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Enterprise-Control System Integration Part 3: Activity Models of Manufacturing Operations Management

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Enterprise-Control System Integration Part3: Activity Models of Manufacturing Operations Management

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FOREWORD

This standard is Part 3 of a multi-part set of standards that defines the interfaces between enterprise activities and control activities.

Clause 4 of this standard is informative. The intent is to provide an overview of activities associated with production operations management, maintenance operations management, inventory operations management, and quality operations management.

Clause 5 is normative. It defines a standard template that can be applied to different categories of manufacturing operations management and defines the standard terminology to apply to the equipment hierarchy model.

Clause 6 is normative. It defines the standard terminology to apply to information and activities associated with production operations management.

Clause 7 is normative. It defines the standard terminology to apply to information and activities associated with maintenance operations management.

Clause 8 is normative. It defines the standard terminology to apply to information and activities associated with quality operations management.

Clause 9 is normative. It defines the standard terminology to apply to information and activities associated with inventory operations management.

Clause 10 is informative. The intent is to describe other activities in manufacturing operations management, not defined in previous clauses, and to list relevant standards in those areas.

Clause 11 is normative. It defines the criteria for completeness, compliance and conformance in applying the standard.

Annex A is informative. It illustrates how the rules for determining the manufacturing operations management responsibility and technology boundaries can be applied to different manufacturing enterprises.

Annex B is informative. It illustrates an example of the hierarchy of scheduling within an enterprise.

Annex C is informative. It lists standards associated with the other activities in manufacturing operations management listed in Clause 10.

Annex D is informative. It answers a list of frequently asked questions about this standard.

As currently envisioned, the ANSI/ISA-95 series will consist of the following parts under the general title, Enterprise-Control System Integration:

- Part 1: Models and terminology (published 2000)
- Part 2: Object model attributes (published 2001)
- Part 3: Activity models of manufacturing operations management (published 2005)
- Part 4: Object models and attributes of manufacturing operations management activities (in development at the time of publication of this standard)
- Part 5: Business-to-manufacturing transactions (in development at the time of publication of this standard)
- Part 6: Manufacturing operations transactions (in development at the time of publication of this standard)

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INTRODUCTION

This Part 3 standard shows activity models and data flows for manufacturing information that enables enterprise-control system integration. The modeled activities operate between Level 4 logistics and planning functions and Level 2 manual and automated process control functions. The models are consistent with the ANSI/ISA-95.00.01-2000 (hereinafter referred to as “Part 1”) object models and the Level 3 (Manufacturing Operations and Control) definitions.

The goal of the ANSI/ISA-95 series of standards is to reduce the risk, cost, and errors associated with implementing enterprise systems and manufacturing operations systems in such a way that they interoperate and easily integrate. The standards may also be used to reduce the effort associated with implementing new product offerings.

This Part 3 standard provides models and terminology for defining the activities of manufacturing operations management. The models and terminology defined in this standard:

- Emphasize good practices of manufacturing operations.
- Can be used to improve existing manufacturing operations systems.
- Can be applied regardless of the degree of automation.

Some potential benefits produced when applying the standard may include:

- Reducing the time to reach full production levels for new products.
- Enabling vendors to supply appropriate tools for manufacturing operations.
- Enabling more uniform and consistent identification of manufacturing needs.
- Reducing the cost of automating manufacturing processes.
- Optimizing supply chains.
- Improving efficiency in life-cycle engineering efforts.

It is not the intent of this standard to:

- Suggest that there is only one way of implementing manufacturing operations.
- Force users to abandon their current way of handling manufacturing operations.
- Restrict development in the area of manufacturing operations.
- Restrict use only to manufacturing industries.

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1 Scope

This Part 3 standard defines activity models of manufacturing operations management that enable enterprise system to control system integration. The activities defined in this Part 3 standard are consistent with the Part 1 object models definitions. The modeled activities operate between business planning and logistics functions, defined as the Part 1 Level 4 functions, and the process control functions, defined as the Part 1 Level 2 functions.

The scope of this Part 3 standard is limited to:

- A model of the activities associated with manufacturing operations management, Level 3 functions.
- An identification of some of the data exchanged between Level 3 activities.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid normative documents.

a) ANSI/ISA-95.00.01-2000, Enterprise-Control System Integration Part 1: Models and Terminology

b) ANSI/ISA-95.00.02-2001, Enterprise-Control System Integration Part 2: Object Model Attributes

c) IEC/ISO 62264-1:2003, Enterprise-control system integration - Part 1: Models and terminology

d) IEC/ISO 62264-2:2004, Enterprise-control system integration - Part 2: Object model attributes

e) ANSI/ISA-88.01-1995, Batch Control Part 1: Models and Terminology

f) ANSI/ISA-88.00.02-2001, Batch Control Part 2: Data Structures and Guidelines for Languages

g) IEC 61512-1:1997, Batch control - Part 1: Models and terminology

h) IEC 61512-2:2001, Batch control - Part 2: Data structures and guidelines for languages

3 Definitions and abbreviations

3.1 Definitions

For the purposes of this standard, the following definitions apply:

3.1.1 detailed production schedule:

organized and structured collection of production work orders and sequencing involved in production of one or more products.

3.1.2 finite capacity scheduling:

a scheduling methodology in which work is scheduled for production resources, such that no production resource capacity requirement exceeds the capacity available to the production resource.

3.1.3 inventory operations management:

activities within Level 3 of a manufacturing facility that coordinate, direct, manage, and track inventory and material movement within manufacturing operations.

3.1.4 Level 0:

the actual physical process.

3.1.5 Level 1:

the functions involved in sensing and manipulating the physical process.

3.1.6 Level 2:

the functions involved in monitoring and controlling the physical process.

3.1.7 Level 3:

the functions involved in managing the work flows to produce the desired end products.

3.1.8 Level 4:

the functions involved in the business-related activities needed to manage a manufacturing organization.

3.1.9 maintenance operations management:

activities within Level 3 of a manufacturing facility that coordinate, direct, and track the functions that maintain the equipment, tools, and related assets to ensure their availability for manufacturing and ensure scheduling for reactive, periodic, preventive, or proactive maintenance.

3.1.10 manufacturing facility:

a site, or area within a site, that includes the resources within the site or area, and includes the activities associated with the use of the resources.

3.1.11 manufacturing operations management:

activities within Level 3 of a manufacturing facility that coordinate the personnel, equipment, and material in manufacturing.

NOTE 1 — This Part 3 standard details manufacturing operations management in terms of four categories (production operations management, maintenance operations management, quality operations management, and inventory operations management) and provides references for other enterprise activities affecting manufacturing operations.

NOTE 2 — In the PERA (see clause 3.2) model the concept of manufacturing defines the physical resources used in production. The manufacturing operations management activities defined in this standard pertain to the information-handling functions of the PERA model.

3.1.12 production dispatch list:

a set of specific production work orders to be performed on or by a particular set of resources, at a given location, and the time or event to start or stop the activity.

NOTE 1 — This may take the form of setup instructions for machines, operating conditions for continuous processes, material movement instructions, or batches to be started in a batch system.

NOTE 2 — Dispatch lists are applicable to other operations management areas, such as maintenance dispatch lists, quality test dispatch lists, and inventory dispatch lists.

3.1.13 production operations management:

activities within Level 3 of a manufacturing facility that coordinate, direct, manage, and track the functions that use raw materials, energy, equipment, personnel, and information to produce products, with the required costs, qualities, quantities, safety, and timeliness.

3.1.14 production work order:

unit of scheduled work that may be dispatched to a work center and that consists of lower-level elements.

3.1.15 quality operations management:

activities within Level 3 of a manufacturing facility that coordinate, direct, and track the functions that measure and report on quality.

3.1.16 storage unit:

subordinate entity within a storage zone that consists of equipment and information required to contain, move, condition, and handle material.

NOTE — A storage unit is an element of the equipment hierarchy.

3.1.17 storage zone:

logical grouping of resources that defines a span of logistical control and includes the equipment and information required for containing, moving, conditioning, and handling of one or more material items.

NOTE — A storage zone is an element of the equipment hierarchy.

3.1.18 tracing:

activity that provides an organized record of resource and product use from any point, forward or backward, using tracking information.

3.1.19 tracking:

activity of recording attributes of resources and products through all steps of instantiation, use, change, and disposition.

3.1.20 work center:

process cell, production unit, production line, storage zone, or any other equivalent-level equipment element defined as an extension to the equipment hierarchy model.

3.2 Abbreviations

For the purposes of this standard, the following abbreviations apply:

AGV	Automated Guided Vehicles
AMS	Asset Management System
ASRS	Automated Storage and Retrieval System
CAPE	Computer Aided Process Engineering
CAD	Computer Aided Design
CAE	Computer Aided Engineering
CASE	Computer Aided Software Engineering
CIM	Computer Integrated Manufacturing
CNC	Computerized Numerical Control
DCS	Distributed Control System
ERP	Enterprise Resource Planning
EWI	Electronic Work Instructions
HR	Human Resources
KPI	Key Performance Indicator
LIMS	Laboratory Information Management System
MES	Manufacturing Execution System
MPS	Master Production Schedule
MRP	Material Resource Planning
OEE	Overall Equipment Effectiveness

PAT	Process Analytical Technology
PERA	Purdue Enterprise Reference Architecture
PDM	Product Data Management
PLC	Programmable Logic Controller
PLM	Product Lifecycle Management
PRM	Purdue Reference Model for computer integrated manufacturing
QA	Quality Assurance
R&D	Research and Development
RFQ	Request For Quote
ROA	Return On Assets
SCADA	Supervisory Control and Data Acquisition
SOC	Standard Operating Conditions
SOP	Standard Operating Procedure
SQC	Statistical Quality Control
SPC	Statistical Process Control
WIP	Work In Process
WMS	Warehouse Management System

4 Manufacturing operations management overview

4.1 Manufacturing operations management

The activities of manufacturing operations management are those activities of a manufacturing facility that coordinate the personnel, equipment, material, and energy in the conversion of raw materials and/or parts into products. Manufacturing operations management includes activities that may be performed by physical equipment, human effort, and information systems.

Manufacturing operations management includes the activities of managing information about the schedules, use, capability, definition, history, and status of all of the resources (personnel, equipment, and material) within and associated with the manufacturing facility.

NOTE — Resources associated with the manufacturing facility but not within it may include, among others, government inspectors, regulatory certifications, resource coordination with other entities, outsourced activities, and processes.

The manufacturing operations management activities correspond to the activity set defined in the Part 1 standard. These are the activities contained within the heavy dotted line shown in Figure 1. The heavy dotted line is equivalent to the Level 3/Level 4 interface defined in Part 1. Manufacturing operations management is subdivided into four categories: production operations management, maintenance operations management, quality operations management, and inventory operations management, as shown in shaded areas in Figure 1. There are also other activities of a manufacturing facility, not shown in Figure 1, but described in Clause 4.8 and Clause 10.

The model structure does not reflect a business organizational structure within a company, but is a model of activities. Different companies assign responsibilities for activities or subactivities to different business organizational groups.

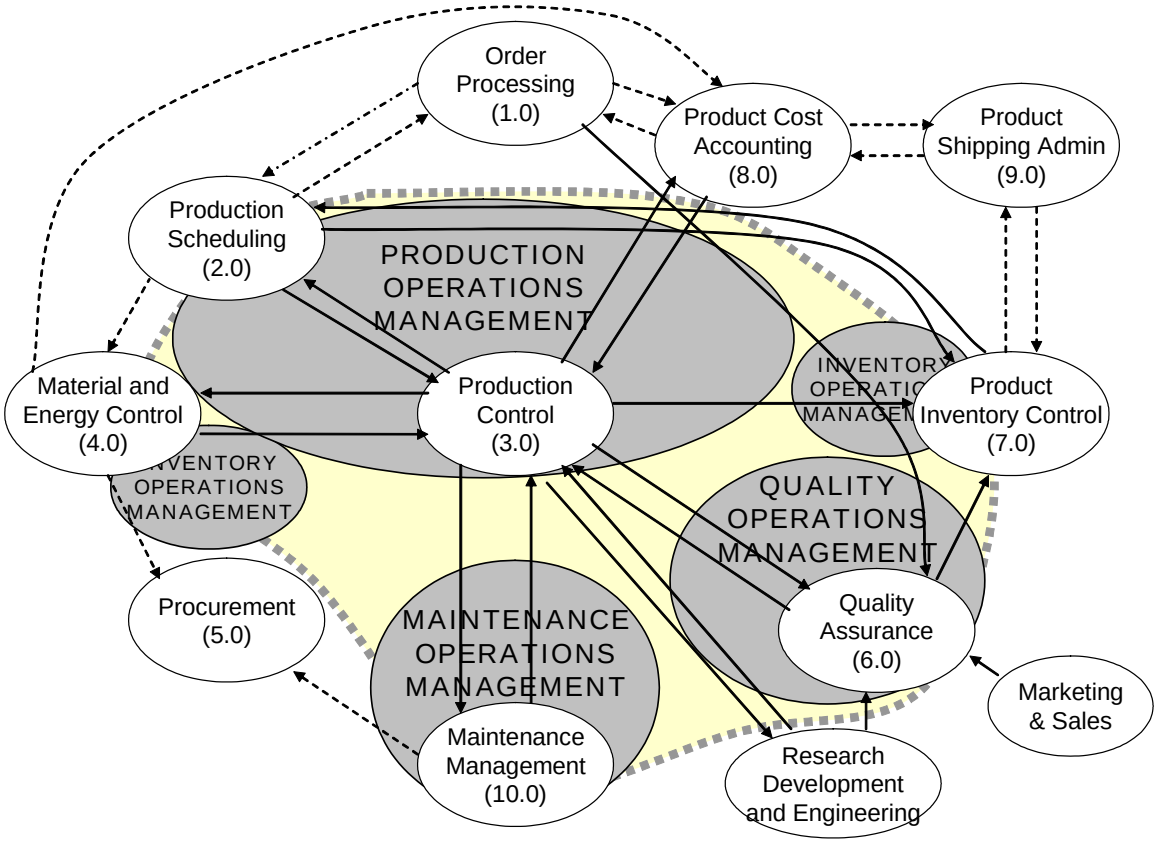

Figure 1 – Manufacturing operations management model

4.2 Functional hierarchy

The Part 1 standard defines a functional hierarchy model. Each level provides specialized functions and has characteristic response times, as shown in Figure 2.

a) Level 0 defines the actual physical processes.

b) Level 1 defines the activities involved in sensing and manipulating the physical processes. Level 1 typically operates on time frames of seconds and faster.

c) Level 2 defines the activities of monitoring and controlling the physical processes. Level 2 typically operates on time frames of hours, minutes, seconds, and subseconds.

d) Level 3 defines the activities of work flow to produce the desired end products. It includes the activities of maintaining records and coordinating the processes. Level 3 typically operates on time frames of days, shifts, hours, minutes, and seconds.

e) Level 4 defines the business-related activities needed to manage a manufacturing organization. Manufacturing-related activities include establishing the basic plant schedule, (such as material use, delivery, and shipping), determining inventory levels, and making sure that materials are delivered on time to the right place for production. Level 3 information is critical to Level 4 activities. Level 4 typically operates on time frames of months, weeks, and days.

NOTE — There are other business-related activities that may be in Level 4 or higher levels, but these are not defined in this standard.

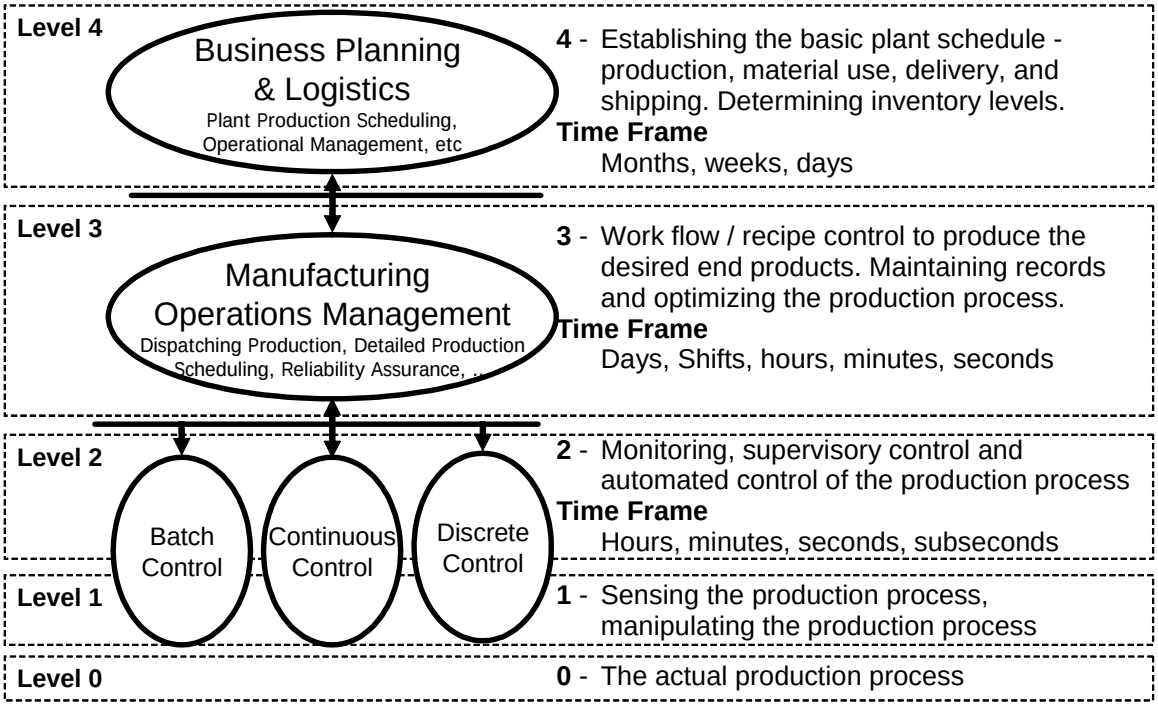

Figure 2 - Multi-level functional hierarchy of activities

4.3 Manufacturing operations management elements

The shaded areas in Figure 1 represent the manufacturing operations management activities modeled in this Part 3 standard. Manufacturing operations management is the collection of production operations management, maintenance operations management, quality operations management, inventory operations management, and other activities of a manufacturing facility.

