the execution of procedural elements, propagates modes and states, collects and stores data, assesses the availability and suitability of **resources** (equipment entities) and manages the **allocation** of resources and **arbitration** of simultaneous requests for resources
- Coordination Control exists at all levels of the Equipment Entity Model

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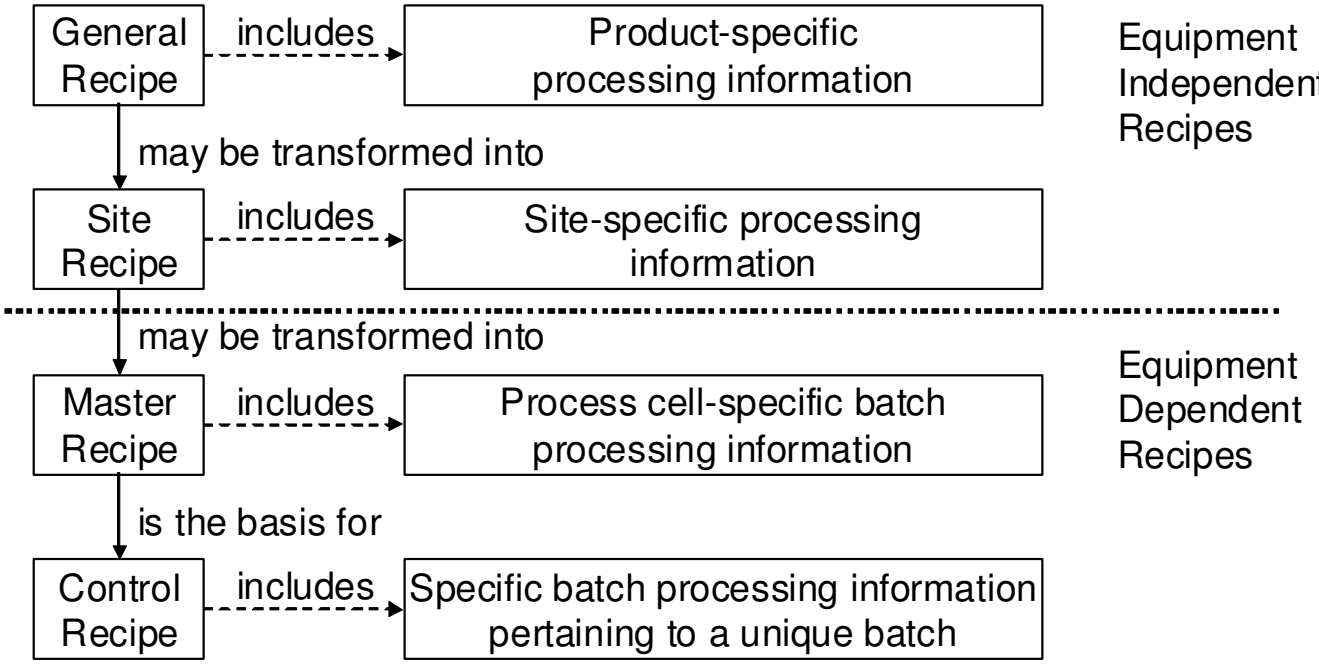
Recipe Types Model: Model Definition

- **Recipe:** "the necessary set of information that uniquely defines the production requirements for a specific product or operational task"
- **Recipe Types Model:** "a conceptual model identifying the relationships between the types of recipes that are defined in an enterprise"



Recipe Types Model: Level Definitions

- **General Recipe:** "a type of recipe that expresses equipment and site independent processing requirements"
- **Site Recipe:** "a type of recipe that is site specific"

  "NOTE - Site recipes may be derived from general recipes recognizing local constraints, such as language and available raw materials."

  "NOTE - Site recipes may include routing information necessary for coordinating manufacturing across process cells and production scheduling activities."
- **Master Recipe:** "a type of recipe that accounts for equipment capabilities and may include process cell-specific information"
- **Control Recipe:** "a type of recipe which, through its execution, defines the manufacture of a single batch of a specific product"
  - Only Control Recipes are directly used to control batches. Each is created from a Master Recipe and modified as the batch executes. Consequently, both Master and Control Recipes are required levels in the model; the others are not.