Four formal models are defined: production operations management, maintenance operations management, quality operations management, and inventory operations management.

a) The production operations management model includes the activities of production control (3.0) that operate as Level 3 functions and the subset of the production scheduling (2.0) that operate as Level 3 functions and as shown in Figure 1.

b) The maintenance operations management model includes the activities of maintenance management (10.0) that operate as Level 3 functions.

c) The quality operations management model includes the activities of quality assurance (6.0) that operate as Level 3 functions.

d) The inventory operations management model includes the activities of management of inventory and material including product inventory control (7.0) and material & energy control activities (4.0) defined as operating as Level 3 functions and as shown in Figure 1.

Other categories of operation management may exist depending on company policy or organization. They are not formally modeled in this Part 3 standard, but they can make use of the generic standard model.

4.4 Criteria for defining activities below Level 4

In this Part 3 standard an activity is included as a Level 3, 2, or 1 activity if the activity is directly involved in manufacturing, includes information about personnel, equipment, or material, and meets any of the following conditions:

a) The activity is critical to plant safety.

b) The activity is critical to plant reliability.

c) The activity is critical to plant efficiency.

d) The activity is critical to product quality.

e) The activity is critical to maintaining regulatory compliance.

NOTE — This includes such factors as safety, environmental, and cGMP (current good manufacturing practices) compliance.

EXAMPLE:

Maintaining regional, government, and other agency compliance.

NOTE 1 — This list is a clarification of the criteria for inclusion of an activity in Level 3, 2, or 1 domain defined in the Part 1 standard. This list supersedes the criteria defined in Part 1.

NOTE 2 — There are other criteria such as company policy and organizational structure, or the nature of the operations that could expand the scope of manufacturing operations management. See Annex A.

NOTE 3 — Such activities as personnel management of salaries and job titles may be important for running a manufacturing business, but they are not considered part of manufacturing operations management.

NOTE 4 — Absolute plant efficiencies may be dependent upon factors that are outside the control of a facility (MRP schedules, product mixes, etc). These activities are not part of Level 3, 2, or 1.

4.5 Activity relationships

Figure 3 illustrates the activity models of this Part 3 standard in relationship to Parts 1 and 2. The activities in this Part 3 exchange information with Level 4 and Level 2 activities. The gray circles indicate the activities detailed in this Part 3 standard. The information flows between the Part 3 activities, indicated as heavy dashed lines, are described in general in this Part 3 standard. In addition, the information flows between the Part 3 activities and dependent Level 2 activities are identified.

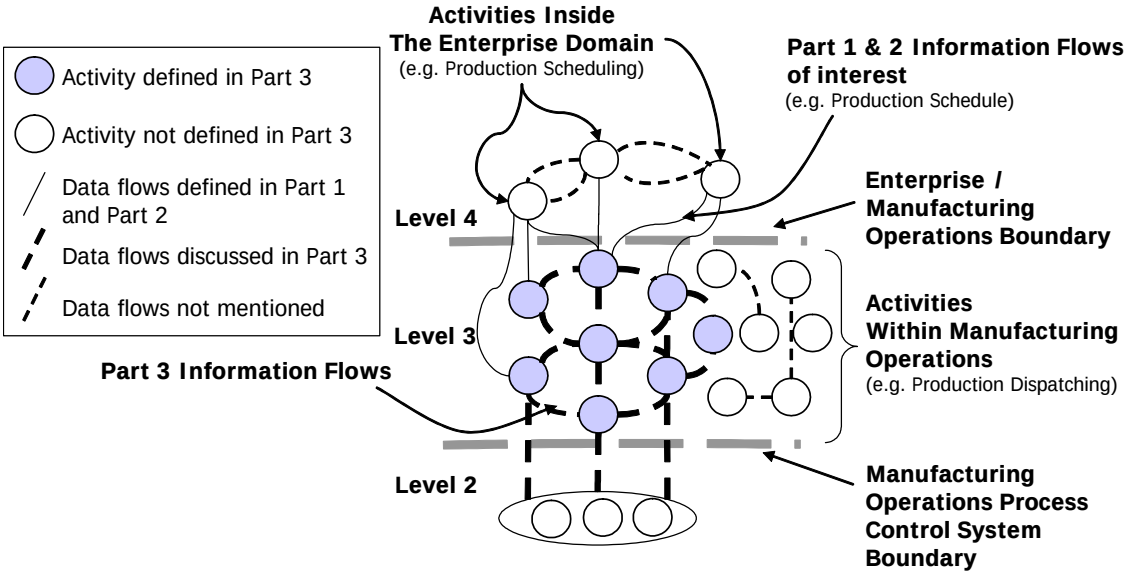

Figure 3 - Activity relationships

4.6 Expanded categories of information

The Part 1 standard defines the models and terminology to be used for enterprise-control system integration. Part 1 contains a definition of three general categories of information that should be exchanged between the business planning system (Level 4) and the manufacturing operations system (Level 3). The result of Part 1 includes object models for the three categories. This is expanded to four

categories in this Part 3 by splitting production information into the separate schedule and performance components of production schedule information and production performance information. See Figure 4.

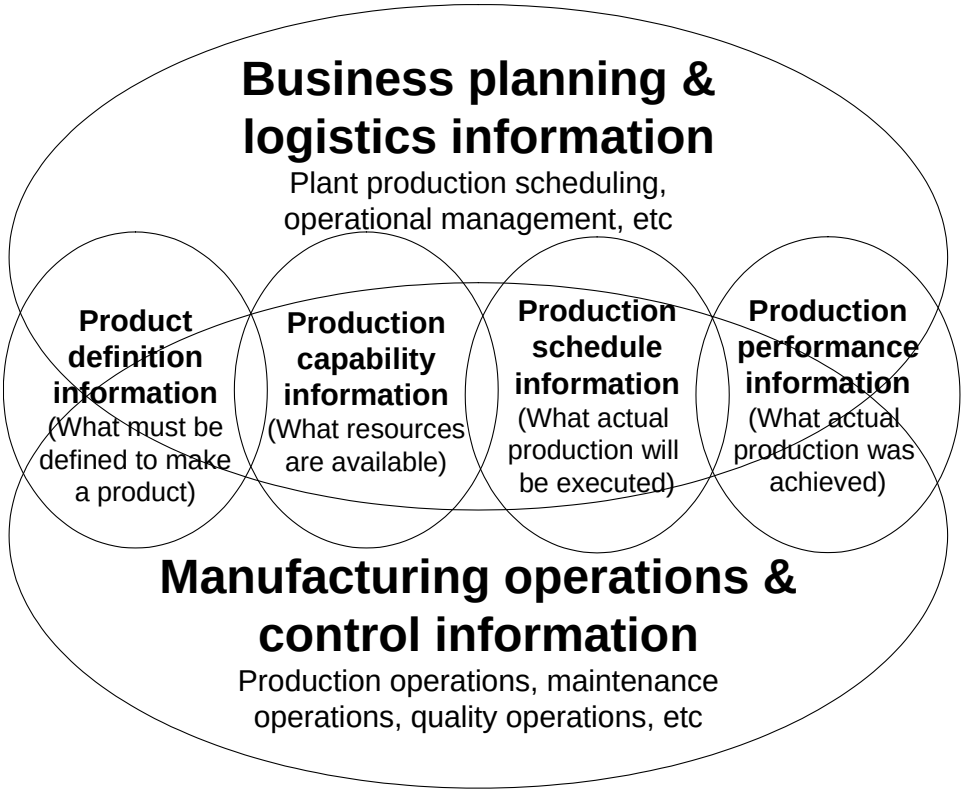

Figure 4 – Categories of information exchange

4.7 Manufacturing operations information

The structure of the production information defined in Part 1 and depicted in Figure 4 can also be applied to maintenance information, quality test information, and inventory transfer information as depicted in Figure 5. The production schedule, production performance, product definition management, production capability, maintenance request, and maintenance response, shown in Figure 5 as bold and underlined text, are defined in the Part 1 standard. There are equivalent information structures for maintenance, quality test, and inventory management that are of importance for manufacturing operations that are also discussed in this Part 3 standard.

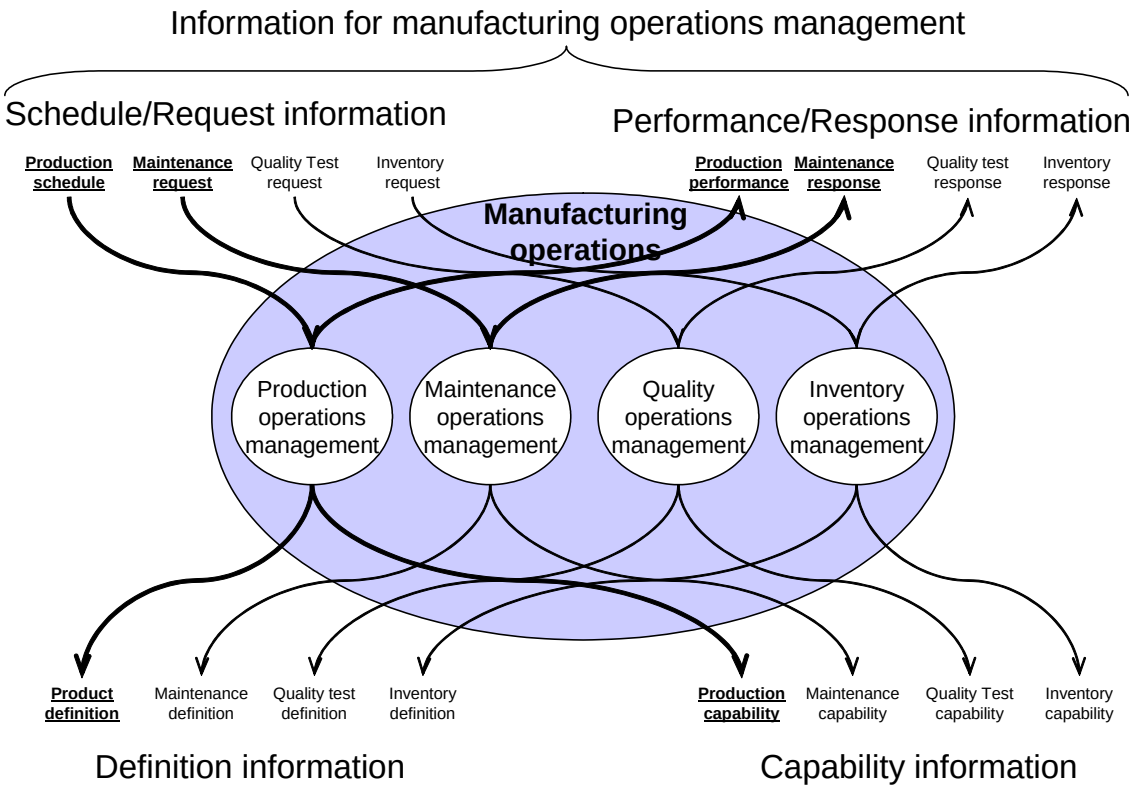

Figure 5 - Manufacturing operations information

4.8 Other activities within manufacturing operations management

In addition to the activities of production operations, maintenance operations, quality operations, and inventory operations management, there are many supporting management activities that occur in manufacturing operations. Elements of these supporting activities may occur in any of the production, maintenance, quality operations, or inventory operations management activities. Elements of these supporting activities may not be unique to manufacturing operations in an enterprise, but typically also apply to many other areas of the enterprise.

These supporting activities include:

a) Management of security within manufacturing operations.

b) Management of information within manufacturing operations.

c) Management of configurations within manufacturing operations.

d) Management of documents within manufacturing operations.

e) Management of regulatory compliance within manufacturing operations.

f) Management of incidents and deviations.

The definition of the supporting activities is not within the scope of this standard, because those activities often are enterprise wide; however, requirements for the activities as they relate to manufacturing operations are described briefly in Clause 10.

5 Structuring models

5.1 Generic template for categories of manufacturing operations management

5.1.1 Template for management of operations

A generic model for management of operations is used as a template to define the production operations management, maintenance operations management, quality operations management, and inventory operations management models. This model is shown in Figure 6. This generic model is extended for each specific area in later clauses.

NOTE — The fine details of the generic model are different for each of the manufacturing operations management areas.

5.1.2 Use of the generic model

The generic model is instantiated for the four categories listed in Clause 5.1.1. However, this same template could be instantiated for other possible manufacturing operations categories, or for other operations areas within the enterprise.

EXAMPLE:

A company could apply the model to receiving operations management and shipping operations management where these are separately managed.

EXAMPLE:

A company could apply the model to cleaning and sterilization operations management, where these are separately managed.

EXAMPLE:

A company could apply the model to independent logistics operations management categories for inbound logistics, outbound logistics, internal transfer, and inventory control.

NOTE — This clause is normative so that companies that apply the generic model to areas other than the four detailed in this standard can determine and document their degree of conformance to the model.

When the generic model is instantiated for a new category, the activities within a category shall include the definitions of resource management, definition management, dispatching, tracking, data collection, analysis, detailed scheduling, and execution management.

5.1.3 Generic activity model

There is a hierarchy used in this standard that starts at a category of operations management. Each category is composed of a collection of activities, and each activity is composed of a set of tasks. The generic model applies to the sets of activities.

The generic activity model defines a general request-response cycle that starts with requests or schedules, converts them into a detailed schedule, dispatches work according to the detailed schedule, manages the execution of work, collects data, and converts the collected data back into responses. This request-response cycle is supported with:

- Analysis of the work performed for improvements or corrections.
- Management of the resources used in execution of the performed work.
- Management of the definitions of the performed work.

The generic activity model and the detailed models are not intended to represent an actual implementation of a manufacturing information system. However, they do provide a consistent framework for such systems. Actual systems may use different structures supporting other task arrangements. The purpose of these models is to identify possible data flows within manufacturing operations. The ovals in the model indicate collections of tasks, identified as the main activities. Lines with arrowheads indicate a set of important information flows between the activities.

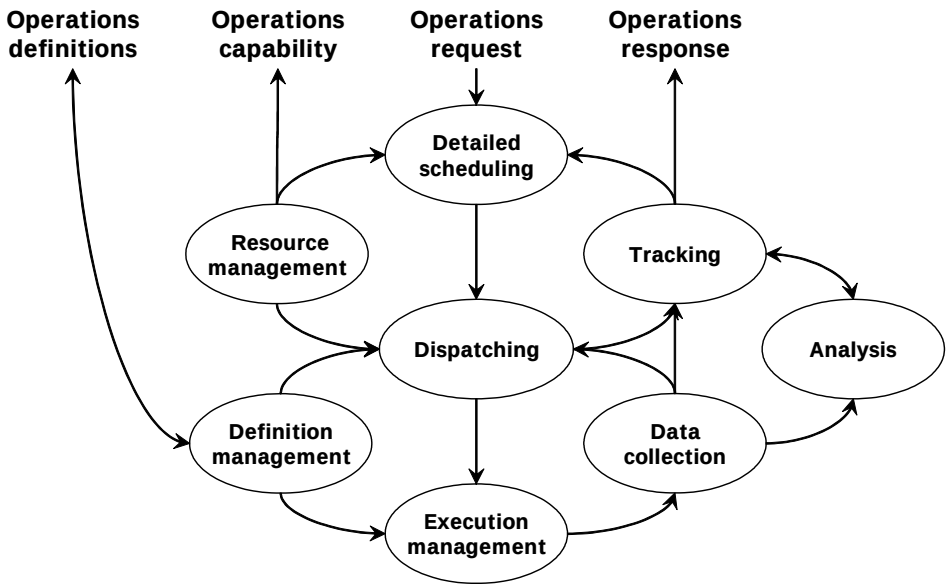

Figure 6 - Generic activity model of manufacturing operations management

Not all information flows are depicted in Figure 6. In any specific implementation, information from any activity may be required by any other activity. Where the model is expanded for specific activities, the lines indicating information flows are not intended to be exclusive lists of information exchanged.

5.2 Interaction among generic activity models

5.2.1 Information flows between generic activity models

In addition to the information flows within the activities of specific operations categories, there are also information flows between the different categories. Some of this information is defined in following clauses, but not all information flows are explicitly defined in this standard.

NOTE — Specific implementations of activity models may give prominence to one specific activity model over others.

EXAMPLE 1:

In pharmaceutical industries, quality operations may provide the direction for other operations.

EXAMPLE 2:

In distribution centers, inventory operations may provide the direction for other operations.

EXAMPLE 3:

In consumer packaged goods, production operations may provide the direction for other operations.

EXAMPLE 4:

In refining, inventory operations may provide the direction for production operations.

5.2.2 Handling Resources within the Generic Activity Models

Information about resources (materials, personnel, and equipment) can be handled within any one of the four activity models of manufacturing operations (production, quality, maintenance, and inventory) presented in this standard.

Although data for different resources may be found in different models, there are primary reporting paths through which information should be obtained:

a) Personnel information specific to each activity model may be obtained from the specific activity model.

b) Equipment information specific to each activity model may be obtained from the specific activity model.

c) Material information specific to each activity model may be obtained from the specific activity model. However, material inventory information, including finished goods, and raw materials may be obtained from the inventory activity model. Material movement operations may be managed by activities in the production, quality, maintenance, or inventory activity models. A specific material movement instance only exists within one activity model at any given point in time.

5.3 Expanded equipment hierarchy model

5.3.1 Equipment hierarchy model

The equipment hierarchy model, defined in Part 1, is extended in this Part 3 standard to the model shown in Figure 7. Additional items are included for inventory operations management and management of material. Lower-level groupings are combined to form higher levels in the hierarchy. In some cases, a grouping within one level may be incorporated into another grouping at that same level as a recursive structure. The models may be collapsed or expanded as required for specific applications.

NOTE — Specific rules for collapsing and expanding these models are not defined in this standard. The following guidelines should be considered for collapsing and expanding the models:

Collapsing — Elements in the models may be omitted as long as the models remain consistent, and the functions of the element removed are taken into account.

Expanding — Elements may be added to the models. When they are added between related elements, the integrity of the original relationship should be maintained.

There is at least one site within the enterprise, at least one work center in an area (or site if the area is collapsed out) and at least one work unit within a work center.

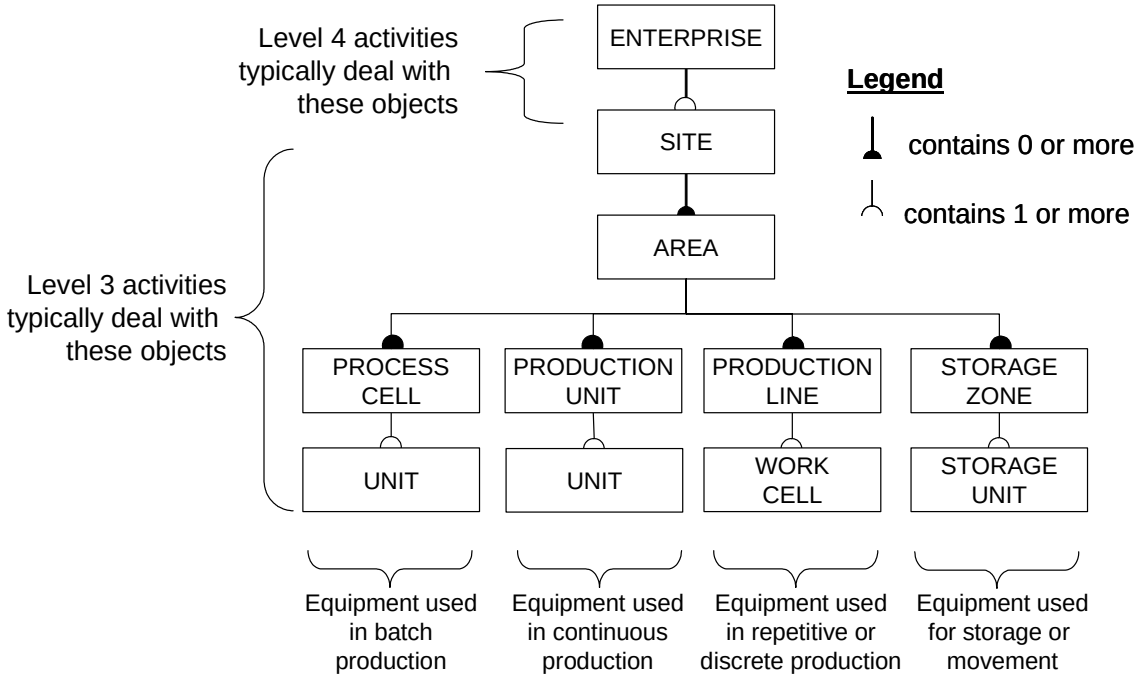

Figure 7 – Typical expanded equipment hierarchy

Storage zones and storage units have been added as elements under an area. These are the lower- level elements used in material storage.

NOTE — Material is also temporarily stored in process cells, production units, and production lines. This material is typically considered WIP and is usually distinct from inventory managed materials.

5.3.2 Storage zone

A storage zone typically has the capability needed for the receipt, storage, retrieval, movement, and shipment of materials. This may include the movement of materials from one work center to another work center within or between enterprises.

5.3.3 Storage unit

Storage units are typically of interest to business systems only when business functions maintain inventory to a finer level of detail than a storage zone. The physical location of a storage unit may change over time; for example, for goods in transit.

Storage units may be dedicated to a given material, group of materials, or method of storage.

5.3.4 Storage zone and storage unit examples

Table 1 lists examples of a hierarchy of storage zones and the associated storage units.

Table 1 - Storage zone and storage unit examples

Storage Zone	Storage Unit
Warehouse	Rack/Bin/Slot
Trailer Yard	Trailer, Container
Tank Farm	Tank, Pipe Section
Silo Farm	Silo, Pipe Section
Ship Terminal	Ship, Ship's Hold, Container, Barrel, Tank
Rail Yard	Railcar
Holding Area	Pallet, Barrel

NOTE — Some storage zones and storage units could also be identified as equipment used in a transport request.

5.3.5 Work center

A work center may be defined as any element of the equipment hierarchy under an area. Work centers may be used when the specific type of the equipment element is not significant for the purpose of the discussion. A work center may be a process cell, production unit, production line, storage zone, or any other equipment element subordinate to an area that may be defined by the user in an extension to the equipment hierarchy model. See Figure 8.

5.3.6 Work unit

A work unit may be defined as any element of the equipment hierarchy under a work center. Work units are typically the most elemental schedulable item by Level 3 functions. See Figure 8.

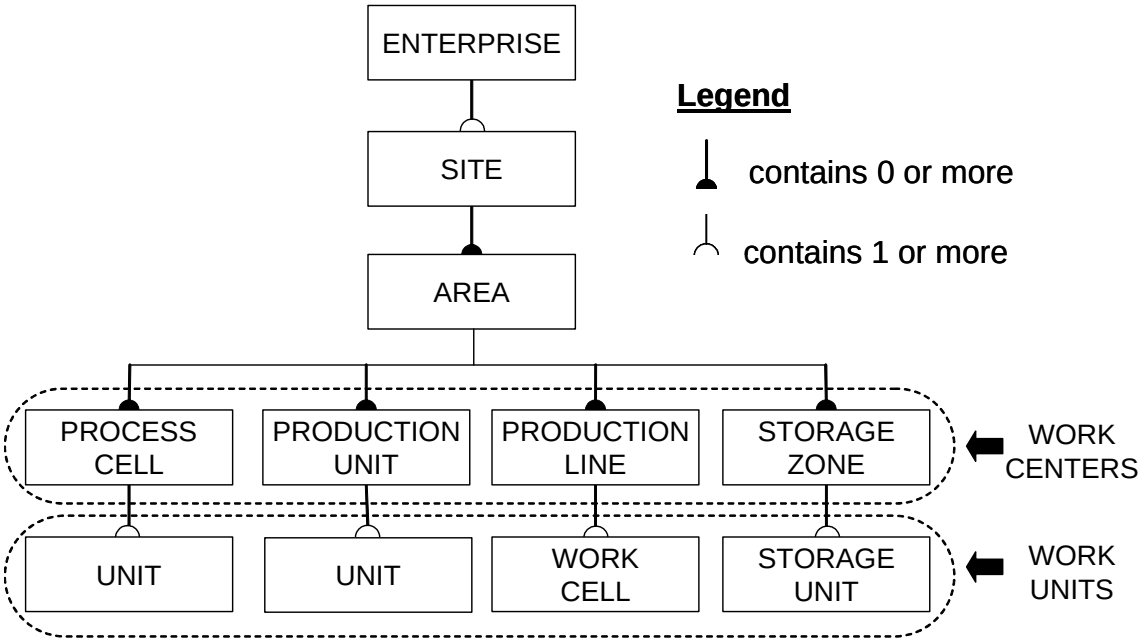

Figure 8 - Work centers and work units

Work centers are typically the grouping of equipment scheduled by the Level 4 or Level 3 functions for continuous, batch, and discrete manufacturing. Work centers have well-defined capabilities and capacities and these are used for Level 3 functions. The capacities and capabilities are also often used as input to Level 4 business processes. Scheduling functions may identify specific work units.

6 Production operations management

6.1 General activities in production operations management

Production operations management shall be defined as the collection of activities that coordinate, direct, manage and track the functions that use raw materials, energy, equipment, personnel, and information to produce products, with the required costs, qualities, quantities, safety, and timeliness. The general activities in production operations management are listed in the Part 1 standard and include:

a) Reporting on production including variable manufacturing costs.

b) Collecting and maintaining data on production, inventory, manpower, raw materials, spare parts, and energy usage.

c) Performing data collection and off-line analysis as required by engineering functions. This may include statistical quality analysis and related control functions.

d) Performing needed personnel functions, such as work period statistics (for example, time, task), vacation schedule, work force schedules, union line of progression, and in-house training and personnel qualification.

e) Establishing the immediate detailed production schedule for its own area accounting for maintenance, transportation, and other production-related requests.

f) Locally optimizing the costs for individual production areas while carrying out the production schedule established by the Level 4 functions.

g) Modifying production schedules to compensate for plant production interruptions that may occur in its area of responsibility.

6.2 Production operations management activity model

The production operations management model illustrated by the shaded area in Figure 1 is expanded to a more detailed activity model of production operations, shown in Figure 9. The four elements of information (product definition, production capability, production schedule, and production performance) correspond to the exchanged information defined in Part 1, and illustrated in Figure 4 of this standard. The oval labeled Production Level 1-2 functions represent the Level 1 and 2 sensing and control functions. The other ovals (with solid outlines) represent the activities of production operations.

The activities defined here are not intended to imply an organizational structure of systems, software, or personnel. The model is provided to help in the identification of activities that may be performed and in the identification of roles associated with the activities. It defines what is done, not how it should be organized. Different organizations may have a different arrangement of roles and assignment of roles to personnel or systems.

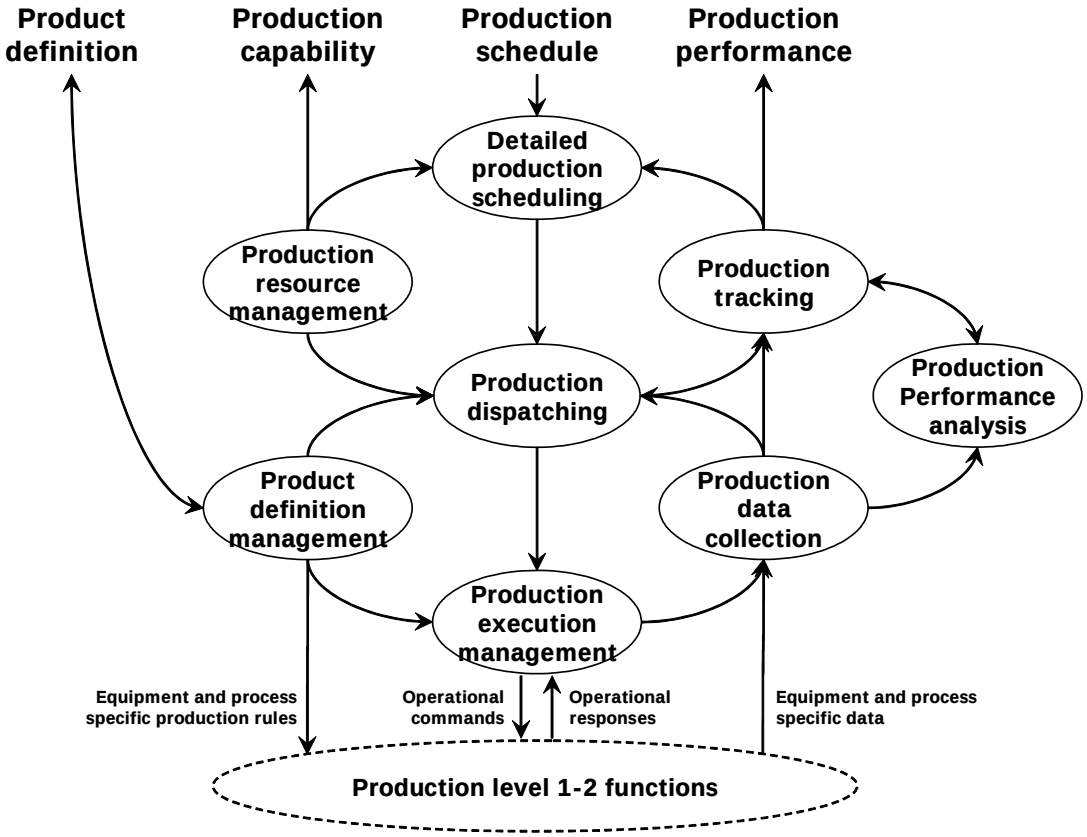

Figure 9 - Activity model of production operations management

Not all production requests and production responses cross the boundary to business systems. While production operations may be driven by production schedules there can be production requests and production responses used internally within manufacturing operations management to handle situations such as rework, local intermediates, or consumable production.

Not all information flows within production operations management are depicted in Figure 9. In any specific implementation, information from any activity may be required by any other activity. Where activities in the production operations management model are defined in detail in this clause, some additional information flows are identified. Not all data sources and data sinks are identified in the detailed models.

6.3 Information exchange in production operations management

6.3.1 Equipment and process specific production rules

Equipment and process specific production rules shall be defined as the specific instructions sent to Level 2 based on the specific assigned tasks.

EXAMPLE:

Programs for CNC machines for a specific product type, PLC programs that change based on the process under control, or unit recipes where these are executed in Level 2 or Level 1 equipment.

NOTE — See IEC 61131-3, “Programmable controllers - Part 3: Programming languages,” for examples of this type of data.

6.3.2 Operational commands

Operational commands shall be defined as the request information sent to Level 2. These are typically commands to start or complete elements of a work order. This information may also be SOPs displayed or given to operators, such as procedures for setting up machines or cleaning of machines.

NOTE — This information exchange corresponds to the recipe-equipment interface defined in IEC 61512-1 (see Clause 2).

6.3.3 Operational responses

Operational responses shall be defined as information received from Level 2 in response to commands. These typically correspond to the completion or status of elements of work orders.

NOTE — This information exchange corresponds to the recipe-equipment interface defined in IEC 61512-1 (see Clause 2).

6.3.4 Equipment and process specific data

Equipment and process specific data shall be defined as information received as a result of monitoring Level 2. This is typically information about the process being performed and the resources involved.

6.4 Product definition management

6.4.1 Activity definition

Product definition management shall be defined as the collection of activities that manage all of the Level 3 information about the product required for manufacturing, including the product production rules.

Product definition information is shared between product production rules, bill of material, and bill of resources. The product production rules contain the information used to instruct a manufacturing operation how to produce a product. This may be called a general, site, or master recipe (IEC 61512-1 and ANSI/ISA-88.01-1995 definition), standard operating procedure (SOP), standard operating conditions (SOC), routing, or assembly steps based on the production strategy used. The product definition information is made available to other Level 3 functions and to Level 2 functions as required.

Product definition management includes management of the distribution of product production rules. Some of the product production rules may exist in Level 2 and Level 1 equipment. When that is the case, downloads of this information shall be coordinated with other manufacturing operations management functions to avoid affecting production. This information may be included as part of operational commands when the download is part of a production execution management activity.

6.4.2 Activity model

Figure 10 illustrates some of the interfaces to product definition management.

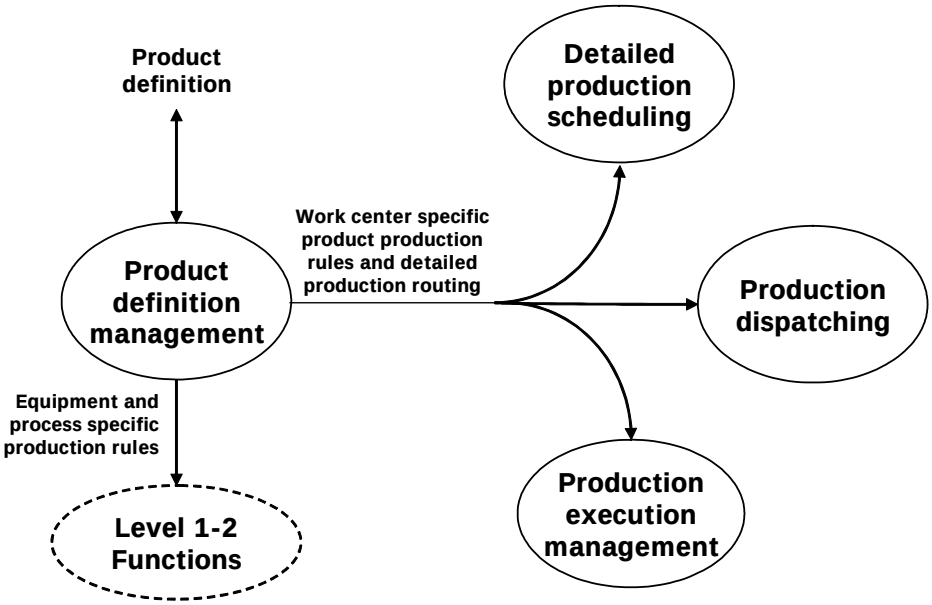

Figure 10 - Product definition management activity model interfaces

6.4.3 Tasks in product definition management

Product definition management tasks may include:

a) Managing documents such as manufacturing instructions, recipes, product structure diagrams, manufacturing bills, and product variant definitions.

b) Managing new product definitions.

c) Managing changes to product definitions. This may include the ability to route designs and manufacturing bill changes through an appropriate approval process, management of versions, tracking of modifications, and security control of the information.

d) Providing product production rules to personnel or other activities.