Recipe Contents: Categories of Information

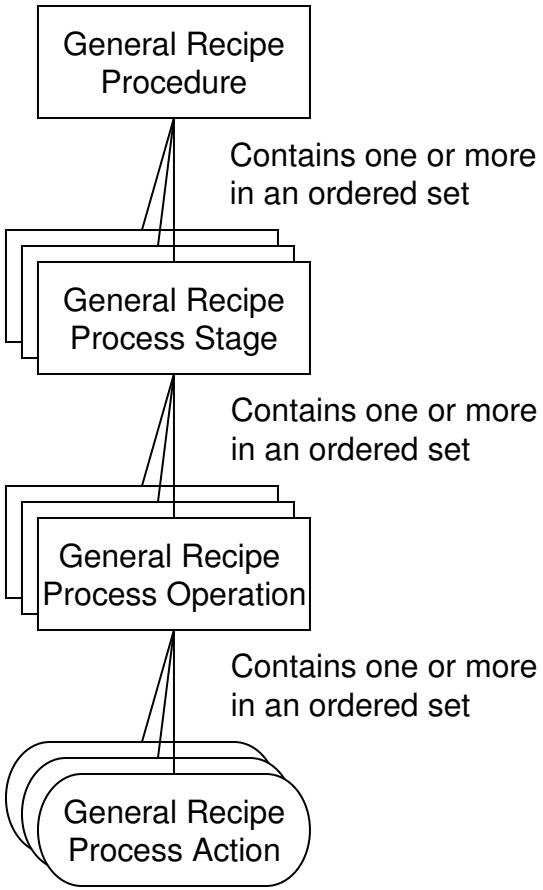
- Recipes contain the following categories of information:
  - **Header:** "information about the purpose, source and version of the recipe such as recipe and product identification, creator, and issue date"
  - **Formula:** "a category of recipe information that includes process inputs, process parameters, and process outputs"
    - process inputs, process outputs, and process parameters contain data pertaining to materials consumed and produced and other operational values
  - **Equipment Requirements:** Equipment requirements constrain the choice of the equipment that will eventually be used to implement a specific part of the procedure.
  - **Recipe Procedure:** The recipe procedure defines the strategy for carrying out a process. Recipe procedures are created graphically from building blocks
  - **Other Information:** Other information is a category of recipe information that may contain batch processing support information not contained in other parts of the recipe. Examples include regulatory compliance information, materials and process safety information, process flow diagrams, and packaging/labeling information

Recipe Contents: Relationship to Recipe Types

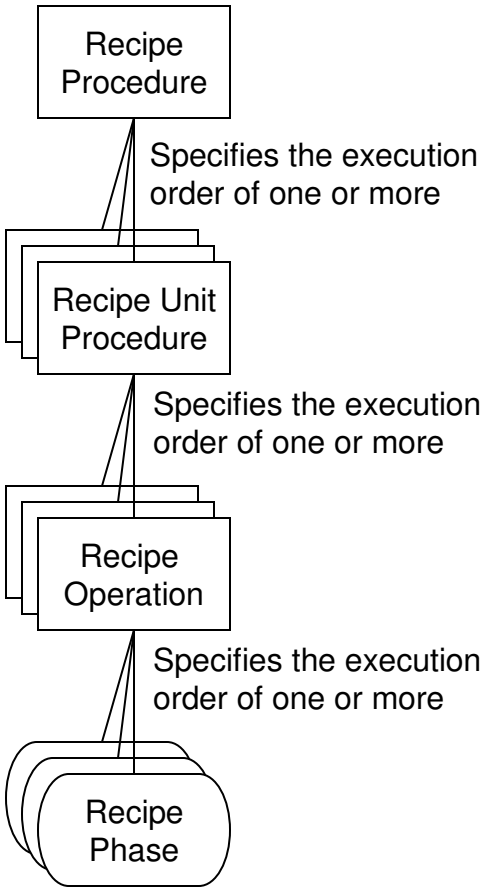
- The information provided in each category varies by recipe type
- General and Site Recipes are Equipment Independent, defining in principle how to make a product, so their procedures structurally conform to the Process Model
- Master and Control Recipes are Equipment Dependent, defining in practice how to a product using the resources of a particular process cell, so their procedures structurally conform to Procedural Control Model
- The mapping of procedural elements between different recipe types may not be 1:1, depending what processing capabilities exist in each site and process cell