EXAMPLE:

These may take the form of manufacturing steps, master recipes, machine setup rules, and process flowsheets.

e) Maintaining the feasible detailed production routings for products.

f) Providing the product segment route to manufacturing operations in the level of detail required by manufacturing operations.

g) Managing the exchange of product definition information with Level 4 functions at the level of detail required by the business operations.

h) Optimizing product production rules based on process analysis and production performance analysis.

i) Generating and maintaining local production rule sets indirectly related to products, such as for cleaning, startup, and shutdown.

j) Managing the Key Performance Indicator (KPI) definitions associated with products and production.

NOTE — There are a number of tools to assist in the product definition management activity, including mechanical and electronic computer-aided design (CAD), Computer-Aided Engineering (CAE), and Computer-Aided Software Engineering (CASE), recipe management systems, Computer-Aided Process Engineering (CAPE), and Electronic Work Instructions (EWIs).

6.4.4 Product definition rule information

Product definition is the information exchanged with engineering, R&D and others to develop the site-specific product production rules. This information may include R&D manufacturing definitions that are translated and extended by product definition management into site-specific definitions using local material, equipment, and personnel. This may also involve translation to elements of a work order.

EXAMPLE:

Translation to master recipes, machine setup rules, and process flow diagrams.

Product definition management may also include managing other product information in conjunction with manufacturing information. This may include:

— Customer requirements, product design, and test specifications.

— Process design and simulation.

— Technical publications and service materials.

— Regulatory filings requirement information.

The product definition management activity interacts with production dispatching and production execution management to get the work done and interacts with research development and engineering to obtain the product production rules for executing the work.

EXAMPLE:

Production dispatching activities may need to refer to production dependencies to identify when a specific resource will be required.

The product production rule identifies elements of a work order and establishes relationships between them. Each element can contain information regarding personnel, equipment, material, and product parameters. To perform these functions, product definition management may need to exchange information with resource management.

6.4.5 Detailed production routing

The product definition information includes dependencies of work order elements. Detailed work order element routing may contain a finer granularity of definition than is visible to business systems, but is required for detailed routing of work between work centers (process cells, production lines, and production units). Detailed work order element routing is organized by the physical production process.

NOTE — A detailed production routing is sometimes called a production route, master business system route, master route, or business route.

6.5 Production resource management

6.5.1 Activity definition

Production resource management shall be defined as the collection of activities that manage the information about resources required by production operations. The resources include machines, tools, labor (with specific skill sets), materials, and energy, as defined in the Part 1 object models. Direct control of these resources in order to meet production requirements is performed in other activities, such as production dispatching and production execution management. Management of information about segments of production is also an activity in resource management.

Management of the resource information may be handled by computer systems, but it may be partly or entirely handled by manual processes.

Management of the resources may include local resource reservation systems to manage information about future availability. There may be separate reservation systems for each managed critical resource. There may be separate activities for each type of resource, or combined activities for sets of resources.

Information about resources needed for a segment of production must be maintained and provided on the available, committed, and unattainable capacity for specific periods of time of specified resources as defined in Part 1.

6.5.2 Activity Model

Figure 11 illustrates some of the interfaces to production resource management.

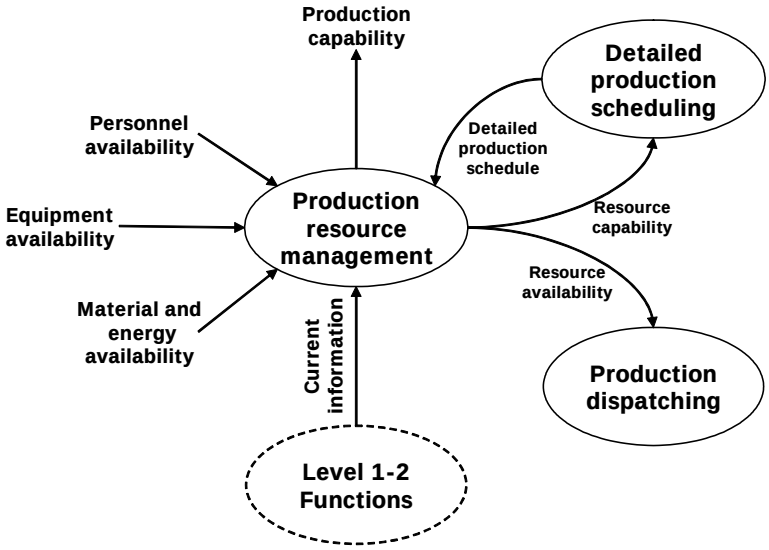

Figure 11 – Production resource management activity model interfaces

6.5.3 Tasks in production resource management

Production resource management tasks may include:

a) Providing personnel, material, and equipment resource definitions. The information may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities.

b) Providing information on resource (material, equipment, or personnel) capability (committed, available, or unattainable). The information is based on the current statuses, future reservations, and future needs (as identified in the production plan and detailed production schedule) and is specific for resources, for defined time spans and process segments. It may include information on current balance and losses to product cost accounting and may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities.

c) Ensuring that requests for acquisition of resources to meet future operational capabilities are initiated.

d) Ensuring that equipment is available for the assigned tasks, and that job titles are correct and training is current for personnel assigned to tasks.

   EXAMPLE:

   Checking that an equipment sterilization status is correct (“Clean”) before it is assigned to a production operation.

e) Providing information on the location of resources and assignment of resources to areas of production.

   EXAMPLE:

   Providing a location for a mobile inspection machine that can be used in multiple locations.

f) Coordinating the management of resources with maintenance resource management and quality resource management.

g) Collecting information on the current state of personnel, equipment, and material resources and on the capacity and capability of the resources. Information may be collected based on events, on demand and/or on a defined schedule, and may be collected from equipment, people, and/or applications.

h) Collecting future needs such as from the production plan, current production, maintenance schedules, or vacation schedules.

i) Maintaining personnel qualification test result information.

j) Maintaining equipment capability test result information.

k) Managing reservations for future use of resources.

6.5.4 Resource availability

Resource availability provides time-specific definitions needed for scheduling and reporting on a resource. The resource availability must take into account elements such as working hours, labor regulations, holiday calendar, breaks, plant shutdowns, and shift schedules.

EXAMPLE:

The available time can be a fixed time or a flexible time. For example, in personnel resource management the time for lunch may be flexible between 11:00 AM and 2:00 PM, or a machine may be unavailable for 8 hours within a 16-hour period. Personnel availability may define working days and days off; Monday to Friday are available for work, Saturday and Sunday are unavailable for work, or available for 2 days early shift, 2 days late shift, 2 days night shift, and 3 days off.

Figure 12 illustrates the types of information about the capacity of a single resource that may be provided by resource management.

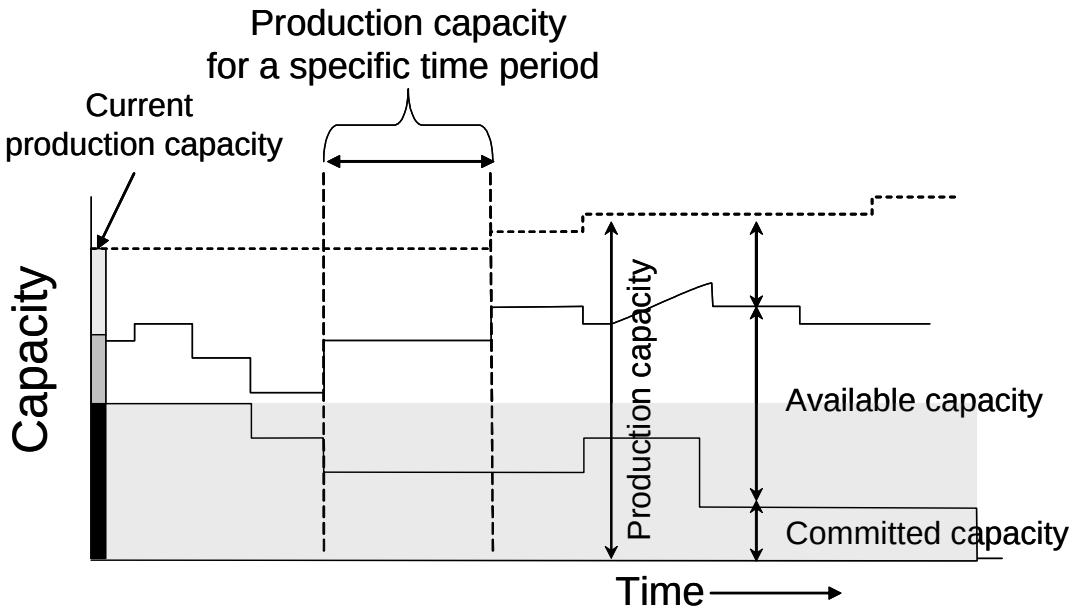

Figure 12 - Resource management capacity reporting

6.5.5 Collecting future committed resource information

Production resource management manages committed resource availability based on the detailed production schedule and product requirements. An assigned resource changes from available to committed for the period of time defined by the production plan, or until the completion of the scheduled task.

NOTE — Once the schedule window requiring the resource is completed, the resource is typically taken back to the available state, unless it was already dispatched for a new assignment. In the most basic systems, the end of the planned schedule window triggers this ending of committed time window. But for more sophisticated systems, it may be triggered by production tracking that relays the actual time the work is completed to production resource management.

6.5.6 Collecting resource definition changes

The production resource management activity includes collecting information about new, modified, or deleted resource definitions, classes, and instances. This includes information on resource property definitions.

6.5.7 Personnel resource information management

Management of information about personnel resources and future personnel availability is part of resource management.

EXAMPLE:

If an individual has vacation planned or is known sick for a certain period of time, then a business-level Human Resource (HR) function may report this situation to production resource management. This prevents production from assigning the resource within this period of time. As an extension, the whole working schedule of the personnel must be known by production in order to make the right allocation decisions.

This may include information such as levels of certification, tracking of time spent for specific tasks, and managing availability of personnel resources. In some cases this information is maintained and managed in corporate HR (Human Resource) systems, but must be available to manufacturing. Often the level of detail required for manufacturing, such as certification expiration dates and union line of seniority, is not maintained in the HR systems. In these cases labor management can be considered part of the manufacturing operations activities.

The production resource management activity also has to address skill levels. Each member of the personnel may have recognized skills through qualification tests results. This defines a skill profile utilized by production resource management to allow the dispatch of the qualified personnel to each specific production activity.

6.5.8 Equipment resource information management

Management of information about equipment resources and future equipment availability is part of resource management.

Maintenance operations often have a major impact on resource utilization. Periods of future unavailability, based on yet unscheduled maintenance requirements, also affect utilization.

EXAMPLE:

When a piece of equipment is reported defective, a maintenance task request could request the equipment to be classified as unavailable. The equipment would be also classified as unavailable if preventive maintenance is scheduled for this equipment. When the equipment is repaired or the preventive maintenance activity is over, the maintenance task would request that the equipment is to be taken back to its available status.

Selected equipment may be submitted to an equipment capability test as defined in the Part 1 standard. This test result determines if specific equipment may be assigned for a specific task in a specific process segment.

6.5.9 Material resource information management

Management of information about material and energy resources and future material and energy availability is part of resource management. Production resource management is informed as material is received or energy is made available. Future availability is also maintained to provide information for production scheduling.

Production resource management includes managing information about changes in material conditions, such as when material lot/sub lot or energy source is found to have changed its specification. Changes are often indicated from QA test results.

EXAMPLE:

A material lot may change from “dry” to “wet”, a pH may change from 7.0 to 7.1, or available electrical power may change from 300 kW to 280 kW.

6.6 Detailed production scheduling

6.6.1 Activity definition

Detailed production scheduling shall be defined as the collection of activities that take the production schedule and determine the optimal use of local resources to meet the production schedule requirements. This may include ordering the requests for minimal equipment setup or cleaning, merging requests for optimal use of equipment, and splitting requests when required because of batch sizes or limited production rates. Detailed production scheduling takes into account local situations and resource availability.

NOTE — Enterprise-level planning systems often do not have the detailed information required to schedule specific work centers, work center elements, or personnel.

6.6.2 Activity model

Figure 13 illustrates some of the interfaces to detailed production scheduling.

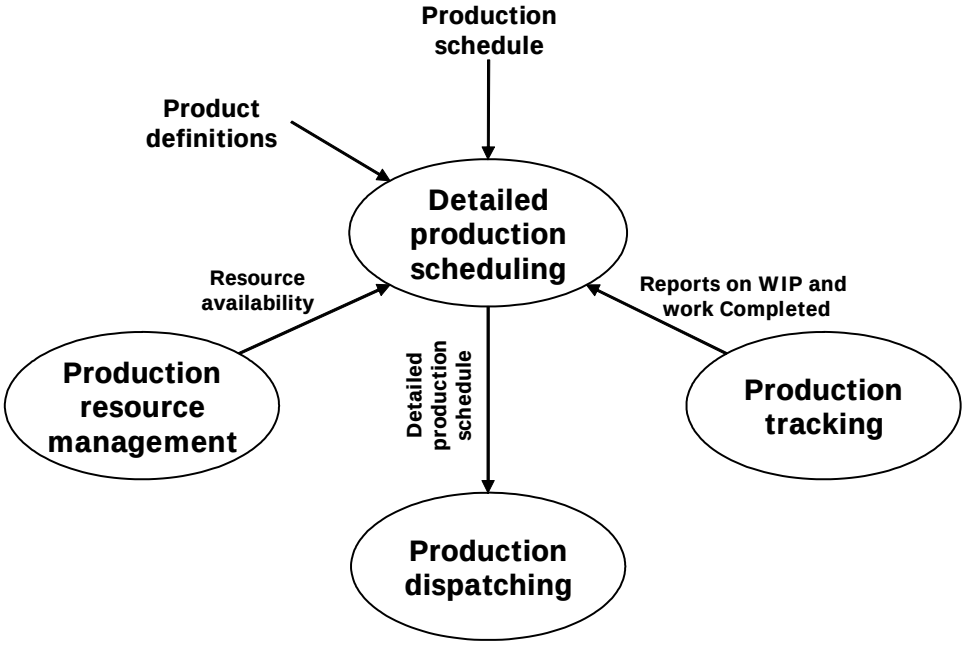

Figure 13 - Detailed production scheduling activity model interfaces

6.6.3 Tasks in detailed production scheduling

Detailed production scheduling tasks may include:

a) Creating and maintaining a detailed production schedule.

b) Comparing actual production to planned production.

c) Determining the committed capacity of each resource for use by the production resources management function.

d) Obtaining information from maintenance operations management, quality operations management, and inventory operations management.

e) Executing what-if simulations. This task may include activities such as: calculating production lead time or final completion time for each production request provided by Level 4 functions; determining bottleneck resources for each period; and ensuring the time of future production availability for particular production.

EXAMPLE:

Capable to promise inquiry from a Level 4 system.

A detailed production schedule is created from a Level 4 production schedule. A detailed production schedule is based upon the requirements defined in the Level 4 schedule, the product definition and the resource capability. It accounts for constraints and availability and uses information from production tracking activities to account for actual work in progress. It may be provided either on demand or on a defined schedule. It may be recalculated based on unanticipated events such as equipment outages, manpower changes and/or raw material availability changes. It may be provided to people, to applications, or to other activities.

EXAMPLE:

Detailed production scheduling may enforce a scheduling strategy such as forward (push) or backward (pull) selection, priority assignment for each work order, application of specific constraints for the plant, time buffer allocation on bottleneck resource, and so forth.

6.6.4 Finite capacity scheduling

Detailed production scheduling may take the form of finite capacity scheduling. Finite capacity scheduling is a scheduling methodology where work is scheduled for production resources, such that no production requirement exceeds the capacity available to the production resource.

Finite capacity scheduling is typically accomplished locally, at the site or area, because of the amount of detailed local information required to generate a valid detailed production schedule. Information on current and future resource capability and capacity, as defined in Part 1, is required for detailed production scheduling and is provided by production resource management activities.

6.6.5 Splitting and merging production schedules

Figure 14 illustrates how production schedules can be split or merged prior to being sent to dispatching. The left side of Figure 14 illustrates how a single schedule is split into multiple detailed production schedules, and the right side illustrates how multiple production schedules from multiple sources can be merged into a detailed schedule.

EXAMPLE:

Multiple detailed production schedules may be generated from a weekly production schedule, one schedule for each day of production.

EXAMPLE:

A single detailed production schedule may be created that combines multiple production schedule elements in order to reduce setup time and optimize production.

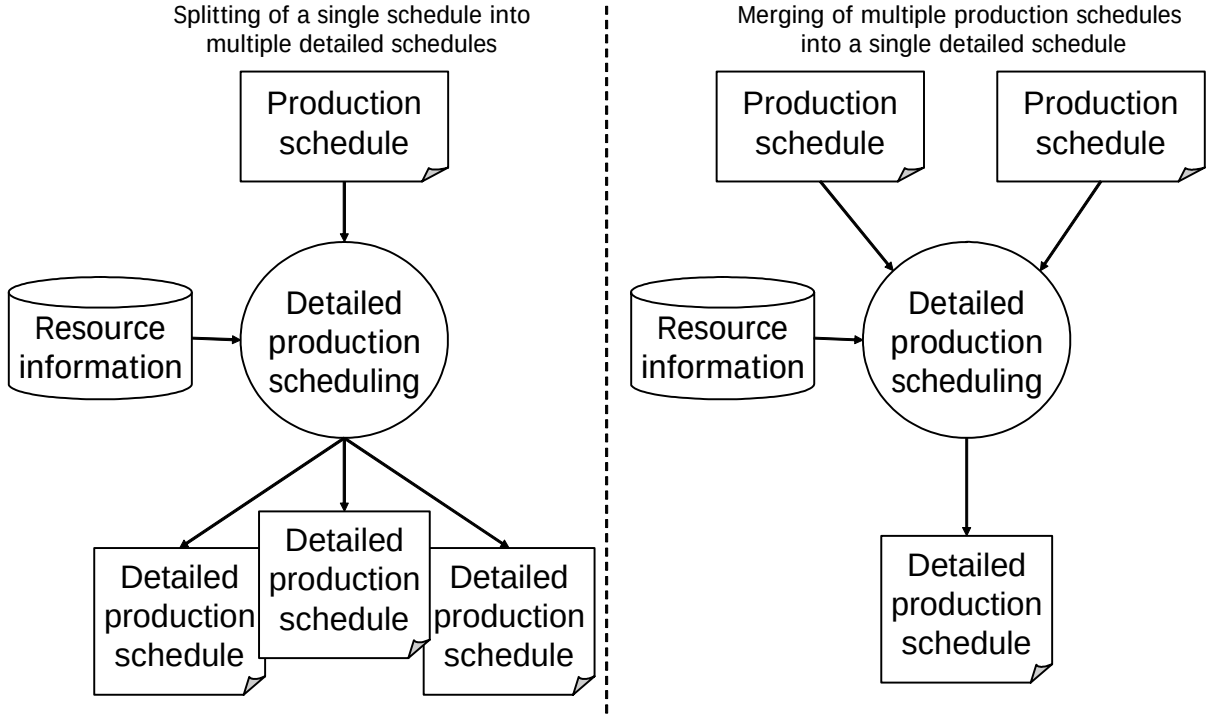

Figure 14 - Splitting and merging production schedules to detailed production schedules

One common function of detailed production scheduling involves merging production requests into single elements of work for purposes of reducing startup and switchover times. This is common in scheduling for dispensing operations, where the same material is dispensed for multiple production requests at the same time in order to minimize setup and cleaning time. This may also involve the definition of a detailed production schedule so that related products may be produced in series, reducing or eliminating product changeover delays. Another optimization may be the optimization of batch sizes by the merging of multiple requests for the same product.

NOTE — A benefit of optimizing a detailed production schedule for selected objective functions may be the solving of conflicts or reducing penalty of constraint violations by better sequencing and assignment of production work orders.

6.6.6 Detailed production schedule

A detailed production schedule shall be defined as a collection of production work orders and their sequencing involved in production of one or more products, at the level of detail required for manufacturing. Detailed production scheduling may define the generation of intermediate materials that are not included as part of higher level scheduling definitions. A detailed production schedule ties physical and/or chemical work order elements to specific production equipment or classes of production equipment, with specific starting times or starting events. This is typically accomplished through production work orders. A detailed production schedule may reference specific personnel, or classes of personnel.

A detailed production schedule defines the assignment of resources to production tasks in greater detail than the “business oriented” process segments. A product or process segment, defined in Part 1 of this standard, may be realized through the execution of one or more work order elements. For example the detailed production schedule may define the various sub-levels of “operations oriented” work order elements that may be required.

The detailed production schedule also contains the information required by the production tracking activity to correlate actual production with the requested production.

6.6.7 Sample detailed production schedule

Figure 15 illustrates an example detailed production schedule for equipment represented in a Gantt chart format. The hashed rectangles in the figure represent production work orders and each different hash pattern represents a different production job.

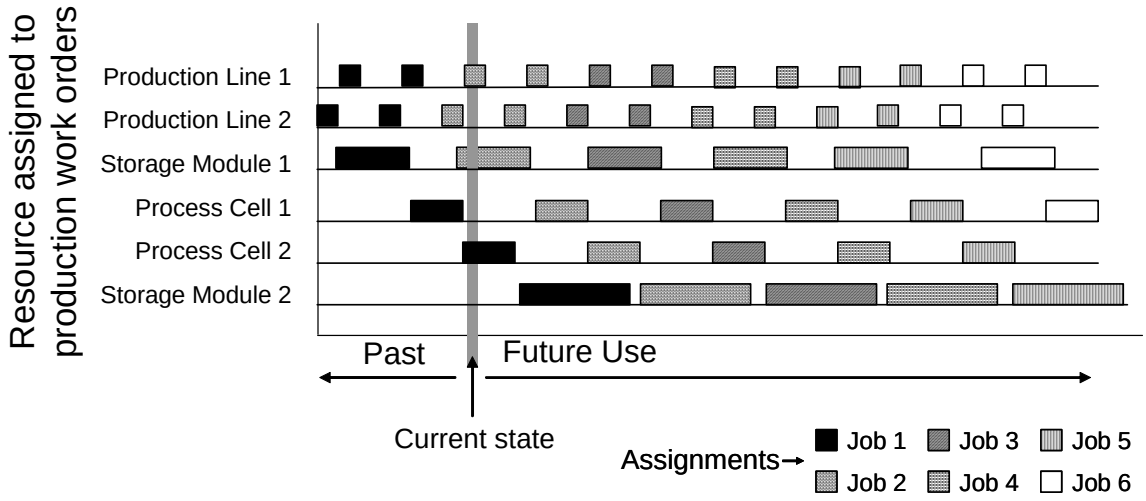

Figure 15 - Detailed production schedule

6.7 Production dispatching

6.7.1 Activity definition

Production dispatching shall be defined as the collection of activities that manage the flow of production by dispatching production to equipment and personnel. This may involve:

a) Scheduling batches to start in a batch control system.

b) Scheduling production runs to start in production lines.

c) Specifying standard operating condition targets in production units.

d) Sending work orders to work centers.

e) Issuing work orders for manual operations.

EXAMPLE:

Dispatched work may be machine setup, grade change switchovers, equipment cleaning, run rate setup, or production flow setup.

6.7.2 Activity model

Figure 16 illustrates some of the interfaces to production dispatching.

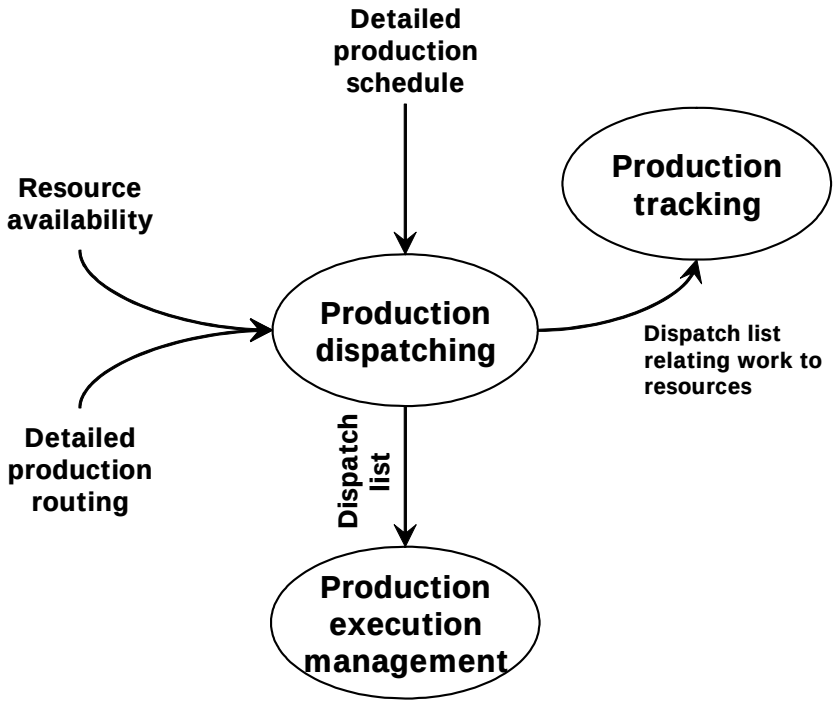

Figure 16 – Production dispatching activity model interfaces

6.7.3 Tasks in production dispatching

Production dispatching tasks may include:

a) Issuing production work orders as identified by the schedule.

b) Assigning local resources to production, where these are not identified as part of the detailed production schedule.

c) Releasing local resources to start work orders.

d) Handling conditions not anticipated in the detailed production schedule. This may involve judgment in managing workflow and buffers. This information may have to be communicated to maintenance operations management, quality operations management, inventory operations management, and/or production resource management operations.

e) Maintaining status of work orders.

   EXAMPLE:

   Approved, fixed, in process, or canceled.

f) Ensuring that process constraints and ordering below the level of detail of the detailed schedule are met in production. This takes place after the schedule is created but before its elements are executed.

g) Informing detailed production scheduling when unanticipated events result in the inability to meet the schedule requirements.

h) Receiving information from quality operations management that indicates unanticipated conditions that may relate to scheduled events.

i) Receiving information from production resource management about unanticipated future resource availability that may relate to scheduled events.

j) Sending, or making available, the production dispatch list specifying the production activities to be performed.

6.7.4 Production dispatch list

A production dispatch list shall be defined as the set of production work orders ready to be executed. Production work orders define the specific work order elements to be performed at work centers and work units. Each item in the production dispatch list shall include the time or event to start the activity as specified in the detailed production schedule.

A production dispatch list may take multiple forms, including batch lists (ref: ANSI/ISA-88.00.02-2001, see Clause 2), operating directives, line schedules, setup times, or process flow specifications. The production dispatch list correlates equipment to detailed production elements and makes this information available to production data collection and production tracking activities.

6.7.5 Sample production dispatch list and production work orders

Figure 17 illustrates an example of a detailed production schedule and production dispatch list represented in a GANTT chart format. Each of the hatched rectangles in the figure represents a production work order and each different hash pattern represents a different production job. A production dispatch list is represented as a set of production work orders for a specific period of time. A production work order is made up of lower-level elements. The collection of production work orders for a specific resource is represented as a detailed resource schedule.

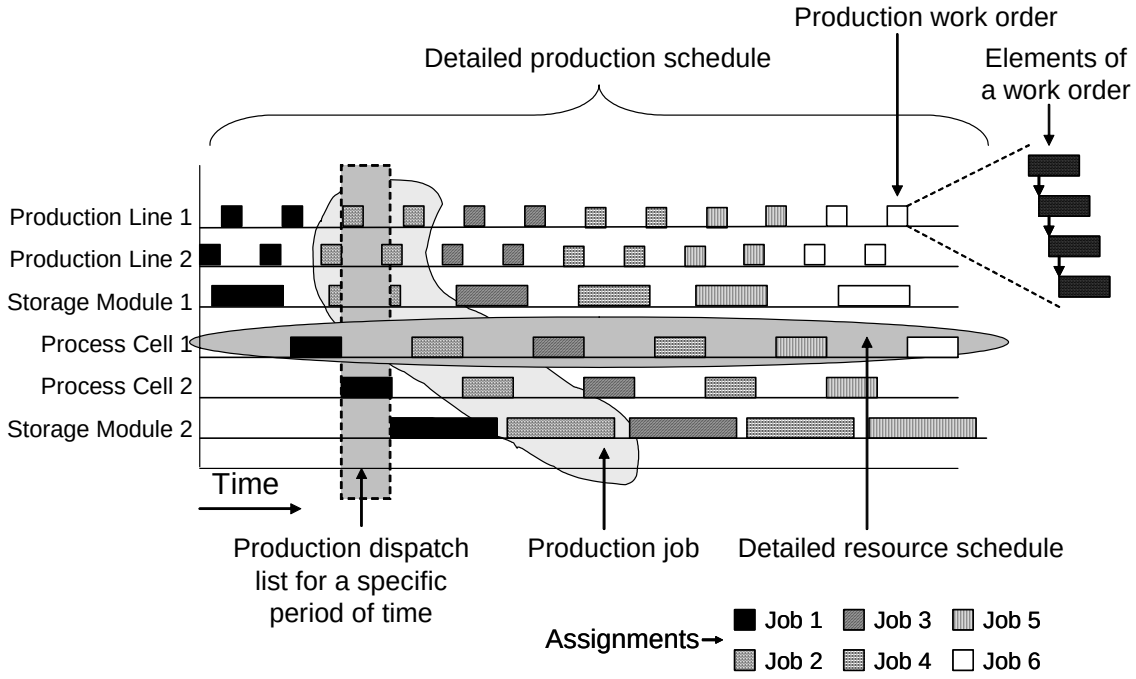

Figure 17 - Sample production dispatch list

6.7.6 Assigning work

Production dispatching may include:

a) Assigning material to be used in a production work order.

b) Assigning equipment to be used in a production work order.

c) Assigning personnel to execute a production work order.

d) Assigning storage and other resources to be used in a production work order.

This activity includes the ability to control the amount of work in process through buffer management and management of rework and salvage processes, using feedback from production execution management. The activity includes the ability to cancel or reduce assigned work.

Figure 18 illustrates an example of how the work dispatching activity may set up work in a mixed facility, with continuous, batch, and discrete production segments. In this example, production dispatch lists would specify setup for a continuous premix operation, including any initial charging. The production dispatch list would then define the sequence of batches for primary production, and would also define the setup of the back-end discrete packaging system.

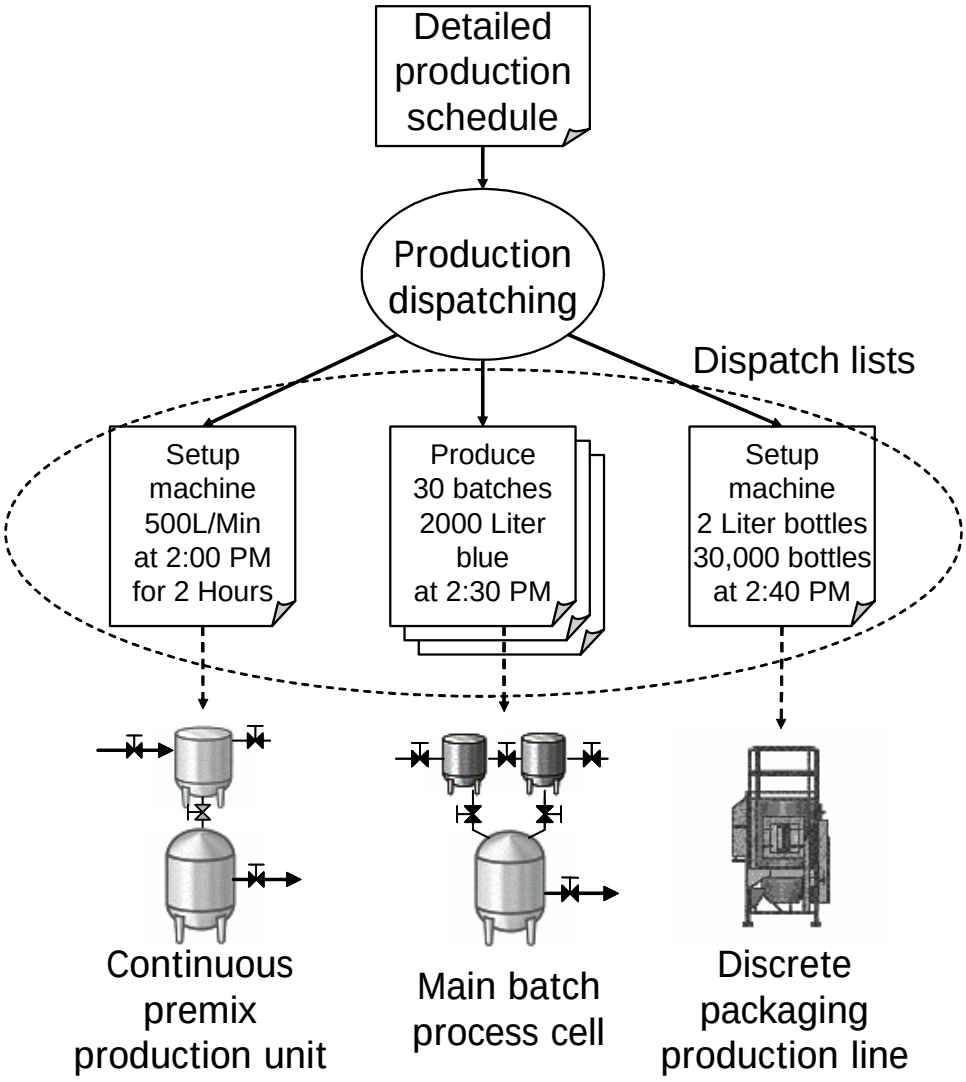

Figure 18 - Work dispatching for mixed process facility

6.8 Production execution management

6.8.1 Activity definition

Production execution management shall be defined as the collection of activities that direct the performance of work, as specified by the contents of the production dispatch list elements. The production execution management activity includes selecting, starting and moving those units of work (for example lots, sublots, or batches) through the appropriate sequence of operations to physically produce the product. The actual work (manual or automatic) is part of the Level 2 functions.

NOTE — The definition of a sequence may take the form of a detailed production route specific for a particular produced item. Production execution transacts the individual units of work from one operation or step to the next, collecting and accounting for such things as actual materials consumed, labor hours used, yields and scrap at each step or operation. This provides visibility into the status and location of each lot or unit of work or production order at any moment in the plant, and offers a way to provide external customers with visibility into the status of an order in the plant.

Production execution management may use information from previous production runs, captured in production tracking, in order to perform local optimizations and increase efficiencies.

6.8.2 Activity model

Figure 19 illustrates some of the interfaces to production execution management.