Recipe Contents: Recipe Procedure Models

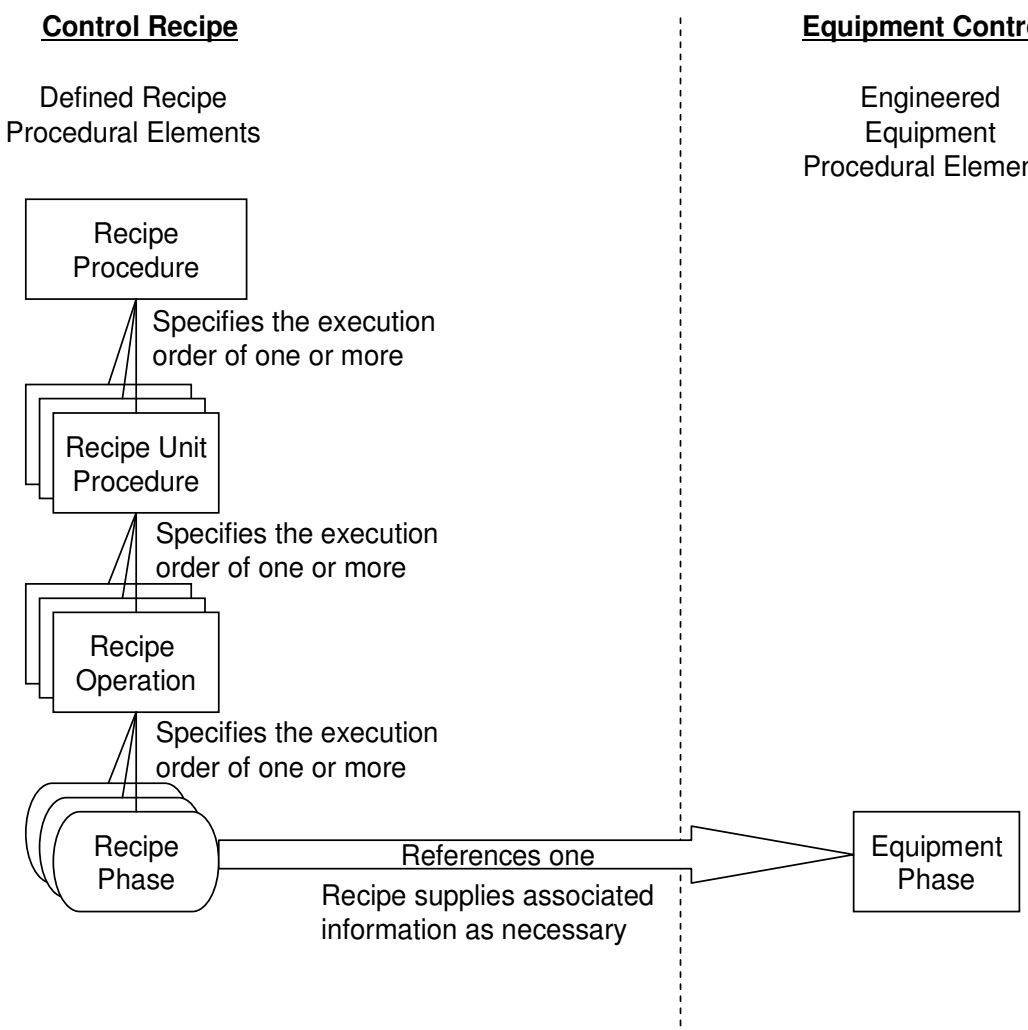
General Recipe Procedure Model



Master Recipe Procedure Model

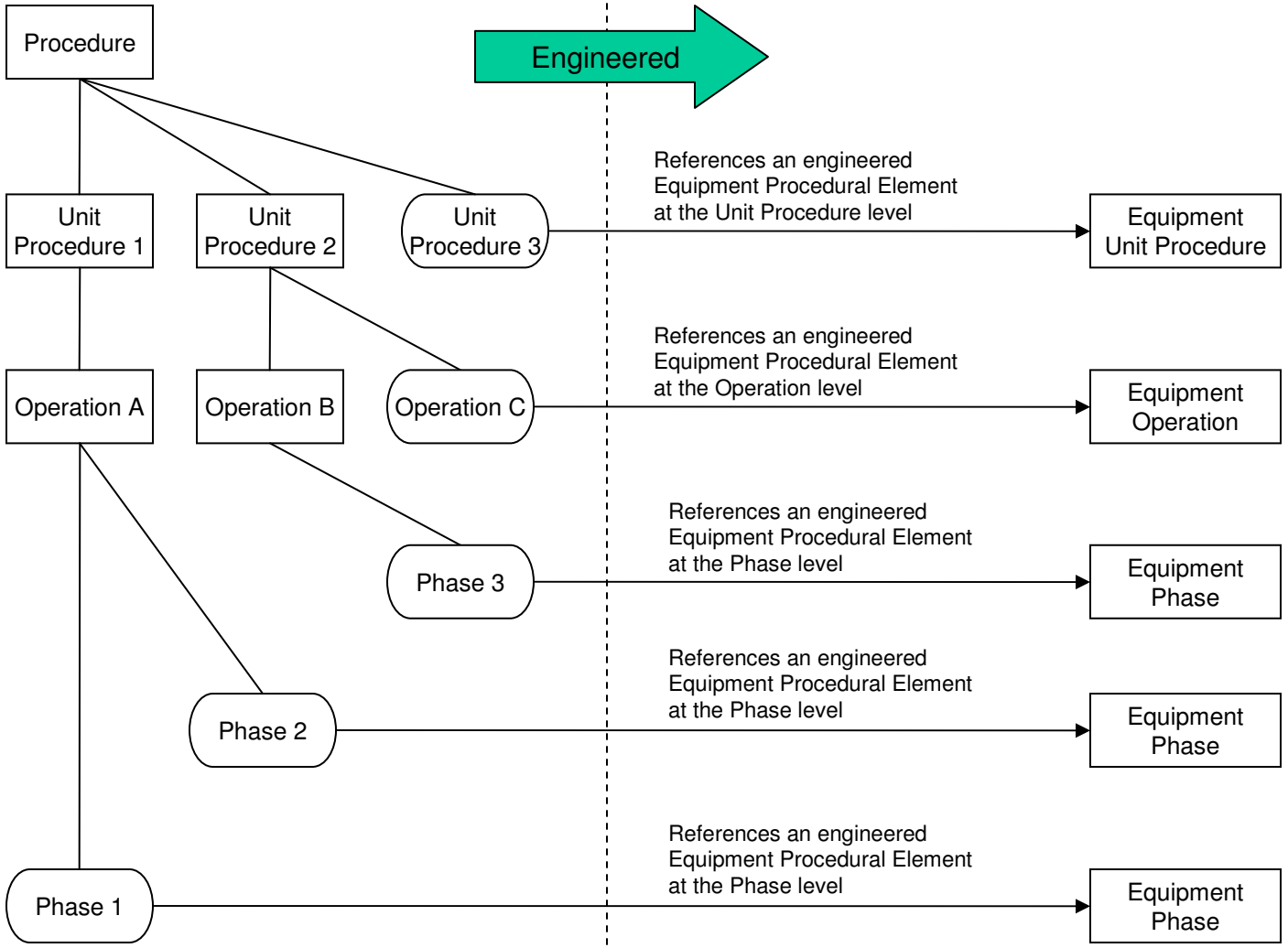


Recipe Links: With Full Recipe Model



- Rather than orchestrate a set of subordinate recipe elements, any control recipe procedural element may instead link to a corresponding element in equipment control. In this way, the control recipe causes the equipment to operate and make batches.
- The figure to the left illustrates this link when the control recipe uses the full (un-collapsed) master recipe procedure model.
- The following slide depicts an example containing some of the other possible scenarios and illustrating the possibility of multiple simultaneous links.