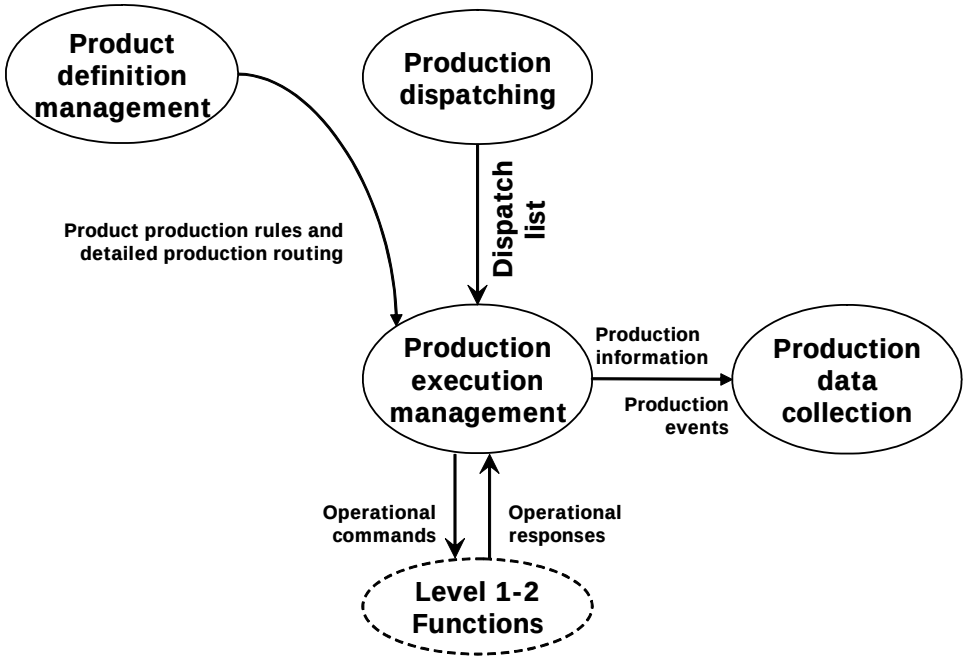

Figure 19 - Production execution management activity model interfaces

6.8.3 Tasks in production execution management

The production execution management activities include the coordination of the manual and automated processes in a site or area. This often requires well-defined communication channels to automated control equipment.

Production execution management tasks may include:

a) Directing the performance of work and initiating Level 2 activities.

b) Ensuring that the correct resources (equipment, materials, and personnel) are used in production.

c) Confirming that the work is performed according to the accepted quality standards. This may involve receiving information from quality activities.

d) Ensuring that resources are valid for the assigned tasks.

EXAMPLE:

This may be ensuring that equipment sterilization status is correct for the assigned operation (e.g., a vessel is “Clean” before use in production).

EXAMPLE:

Equipment certifications are current, personnel qualifications are up to date, and materials are released for use.

e) Assigning resources under local run time control.

EXAMPLE:

The assignment of units to a batch, if the detailed production schedule does not define unit allocation.

f) Informing other activities when unanticipated events result in the inability to meet the work requirements.

g) Receiving information from production resource management about unanticipated future resource availability.

h) Providing production information and events on production execution management, such as timing, yields, labor and material used, start of runs, and completion of runs.

6.9 Production data collection

6.9.1 Activity definition

Production data collection shall be defined as the collection of activities that gather, compile and manage production data for specific work processes or specific production requests. Manufacturing control systems generally deal with process information such as quantities (weight, units, etc.) and associated properties (rates, temperatures, etc.) and with equipment information such as controller, sensor, and actuator statuses. The managed data may include sensor readings, equipment states, event data, operator-entered data, transaction data, operator actions, messages, calculation results from models, and other data of importance in the making of a product. The data collection is inherently time or event based, with time or event data added to give context to the collected information.

6.9.2 Activity model

Figure 20 illustrates some of the interfaces to production data collection.

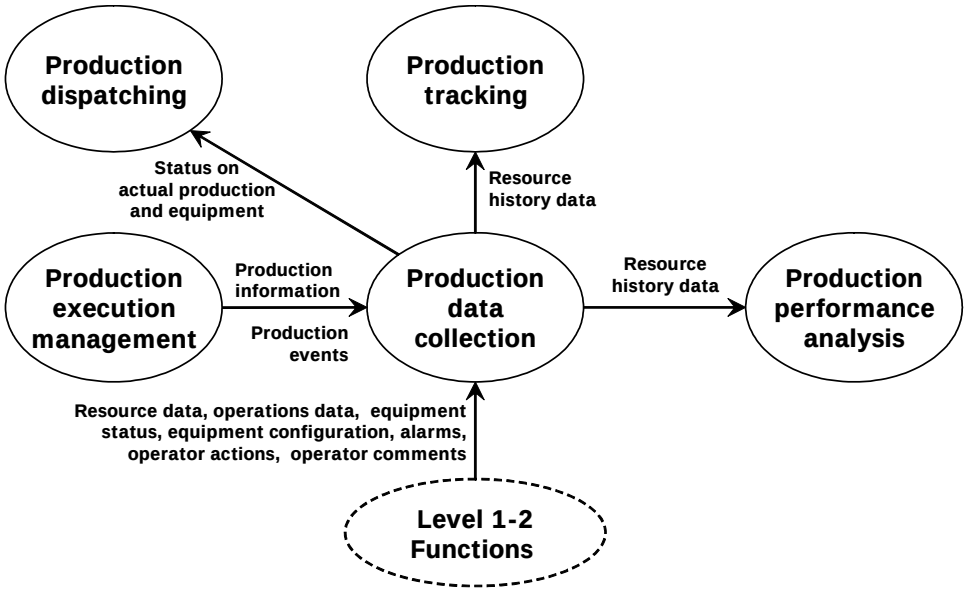

Figure 20 - Production data collection activity model interfaces

6.9.3 Tasks in production data collection

Production data collection tasks may include:

a) Collecting, retrieving, and archiving information related to the execution of production requests, equipment usage, including information entered by production personnel.

EXAMPLE:

This could include the following:

- Process data.
- Equipment status data.
- Lot and sublot location and amount data collection.
- Operations logs (plant entries and comments).

b) Providing interfaces to the basic process or manufacturing line control system, laboratory information management systems, and production management systems for automatic collection of information.

c) Providing reports on production data.

d) Maintaining information for local process and production analysis and for reporting to higher-level logistics systems.

e) Maintaining information for product tracking to enable tracking and tracing capability such as tracing products to specific material lots, equipment, and/or operators.

f) Providing compliance monitoring and alarm management functionality (event logging and sequence of events).

g) Providing collected product quality information for comparison against specifications.

6.10 Production tracking

6.10.1 Activity definition

Production tracking shall be defined as the collection of activities that prepare the production response for Level 4. This includes summarizing and reporting information about personnel and equipment actually used to produce product, material consumed, material produced, and other relevant production data such as costs and performance analysis results. Production tracking also provides information to detailed production scheduling and Level 4 scheduling activities so schedules can be updated based on current conditions.

6.10.2 Activity model

Figure 21 illustrates some of the interfaces to production tracking.

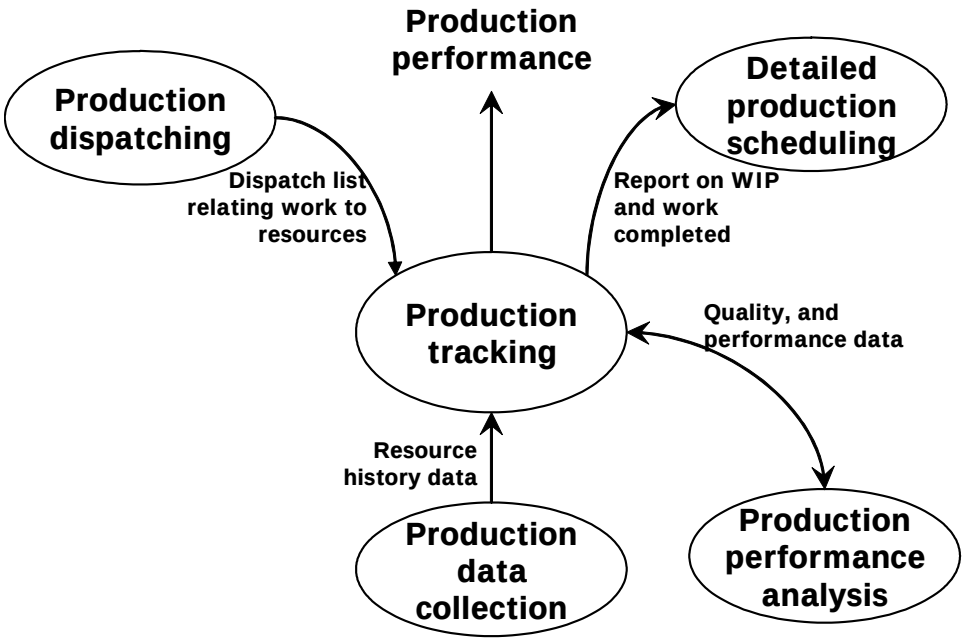

Figure 21 - Production tracking activity model interfaces

6.10.3 Tasks in production tracking

Production tracking tasks may include:

a) Following the movement of material through a plant by maintaining a description of what was in each vessel at specific times and tracing the path of all materials within the production domain.

b) Recording the start and end of movements and collecting updates to lot and sublot quantities and locations as they occur.

c) Receiving information from production data collection and production analysis; for example, information on materials consumed in the production of a lot (an important part of the product tracking and tracing) and information on plant environmental conditions during the production of the lot.

d) Translating process events, including production and movement events, into product information.

e) Providing information for tracking (recording) and tracing (analysis).

f) Generating production responses and production performance information. The information may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities.

g) Generating records related to the production process. This may include records required for regulatory or quality management purposes.

6.10.4 Merging and splitting production information

Production tracking may involve compiling production data into business information on actual production including in-work inventory, raw material usage, and energy usage. Production tracking may require combining resource history data from multiple batches or runs into a single production performance report. Alternately, it may require splitting information about a single batch or run into multiple production performance reports. These are illustrated in Figure 22.

EXAMPLE:

Production history from multiple production lines used in completion of a single order may be combined to produce a single production response for the order.

EXAMPLE:

Information from a single production run may be split into multiple production performance reports, one report for each shift used in the production.

EXAMPLE:

A portion of a product run may be sent to an outside entity to perform a portion of the lifecycle of completing the product. In this case the product would share history until it leaves the internal manufacturing processes and upon return to the normal internal manufacturing processes, the same product would have a slightly different history than its peer product.

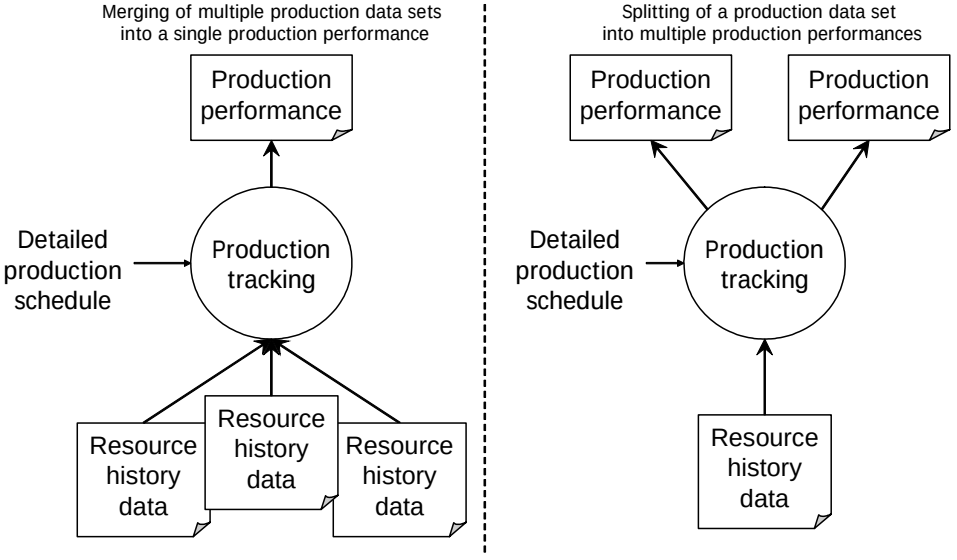

Figure 22 - Merging and splitting production tracking information

6.11 Production performance analysis

6.11.1 Activity definition

Production performance analysis shall be defined as the collection of activities that analyze and report performance information to business systems. This would include analysis of information of production unit cycle times, resource utilization, equipment utilization, equipment performance, procedure efficiencies, and production variability.

Relationships between these analyses and others may also be utilized to develop KPI reports. This information may be used to optimize production and the use of resources. Such information may be provided on a scheduled basis, it may be provided at the end of production runs or batches, or it may be provided on demand.

The process of production performance analysis is ongoing. Once an optimization has occurred and a constraint has been exploited, other system constraints may arise. Additionally, changing market conditions and product mixes may change the optimization criteria and system constraints. In a changing environment, production performance analysis activities regularly re-examine throughput and policies under current and expected conditions in order to maximize system throughput.

6.11.2 Activity model

Figure 23 illustrates some of the interfaces to production performance analysis.

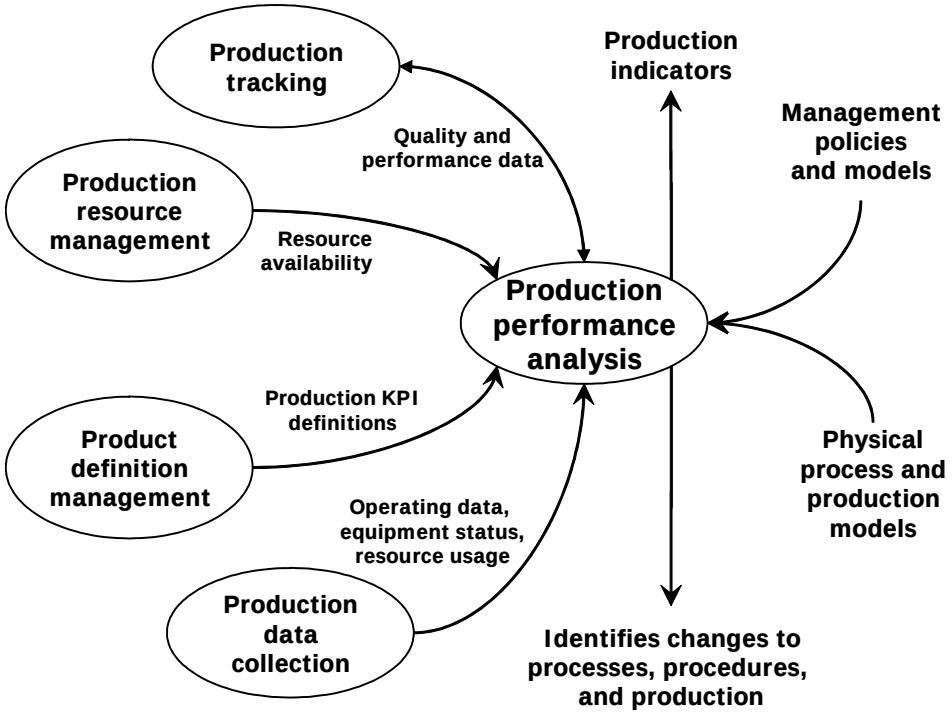

Figure 23 - Production performance analysis activity model interfaces

6.11.3 Tasks in production performance analysis

Production performance analysis tasks may include:

a) Producing reports of performance and cost.

b) Evaluating constraints to capacity and quality.

c) Performing performance tests where necessary to determine capacity.

d) Comparing different production lines and creating average or target runs.

e) Comparing and contrasting one run against another.

f) Comparing production runs to identify “golden” runs.

NOTE — “Golden” runs are runs that are the best run ever produced, where best may be the highest quality, or lowest cost, or any other criteria.

g) Determining why the “golden” runs are exceptional.

h) Comparing runs against defined “golden” runs.

i) Providing changes to process and procedures based on the results of the analysis for continuing process improvements.

j) Predicting the results of a production run, based on the current and past performance. This may include the generation of production indicators.

k) Correlating the product segments with process conditions at the time of production.

EXAMPLE:

The record of work order elements, product segments, and process segments, and their times, quantities, and conditions of production could be searched and manipulated to answer the question of the form, “What activity happened, how it happened (what setpoints were used, which procedure, etc.), where it happened, when it happened, and who performed it?.”

NOTE — In addition to this main question, questions related to resource tracking such as, "What was where, when, and why?" for material tracking may be answered. This ability to track down product and minimize the impact from contamination can be the critical analysis tool needed to ensure future orders from customers.

6.11.4 Resource traceability analysis

Resource traceability analysis shall be defined as the collection of activities that trace the history of all resources (material, equipment, and personnel) in terms of the process actions and events that dealt with the resources in production.

Resource traceability analysis may include analysis on:

— Materials produced, consumed, stored, and moved.

— Equipment used in production, testing, and storage.

— Personnel involved in the production and storage of material, and operation of equipment.

NOTE 1 — As a batch or lot moves through the production facility, on-the-spot decisions are made all along the way regarding raw materials locations to consume from, rework actions required based on analytical results and other similar decisions. When the unit of product moves into finished goods or out to end customers, it may be important to be able to retrace the parent supplier lots from which its raw materials were consumed, which specific personnel or equipment units were involved in the process, whether the unit of work was sent back for rework more than once, or any of a large number of similar questions.

NOTE 2 — The record of a lot’s recent ancestry might be attached as part of the production response back to the enterprise system, or could be of considerable value at the manufacturing operations level for implementing continuous improvement efforts.

NOTE 3 — This clause deals with resource traceability from a production perspective and may need to be combined with equivalent information and functions in maintenance operations management, quality operations management, and inventory operations management.

Resource traceability has two components, tracking and tracing.

1. Tracking is the process of following and recording the movements and change of resources and recording all inputs to the resource through all steps and agents.

2. Tracing is the process that determines a resource’s history of use from any point, forward or backward, using tracking information.