Recipe Links: Multi-Level Example



Recipe Links: Equipment Module Classifications

- The 2010 version of ISA-88 Part 1 defined the following classifications for Equipment Modules, according to whether they are capable of being initiated by a recipe phase.
  - **Recipe-Aware Equipment Module:** "an equipment module containing one or more equipment phases that is capable of being initiated directly through the execution of a recipe"
  - **Generic Equipment Module:** "an equipment module which may be initiated through execution of equipment control but is not capable of being directly initiated through the execution of a recipe"
- Generic equipment modules are often designed with procedural control to make the phases commanding them either: (a) more reusable by removing variable equipment design details or (b) able to manipulate more equipment without growing too complex.

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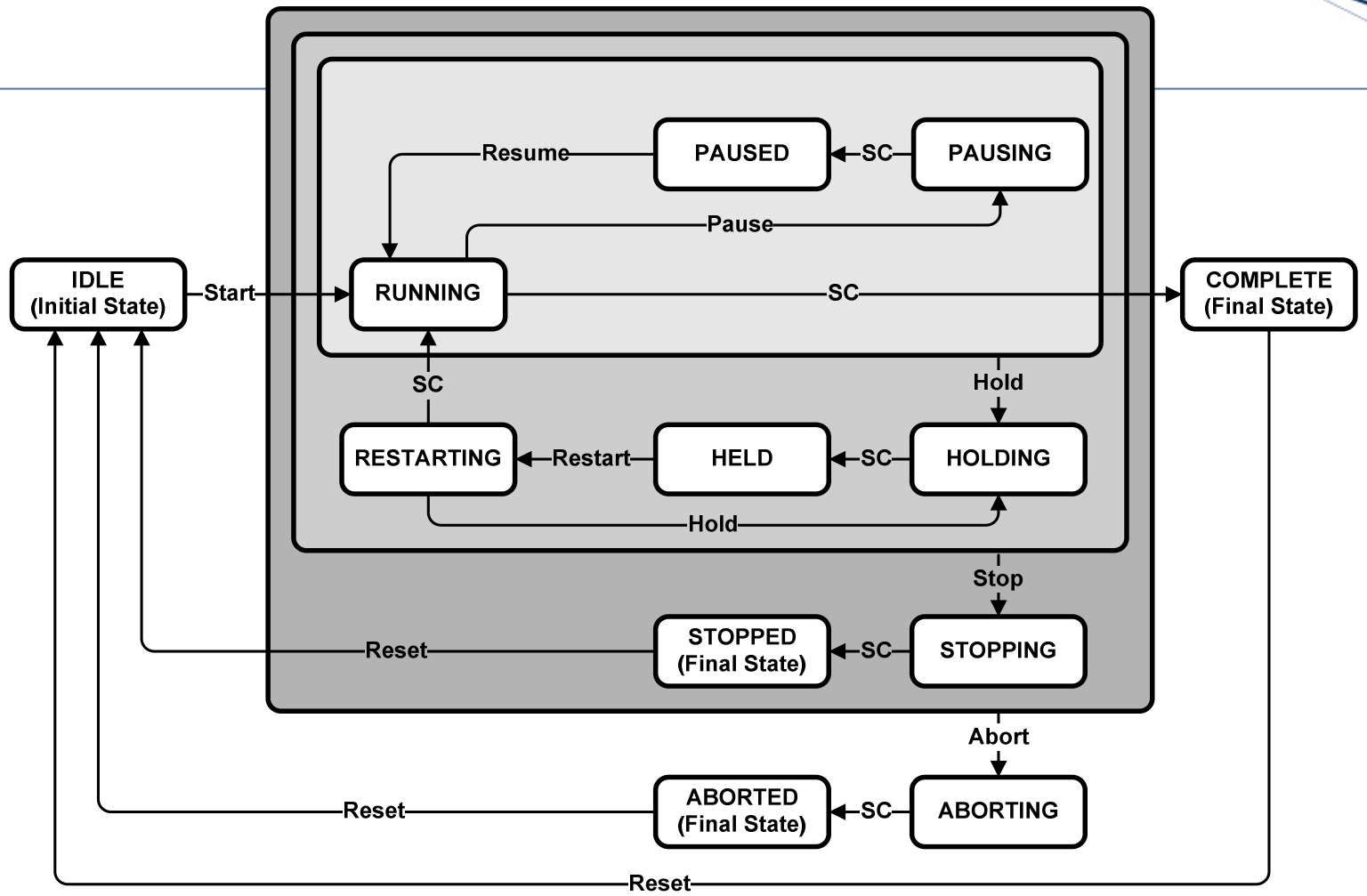
Modes: Definition & Examples