NOTE 4 — For example, material tracing may be characterized as:

a) Backward material tracing — which shows the upstream history of the material as inputs to manufacturing processes and the equipment used to transfer the material.

b) Forward material tracing — which shows the downstream history of the material as inputs for manufacturing processes and the equipment used to transfer the material.

6.11.5 Product analysis

Testing for product quality is one of the most important manufacturing operations activities. The testing may be in-line, at-line, or off-line. Product analysis also includes the off-line analysis typically performed in laboratories and the management of quality test procedures. The activities associated with product analysis are defined in Clause 8.1.5.

Product analysis (quality assurance) activities include display of in-process information, such as SPC (Statistical Process Control) or SQC (Statistical Quality Control) data. Quality management handles the quality test procedures and often maintains quality test results.

6.11.6 Process analysis

Process analysis provides feedback about specific manufacturing processes across multiple production runs or batches. This information is used to optimize or modify specific production processes. The activity includes analysis of bad production runs to determine the root cause, and analysis of exceptional quality production runs to determine optimal running conditions. Process analysis often includes SPC/SQC analysis and process modeling, and uses information collected from the multiple activities that measure operating parameters.

6.11.7 Production performance simulation

Simulation is often used to model how a material flows through the plant and to evaluate how the process responds to changes. It may model changes in the process, changes in the production routing, or changes to the manufacturing procedures. It may also be used to predict the material properties based on the current operating process conditions. Simulation can be used during the life cycle of the plant to track performance, to track change effects, and for operator training.

NOTE — Simulation can show how to provide the following types of benefits to production:

— Adding additional capacity without significant addition of new equipment, machinery, or labor;

— Increasing the efficiency and effectiveness of an existing system;

— Eliminating bottlenecks, using existing assets better;

— Evaluating possibilities for quality and throughput improvements or cost reductions;

— Improving the ability to meet deadlines, customer commitment, and changing customer requirements;

— Educate operators without putting personnel, the environment, physical systems, or production at risk.

6.11.8 Production indicators and KPIs

In addition to the formally defined production performance data model defined in the Part 1 and Part 2 standards, there is additional information about production that provides summaries of past performance, indications of future performance, or indicators of potential future problems. Collectively, this information is defined as "production indicators." One of the activities within production performance analysis is the generation of production indicators. This information may be used internally within manufacturing operations for improvements and optimization. If there is a receiving business process that requires the information, it may also be sent to higher-level business processes for further analysis and decisions.

Production indicators can be as simple as values of process tags used as inputs to complex process models. There is a core set of values related to production output, but there can be a significant variation in the core set based on the vertical industry. Production indicators are often combined at Level 4 with financial information, or at Level 3 using Level 4 financial information to provide cost-based indicators.

EXAMPLE:

Typically KPIs are associated with specific business processes. Examples of Production Indicators include (used with permission from APQC; © APQC 2005*, www.apqc.org*):

- Actual production rate as a percentage of the maximum capable production rate
- Actual versus planned volume
- Average machine availability rate or machine uptime
- First product, first pass quality yield
- Hours lost due to equipment downtime
- Major component first-pass yield
- Manufacturing cycle time for a typical product
- Number of process changes per operation due to errors
- Percentage error in yield projections
- Percentage increase in output per employee
- Percentage of assembly steps automated
- Percentage of lots or jobs expedited by bumping other lots or jobs from schedule
- Percentage of operators with expired certifications
- Percentage of tools that fail certification
- Percentage reduction in component lot sizes
- Percentage reduction in manufacturing cycle time
- Percentage unplanned overtime
- Production and test equipment set-up time
- Production schedules met (percentage of time)
- Productivity: units per labor hour
- Reject or return rate on finished products (ppm-parts per million)
- Reject-rate reduction
- Rework and repair hours compared to direct manufacturing hours
- Rework and repair labor cost compared to total manufacturing labor cost
- Scrap and rework as a percentage of sales
- Scrap and rework percentage reduction
- Standard order-to-shipment lead time for major products
- Time line is down due to sub-assembly shortage
- Time required to incorporate engineering changes
- Units produced per square foot or meter of manufacturing and storage space
- Warranty effort reduction
- Warranty repair costs as a percent of sales
- Yield improvement

6.11.9 Performance management

Performance management shall be defined as the collection of activities that systematically capture, manage, and present performance information in a consistent framework. This includes utilizing corrective actions to affect operational improvement.

There is a business value to aligning lower-level manufacturing indicators with key business objectives. Some typical functions of performance management solutions are the following:

— Monitoring to enable visibility of KPIs;

— Ability to utilize KPI information in a model;

— Root cause analysis;

— Prediction of future KPI values;

— Capability to enact control based on KPI values.

One of the main activities in performance management information is transforming the large volume of raw data into actionable information. A hierarchy model is typically used to analyze performance data in manufacturing, and it may align with the equipment model.

EXAMPLE:

This could be the ability to analyze all inventory by product families down to the individual product stock-keeping unit.

EXAMPLE:

A simple model could be a summation of all subsidiary node values of an indicator.

Performance indicators that are not visible significantly decrease the value of performance management. This can be compared with reports that have thousands of values on a single page. There can be an implied ranking to KPIs where those with greater impact to the enterprise have greater visibility.

EXAMPLE:

An example of a visibility metaphor is the use of a traffic light indicating the status of an indicator. The green light indicates that the indicator is within specification. Yellow and red lights indicate an indicator has exceeded acceptable ranges. No light represents a lack of data or that the data is of poor quality. A single report may be made up of tens or hundreds of indicators allowing a quick survey if large amounts of information.

Root cause analysis is the determination of the key contributors to an indicator's value. Often an indicator's value may be caused by a hidden relationship to other information. The ultimate goal of root cause analysis is to expose the relationship so that corrective action can be taken on the underlying problem.

EXAMPLE:

Performance management activities may be cross functional and may look at the raw information used in the analysis. For example, this may include visibility into a lab system to see detailed results for recent lots. Another example could be visibility into production to see the current active constraints in the process control.

Prediction of future KPI values is an important aspect of performance management. The traditional implementation of this prediction is in the plant plan/schedule. The plan/schedule contains information that shows future asset activity and this can be rolled up into KPIs. Another implementation of predictive indicators is to apply predictive statistics to current KPIs and estimate future values.

EXAMPLE:

An example might be to take the historical mean time between failure values and develop a trend to predict the next failure for a piece of equipment.

Performance management includes the ability to identify and initiate an appropriate action based on an out-of-specification indicator.

EXAMPLE:

A change of a control setpoint could be based on an online SPC high alarm for a key process or derived parameter.

Performance management has aspects that permeate throughout the activity model. Production, maintenance, quality, and inventory operations management have critical metrics that are important not only to that function, but are used across other functions.

7 Maintenance operations management

7.1 General activities in maintenance operations management

Maintenance operations management shall be defined as the collection of activities which coordinate, direct, and track the functions that maintain the equipment, tools and related assets to ensure their availability for manufacturing and ensure scheduling for reactive, periodic, preventive, or proactive maintenance. Maintenance operations management supports four main categories of maintenance:

a) Providing maintenance responses to equipment problems

NOTE — In some industries this is known as corrective maintenance or reactive maintenance response.

b) Scheduling and performing maintenance on a periodic cycle based on time or cycles

NOTE — In some industries this is known as preventive maintenance.

c) Providing condition-based maintenance derived from information obtained from the equipment or inferred about the equipment

NOTE — In some industries this is known as condition-based maintenance.

NOTE — This includes predictive maintenance based on a prognosis of expected future failure.

d) Optimizing resource operating performance and efficiencies

NOTE — In some industries this could also be considered as part of production and process analysis.

NOTE — This includes minor changes in production or support equipment. These minor changes may often consume a significant fraction of maintenance resources.

Maintenance operations management may include:

e) Providing corrective, preventive, and condition-based maintenance

f) Providing equipment monitoring activities to anticipate failure, including equipment self-check and diagnostic activities

g) Developing maintenance cost and performance reports

h) Coordinating and monitoring contracted work

i) Supervising requested maintenance

j) Reporting on performed maintenance, including spare parts used, maintenance labor, and maintenance costs

k) Coordinating planned work with operators and plant supervision

l) Making performance verifications of production equipment

m) Assisting with product changeover needs that involve equipment changes

n) Monitoring and updating maintenance history files

7.2 Maintenance operations management activity model

The maintenance operations management model illustrated by the shaded area in Figure 1 is expanded to a more detailed activity model of maintenance operations, shown in Figure 24, using the generic activity model shown in Figure 6. This maintenance activity model identifies the main maintenance tasks and some of the information exchanged between these activities, but not how the activities are to be performed in a specific organizational structure. Companies differ in the organization of maintenance activity roles and the assignment of these roles to personnel or system resources.

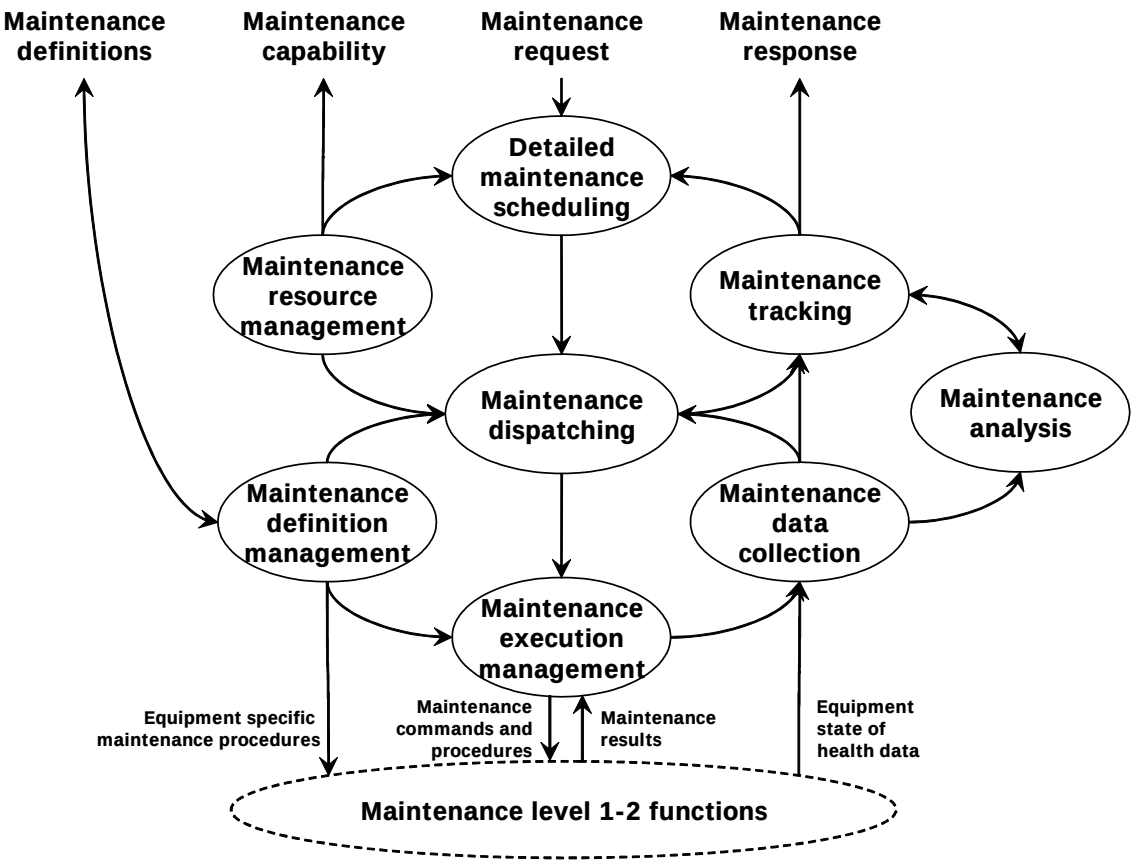

Figure 24 - Activity model of maintenance operations management

The ovals in the maintenance operations model indicate collections of activities, identified as the main activities. Lines with arrowheads indicate an important information flow between the activities. Not all information flows are depicted in the maintenance operations diagram. In any specific implementation, information from any activity may be needed by any other activity. Figure 24 only illustrates some major information flows between activities.

7.3 Information exchanged in maintenance operations management

7.3.1 Maintenance information

Maintenance requests, maintenance work orders, and maintenance responses, as defined in Part 1 and Part 2, do not always cross the boundary between Level 3 and Level 4 systems. Maintenance requests, maintenance work orders, and maintenance responses are often generated internally within manufacturing operations. Maintenance requests and maintenance responses may be exchanged individually or as sets.

Maintenance definitions and maintenance capability definitions also do not always cross the boundary between Level 3 and Level 4 systems. Maintenance definitions are often maintained locally for local equipment. Maintenance capability definitions may be used by local management for maintenance resource planning and preventive maintenance management.

7.3.2 Maintenance definitions

Maintenance definitions shall be defined as the documentation sets for the manufacturing assets under maintenance. These include equipment and system drawings (with maintenance additions and deletions),

engineering documentation, specifications, vendors' manuals, standard operating procedures for repair and servicing, maintenance instructions, and equipment diagnostic and prognostic procedures.

Maintenance definitions include the information used to instruct maintenance personnel on which activities are required to perform the specified maintenance activity, how to perform those activities, how long they typically take, and the resources required for each subactivity--not only in terms of special tools and jigs or test equipment, but also the required qualifications for personnel.

Maintenance definitions also include the definition of the key performance indicators for maintenance.

7.3.3 Maintenance capability

Maintenance capability shall be defined as the collection of the expected future available, committed, and unattainable capability of resources used in maintenance activities. The maintenance capability includes the capacity of the resources. Maintenance capability is based on the capability in:

a) Personnel – Typically based on qualification, training, experience, and discipline (such as system, mechanical, and facility). May also be based on device or equipment-specific proficiencies.

b) Equipment – Such as calibration equipment, transport equipment, and special tools.

c) Material – Such as maintenance-consumable materials and spare parts.

7.3.4 Maintenance request

Maintenance requests shall be defined as requests for maintenance services. Maintenance requests may be for corrective, preventive, proactive, and condition-based maintenance. Maintenance requests may be generated from Level 3, Level 4, or lower-level activities, based on the business and operations processes in place. Intelligent instruments and controllers at Level 1 and control systems at Level 2 may automatically generate condition-based requests for maintenance services. See Part 1 and Part 2 for definitions of maintenance requests and attributes.

In addition, there may be requests for "improvement" services, production changeover, or assistance in production performance problems. This often requires significant coordination with production and process analysis activities to perform tests and implement improvements or changes.

7.3.5 Maintenance response

Maintenance responses shall be defined as the documented information on the corrective or improving action taken as specified in the maintenance request. See Part 1 and Part 2 for definitions of maintenance responses and attributes.

7.3.6 Equipment-specific maintenance procedures

Equipment-specific maintenance procedures shall be defined as the specific instructions for equipment that are sent to Level 2 based on the assigned specific tasks. The maintenance procedures may extend beyond the equipment to maintain the environmental conditions necessary for the processes.

EXAMPLE:

This may include programs that the equipment uses for diagnostic or prognostic purposes, where these are executed in Level 2 or Level 1 equipment, and target values used for determining preventive or predictive maintenance.

7.3.7 Maintenance commands and procedures

Maintenance commands and procedures shall be defined as request information sent to Level 2 needed to perform specific maintenance tasks. The commands may include the specification of the work to be done and all relevant maintenance documentation. The commands may take the form of instructions to personnel or commands to equipment with relevant maintenance information.

7.3.8 Maintenance results

Maintenance results shall be defined as information received from Level 2 in response to maintenance commands and procedures. Maintenance results typically correspond to the completion of maintenance commands and procedures. This may include detailed data on maintenance activities collected during the course of the maintenance activity.

EXAMPLE:

A result may contain information such as, “pressure plate #43 was removed and replaced, set to 0.25 inches clearance gap, and put back into service.”

7.3.9 Equipment state of health data

Equipment state of health data shall be defined as information received as a result of monitoring Level 2 or Level 1 that indicates the health of the equipment. Data can represent past, current, or future conditions. Equipment state of health data are not typically associated with a maintenance command or procedure.

EXAMPLE:

This could include bearing temperature, vibration, and self-test status.

EXAMPLE:

This could be an indication of a valve’s full stroke travel time exceeding a specified limit.

NOTE — See ISO 13374-1:2003, Condition monitoring and diagnostics of machines — Data processing, communication and presentation – Part 1: General Guidelines, for examples of this type of data.

NOTE — This may include equipment self-check and diagnostic activities.

7.4 Maintenance definition management

Maintenance definition management shall be defined as the collection of activities that define, manage, and maintain the information and instructions necessary to complete maintenance tasks.

Maintenance definition management may include:

a) Managing documents such as maintenance instructions, vendor documentation, CAD drawings, database records, and analysis tools.

b) Deriving and managing a set of maintenance definitions.

c) Managing changes to maintenance definitions. This may include the ability to route changes through an appropriate approval process, management of definition versions, tracking of modifications, and security control of the definitions.

d) Providing maintenance definitions to other applications, equipment, personnel, or activities.

e) Managing the exchange of maintenance definition information with Level 4 functions, at the level of detail required by the business operations.

f) Optimizing maintenance definitions based on process and maintenance analysis.

g) Generating and maintaining maintenance definitions not related to production equipment, such as for maintenance of maintenance equipment and validation of maintenance equipment.

h) Managing the KPI definitions associated with maintenance.

i) Managing maintenance definitions related to safety and environmental procedures.

Maintenance definition management includes management of the distribution of maintenance definitions. Some maintenance definitions may exist for Level 2 and Level 1 equipment. When that is the case, downloads of this information shall be coordinated with other manufacturing operations management functions to reduce the impact on production. This information may be included as part of maintenance

commands and procedures when the download is initiated as part of a maintenance execution management activity.