- Equipment entities and procedural elements have modes and states.
- **Mode:** “the manner in which the transition of sequential functions are carried out within a procedural element or the accessibility for manipulating the states of equipment entities manually or by other types of control”
  - Example modes in part 1 for equipment entities (auto, manual) and procedural elements (auto, semi-auto, manual) are used in most batch systems

States: Definition & Examples

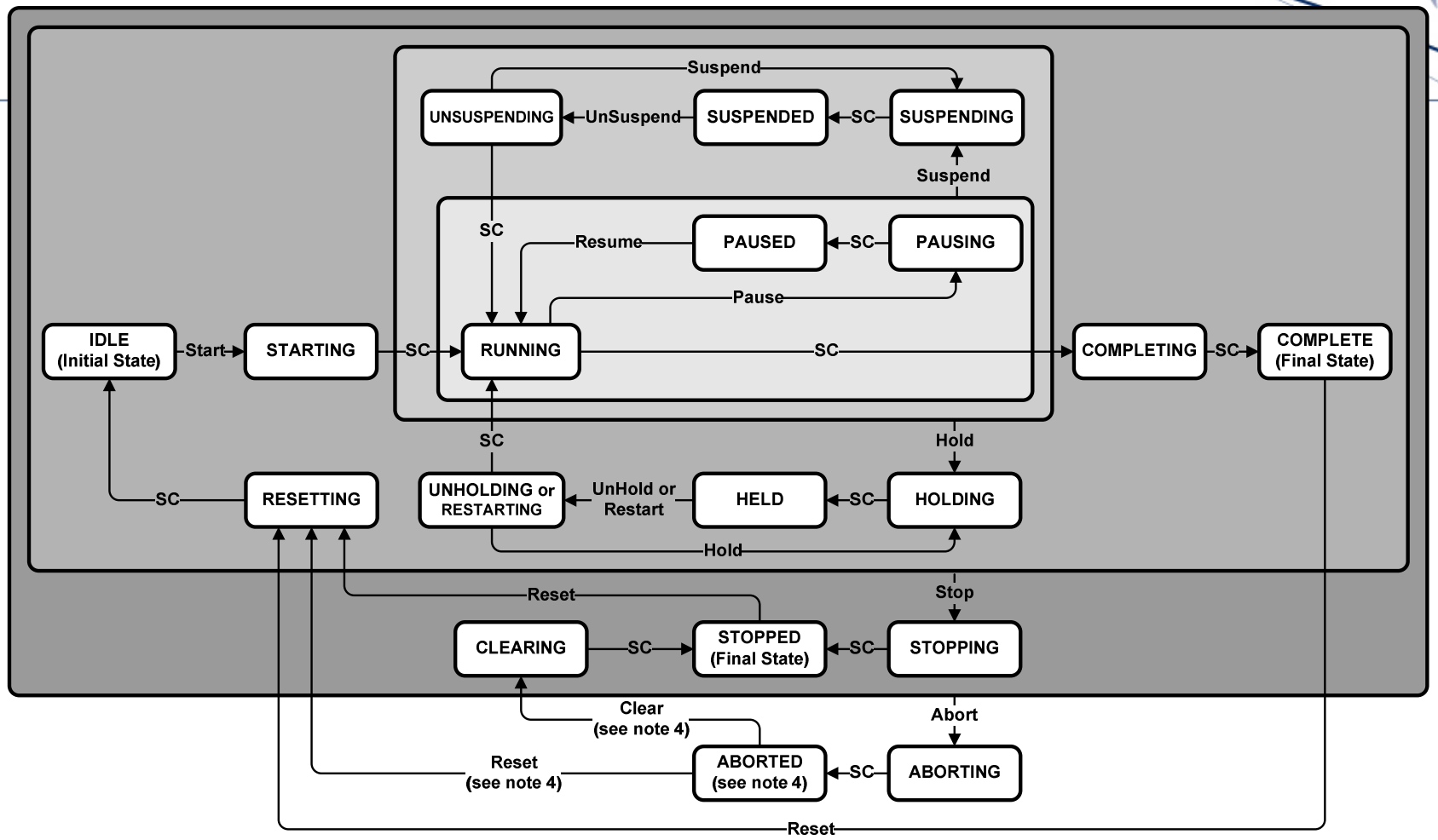
- **State:** "the condition of an equipment entity or of a procedural element at a given time"
  - "NOTE - The number of possible states and their names vary for equipment and for procedural elements."
  - The original *example* states in part 1 for procedural elements (shown as a state chart on the next slide) are inconsistently implemented as fixed states in most batch systems
- Changes in this area that are reflected in the 2010 version of part 1 are
  - The section on exception handling was expanded to describe the role of procedural states
  - A more expansive *example* procedural state model (shown on the subsequent slide) is suggested that is a superset of the old one and the PackML state model published in TR88.00.02
  - It is desired to standardize on the more expansive procedural state model (with collapsibility and expandability) in the future to facilitate interoperability and user understanding of the recipe-equipment link requirements

Procedural States: Example 1



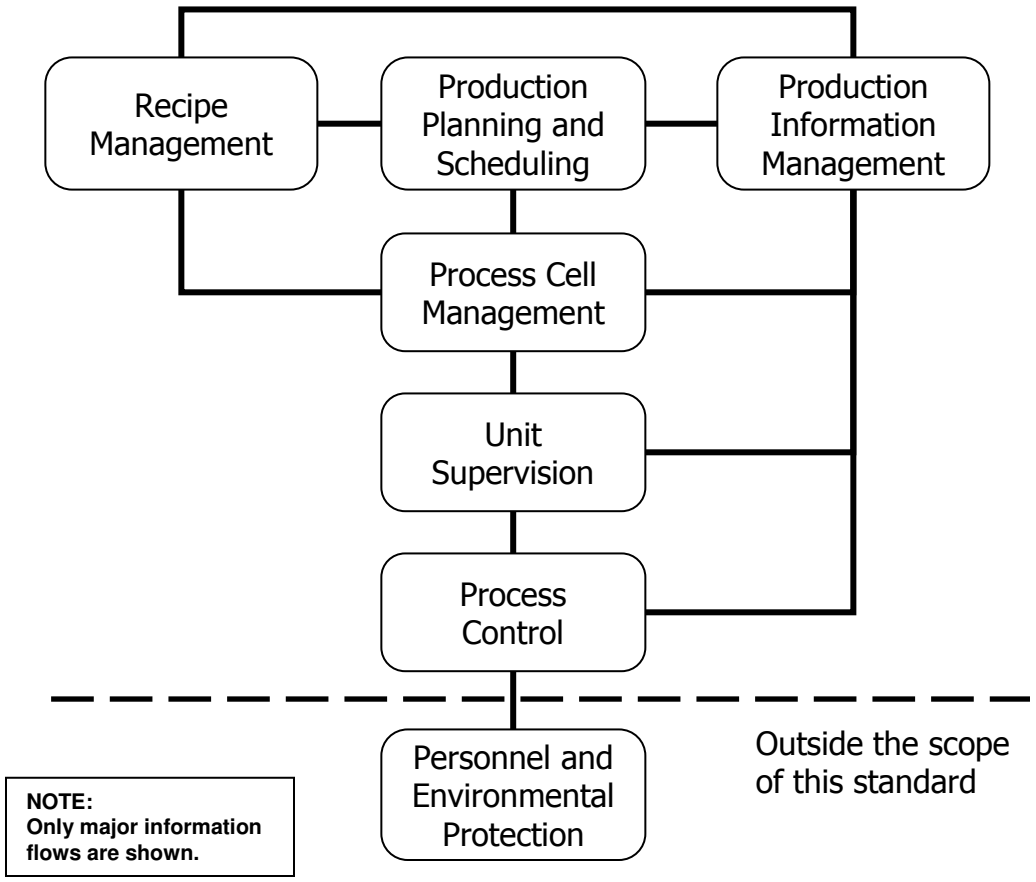
Notes:
1. SC = State Change as a result of state actions completed.
2. Actions of an equipment procedural element are generally defined by its Acting States.
3. The light, light+medium, and light+medium+dark grey boxes represent collections of states that can be preempted using the Hold, Stop, and Abort commands, respectively.

Procedural States: Example 2



Notes:
1. SC = State Change as a result of state actions completed.
2. Actions of an equipment procedural element are generally defined by its Acting States.
3. The light, light+medium, light+medium+dark, and light+medium+dark+very dark grey boxes represent collections of states that can be preempted using the Hold, Stop, and Abort commands, respectively.
4. In any procedural elements using a collapsed version of this model that does not include CLEARING, the Clear command is invalid and ABORTED is a Final State; in those that include CLEARING, Reset is invalid while in the ABORTED state.

Control Activity Model: Model Definition



- **Control Activity Model:** "a conceptual model identifying seven interdependent activities (several of which are subdivided into functions) that manage control definition, operation, and information for batch processes"
- The global model for batch control, which is often neglected because its functionality is process and equipment neutral.

Control Activity Model: Activities

- **Process Cell Management:** "The control activity that includes the control functions needed to manage batch production within a process cell."
- **Unit Supervision:** "The control activity that includes control functions needed to supervise the unit and the unit's resources."
  - "Unit Supervision … ties the recipe to equipment … via Process Control."
  - **Note that most commercially available Batch Servers force the Recipe/Equipment linkage down to the phase level, but some Unit Supervision is still typically required in Equipment Control to meet user requirements.**
- **Process Control:** "The control activity that includes the control functions needed to provide sequential, regulatory, and discrete control and to gather and display data."
  - **The Process Control Activity is generally executed in Equipment Control.**

Control Activity Model: Activities

- **Recipe Management:** "the control activity that includes the functions needed to create, store, and maintain general, site, and master recipes."
- **Production Information Management:** The control activity that is involved in collecting, storing, processing, and reporting production information. All of its control functions except **Manage Batch History** are outside the scope of S88.
- **Production Planning & Scheduling:** The control activity that is associated with producing a batch schedule and providing it to Process Cell Management. All of its control functions except **Develop Batch Schedules** are outside the scope of S88.
- **Personnel & Environmental Protection** (Outside of S88 Scope)**:** The control activity designed to prevent hazardous events from occurring or worsening, which would otherwise jeopardize personnel safety and/or harm the environment.
- **Note that the majority of Coordination Control effort to implement the above Control Activities may be eliminated by using commercially available Batch Server products that are based on ISA-88.**

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Project Execution:
Benefits even without Compliant Software

Issue Solved	ISA-88 Resolution
Communication of requirements is difficult	Use standard terminology and reference models to replace jargon and organize requirements
Traditional functionally grouped PLC constructs with arbitrary interaction mechanisms are difficult to design, debug, validate, and maintain	Parse control into a hierarchy of clearly discernable and reusable *equipment entities* that fully implement equipment capabilities and *procedural elements* that capture all product-specific requirements
Customized manipulation of individual devices per product is very complex and generally prohibitive	*Procedural elements* define how *equipment entities* will be manipulated to execute all required processing actions

Project Execution:
Additional Benefits with Compliant Software

Issue Solved	ISA-88 Resolution
Extensive custom programming required for a complete solution that fully utilizes equipment capabilities	Batch software packages support much of the ISA-88 activity model (schedule and recipe management, procedure execution, exception handling, resource allocation, batch records) and FDA requirements
Programming procedures for each product/equipment combination	*Recipes* contain *procedural elements* that can link high level commands to any suitably capable *equipment entity*
No standard methods for operator interaction	*Recipe* systems provide embedded objects for operator interaction as required
High performance and schedule risks; prohibitive to subsequently change	Reuse of *procedural building blocks* and *equipment entity types* reduces task duration and reliance on system experts

Project Execution: Key Considerations

- As with any OOD effort, it is essential to spend the requisite time up front to properly define the solution
- Start by mapping requirements to existing or proposed library elements to identify all development items
- Keep users involved and keep lines of communication open with stakeholders at all times
- Define interactions and interfaces with other systems and with manual procedures as early as possible
- Determine how the activity model, shared resource requirements, and exception conditions will be handled
- Insure adequate planning and support for rollout, including any interim, training, or data migration issues

Questions?

- Thank you for your attention!
- Please feel free to contact me with any questions at:

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