NOTE — Maintenance definition management typically addresses all aspects of process safety management, including "replacement in kind" part substitutability, if allowed by a company and permitted within the process safety management regulations.

7.5 Maintenance resource management

Maintenance resource management shall be defined as the collection of activities that manage the information about the state of the resources used within the domain of control of maintenance. The managed resources may include maintenance equipment, maintenance tools, personnel (with skill sets), documentation, and material and energy used in maintenance.

The state of resources typically includes equipment health status, capability, location (if applicable), availability, and anticipated use.

Maintenance resource management may include:

a) Maintaining information about maintenance personnel, including qualification information, such as qualification status and qualification test results, as defined in the Part 1 and Part 2 personnel model.

b) Maintaining information about equipment used in maintenance and equipment capability tests, as defined in the Part 1 equipment model.

c) Maintaining information about maintenance supplies, defined as consumable materials, as described in the Part 1 material model.

d) Maintaining information about the health and state, assignment, and availability status of resources to be used and being used in all Level 3 maintenance activities.

e) Coordinating and monitoring contracted work.

f) Supervising requested maintenance.

EXAMPLE:

The information includes such elements as people, skills, skills management, equipment, tools, and repair-spares inventory.

The purpose of maintenance resource management is to safely increase the total production output of a plant at a reduced maintenance cost per unit of output. It achieves this by providing timely information for manufacturing operations personnel to make optimal decisions regarding process operations and equipment maintenance.

7.6 Detailed maintenance scheduling

Detailed maintenance scheduling shall be defined as the collection of activities that generate a detailed maintenance schedule. Tasks within detailed maintenance scheduling may include:

a) Reviewing maintenance requests.

b) Confirming or denying the maintenance request.

c) Determining the priority of the request and the level of effort and availability of all resources.

d) Scheduling the maintenance request to be performed within a detailed maintenance schedule as one or more maintenance work orders.

e) Coordinating planned work with operators and plant supervision.

A detailed maintenance schedule may be generated for each site or area, based on the required maintenance work orders and available resources (personnel, equipment, and materials). Detailed maintenance scheduling maintains the requirements and develops the necessary organization of maintenance work orders. Maintenance requests may originate from one or more higher-level functions, from other Level 3 activities, or even directly from intelligent equipment.

A summary of the detailed maintenance schedule is often generated for communication to the business planning and logistics system (Level 4).

EXAMPLE:

A motor failure, handled as a locally scheduled activity, may take the associated production line out of service and this lost capacity must be reported to a Level 4 scheduling system.

7.7 Maintenance dispatching

Maintenance dispatching shall be defined as the collection of activities that assign and send maintenance work orders to the appropriate maintenance resources as identified by the detailed maintenance schedule and maintenance definitions. Dispatching communicates the task to be performed and the resources to be used and may involve the dispatching of work to employees or contractors to perform the work.

Resources not assigned as part of the detailed maintenance schedule may be assigned by the maintenance dispatching activity.

7.8 Maintenance execution management

Maintenance execution management shall be defined as the collection of activities that direct the performance of maintenance work. Maintenance execution management may have the responsibility to:

a) Ensure that maintenance procedures and regulations are followed during maintenance activities.

b) Document the status and results of the work performed.

c) Inform maintenance dispatching and/or detailed maintenance scheduling when unanticipated events result in the inability to meet the work requirements.

d) Confirm that the work was performed according to the accepted quality standards. This may involve receiving information from quality operations that indicated an unanticipated condition.

e) Ensure that the correct resources are used in maintenance.

f) Verify that equipment and personnel certifications are valid for the assigned tasks.

g) Assist with product changeover needs that involve equipment changes.

7.9 Maintenance data collection

Maintenance data collection shall be defined as the set of activities that summarizes and reports on the information and events related to the disposition of the maintenance work order. Information may include current status, time required, time started, current time, time estimated to completion, actual time, resources used and additional information to present an entire maintenance history for the existing work order and earlier work orders.

7.10 Maintenance tracking

Maintenance tracking shall be defined as the collection of activities that manage the information about the utilization of resources to perform maintenance activities and the relative effectiveness of the results of the maintenance activity.

Maintenance tracking includes the activity of generating or updating records related to the maintained equipment condition and usability. This may include records required for regulatory or quality management purposes.

EXAMPLE:

An equipment condition may be dirty, cleaned, or sterile.

EXAMPLE:

An equipment usability may be “qualified for use” or “unqualified for use.”

Maintenance tracking includes the activity of tracking the state of the equipment used to perform the maintenance.

EXAMPLE:

Equipment used to perform maintenance could be handheld sensor calibration tools, voltmeters, and oscilloscopes.

7.11 Maintenance analysis

Maintenance analysis shall be defined as the collection of activities that examine the personnel, equipment, and material history to identify problem areas or areas for improvement.

Maintenance analysis functions may include identifying conditions such as:

— What equipment may fail if it does not receive maintenance intervention.

— What intervention should be taken and how soon.

— Where routine preventive maintenance activities can be reduced.

— Where efforts can be focused to improve return on assets (ROA) by eliminating costly or repetitive failures.

Maintenance analysis may also assist operations and production planning in identifying conditions such as:

— Should any adjustments be made to the process to prolong the life of critical plant assets.

— At what level can production continue without incurring an unacceptably high risk of process slowdown, downtime, quality problems, or safety shutdowns.

— What is the probability of successfully producing a specified amount of product in a period of time.

Maintenance analysis may also include resource traceability analysis, which traces the history of all resources in terms of the maintenance actions and events that dealt with the resources. This may include such information as:

— Which materials were used in maintenance activities.

— Which tools were used in maintenance activities, and which equipment was maintained.

— Which personnel were involved in maintenance activities.

— Developing maintenance cost and performance reports.

— Reporting on performed maintenance, including spare parts used, maintenance labor, and maintenance costs.

There is information about maintenance that provides summaries of past performance and indications of future performance or potential future problems. Collectively this information is defined as "maintenance indicators." One of the activities within analysis is the generation of maintenance indicators. This information may be used internally within manufacturing operations for improvements and optimization, or if there is a receiving business process that requires the information, it may be sent to higher-level business processes for further analysis and decisions.

NOTE — Maintenance indicators may be combined at Level 4 with financial information, or at Level 3 using Level 4 financial information to provide cost-based indicators. Often maintenance operations management recognizes two categories for

accounting purposes: expense and capital. These are segregated for purposes of reporting, accounting, and asset management.

Expense is typically associated with repair, which is re-establishing the status quo of existing assets. This would include "replacement in kind" of assets that cannot be repaired in a cost-effective manner.

Capital is typically associated with improvement, which is adding asset value to the existing asset base. This would include adding a new asset or upgrading an existing asset with equipment of greater capability.

EXAMPLE:

Examples of maintenance indicators include (used with permission from APQC; © APQC 2005, *www.apqc.org*):

- Labor hours spent on preventive maintenance per area and/or per work center
- Maintenance cost as a percentage of equipment cost
- Maintenance cost per output unit
- Number of unscheduled maintenance calls per area and/or per work center
- Percentage of equipment maintained on schedule
- Unplanned machine downtime as a percentage of scheduled run time

8 Quality operations management

8.1 General activities in quality operations management

8.1.1 Quality operations management activities

Quality operations management shall be defined as the collection of activities which coordinate, direct, and track the functions that measure and report on quality. The broad scope of quality operations management includes both quality operations and the management of those operations in order to ensure the quality of intermediate and final products.

Quality operations management may include:

a) Testing and verifying the quality of materials (raw, final, and intermediate).

b) Measuring and reporting the capability of the equipment to meet quality goals.

c) Certifying product quality.

d) Setting standards for quality.

e) Setting standards for quality personnel certification and training.

f) Setting standards for control of quality.

Potentially relevant standards for quality operations management are defined in Annex C.

8.1.2 Quality operations scope

The following parts of Clause 8 focus only on quality test operations management activities.

NOTE — The model does not address the engineering and construction aspects of design of tests, defining of classification, setting of qualifications, or creation of specifications as related to quality.

Quality operations management activities not addressed in this clause include the setting and issuing of standards and methods from Level 4 activities to manufacturing and testing laboratories in accordance with requirements from technology, marketing, and customer services, such as:

a) Conducting periodic quality evaluations

b) Setting nonempirical standards for material quality

c) Setting nonempirical standards for product specifications

d) Setting nonempirical standards for production specifications

e) Setting nonempirical standards for personnel qualifications

f) Setting nonempirical classifications and certification processes for materials

g) Creating and reviewing nonempirical procedures and processes to ensure that quality is defined and maintained

8.1.3 Quality test operations management

Quality test operations management is an integral part of quality operations management and the generic model can be applied to testing operations. Quality operations management activities may be required in any of the activities shown in Figure 1 to ensure that quality goals are met. There are other aspects of quality operations management not detailed in this Part 3 standard.

Quality operations management activities addressed in this clause include:

a) Raw materials evaluation:
   - Testing of incoming raw materials and approval for use if in accordance with set standards.
   - Collecting and maintaining quality control file for data for quality control analysis.
   - Testing of non-consumed materials used in the process, such as catalysts.

b) Evaluation of product:
   - Testing of intermediate and final product and report results to classification.
   - Collecting and maintaining quality control file for data for quality control analysis.
   - Checking of product data versus customer's requirements to assure adequate quality before shipment.
   - Using at-line process analytics to drive real-time release or disposition of products based on process data.

c) Testing of classification and certification:
   - Classifying quality and properties of end product in accordance with set standards.
   - Reporting on QA results and classification to finished product inventory control.
   - Certifying that product was produced according to standard process conditions.
   - Reporting process data and certification to finished product inventory control.
   - Using at-line process analytics for checking consistency of process.

d) QA measurement validation:
   - Checking of reference sample results against standards.
   - Ongoing analysis of testing methods using statistical quality control methods.
   - Maintaining quality statistics on each item checked for continuing quality control studies.

e) Laboratory and automatic analysis:
   - Conducting metric, chemical, and physical tests on sample product items to obtain data for on-going quality control tests.
   - Transmitting test data to analysis facilities and quality control systems to assure future quality of product.
   - Inferring material attributes based on on-line models.

8.1.4 Types of testing

One important aspect of quality operations is testing and inspections. Some different types of tests include:

a) Tests of material, suppliers, equipment, or other resources - Tests to determine that resources to be used meet defined quality requirements.

b) Environmental tests - Environmental tests are performed to check the environment and the impact of production on the environment; e.g., contamination of equipments or consumables such as water or solvents, the air in the production facility, and/or the discharges.

c) Reference analyses tests - Reference analysis consists of sending known samples to various laboratories in order to check the performance of a specific laboratory.

EXAMPLE:

Performing a test to see if a lab is able to produce correct results.

d) Asset reliability tests - Preventative maintenance tests conducted to provide consistency of product and process.

EXAMPLE:

Examples include vibration profiles to product and equipment setups, oil/fluid testing for physical properties, contaminates and metal contents, and ultrasonic profiling.

8.1.5 When testing occurs

Testing can be performed at different times and places in a manufacturing process. Some examples include:

a) In-line testing - In-line testing is part of the production execution management, where the test equipment is part of the process.

b) At-line testing - At-line testing is when test materials are taken out of the production run, but where test execution is performed at the production line.

c) Off-line testing - Off-line testing is when tests are taken out of the production execution management and performed in a laboratory.

8.1.6 Quality systems

Multiple different systems may support quality operations. Typically these may include laboratory information management systems (LIMS), historian systems, batch management systems, SPC (statistical process control) or SQC (statistical quality control) systems, or OEE (overall equipment effectiveness).

NOTE — All of the above-mentioned systems are involved in testing material, but also are used in testing environment, health, and calibration activities.

8.2 Quality test operations activity model

The quality operations management model illustrated by the shaded area in Figure 1 is expanded to a more detailed activity model of quality test operations, as shown in Figure 25, using the generic activity model shown in Figure 6. The model shown in Figure 25 defines the activities as they relate to inspections or test operations. The model defines what quality test activities should be done and the relative sequencing of the activities, not how they should be performed in a specific organization structure. Different companies may have different organizations of roles and assignments of roles to personnel or systems.

In the quality test operations activity model, quality requests and quality responses do not always cross the boundary between Level 3 and Level 4 systems. Quality test requests are often generated internally within Level 3 systems. Quality test requests and quality test responses may be exchanged individually or as sets. An organized set of requests can be considered a quality test schedule and an organized set of responses can be considered a quality test performance.

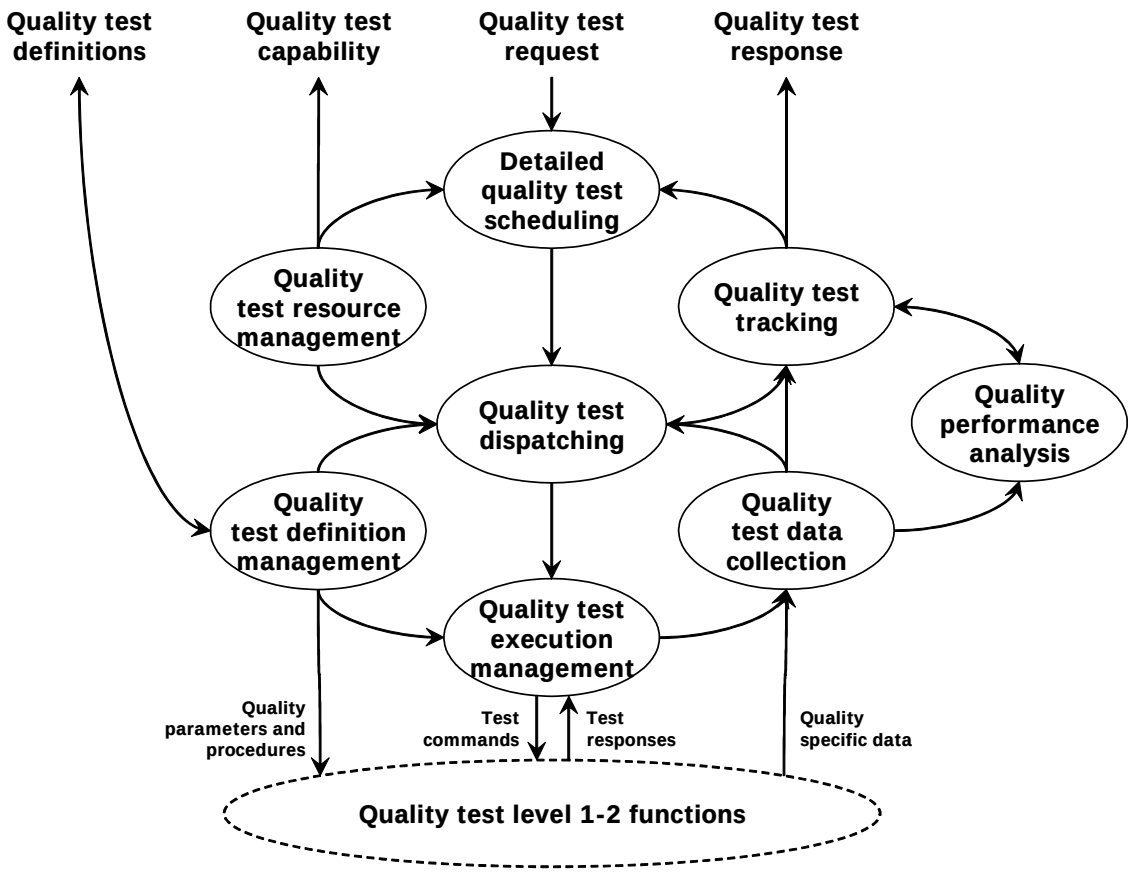

Figure 25 – Activity model of quality test operations management

The ovals in the quality test operations activity model indicate the activities, identified as the main functions. Lines with arrowheads indicate an important information flow between the activities. Not all information flows are depicted in the quality test operations activity model. In any specific implementation, information from any activity may be needed by any other activity. Figure 25 only illustrates some major information flows between activities.

8.3 Information exchanged in quality test operations management

8.3.1 Quality test definitions

Quality test definitions shall be defined as test specifications for testing of materials, environment, and equipment. Quality test definitions may be sent to Level 3 from a Level 4 system, such as from an enterprise resource planning system (ERP), a product lifecycle management system (PLM), or a product data management system (PDM). Within Level 3, the quality test definitions are often complemented with additional plant-specific information.

Quality test definitions may include control methods used in an independent lab to ensure credibility of test results. These include equipment calibration and the use of standards for equipment verification and environmental considerations. There may be significant interaction with maintenance operations in these control methods.

8.3.2 Quality test capability

Quality test capability shall be defined as the combination of required resources that contain information about the resource's status; for example, committed, available, or unattainable. The quality test capability includes the capacity of the resources. Quality test capability is based on the capability in:

a) Personnel – Typically based on qualification, training, experience, and discipline. May also be based on device or equipment specific proficiencies.

b) Equipment – Such as test equipment.

c) Material – Such as test consumable materials.

8.3.3 Quality test request

Quality test requests shall be defined as requests to perform testing activities on material or equipment and may include inspection requests of intermediate products, raw materials, finished products, and test requests for equipment calibration.

Quality test requests may be generated from Level 3 or Level 4 activities, based on the business and operations processes in place. Quality test requests are typically generated in order to test product and equipment to assure that process, product, and equipment characteristics are within specification limits defined for the product. Intelligent instruments and controllers at Level 1 and control systems at Level 2 may automatically generate requests for quality test services.

8.3.4 Quality test response

Quality test responses shall be defined as the result of testing activities called for in the quality test requests. Quality test responses may be a pass/fail response or may be measures of property values for tests.

Measures of property values passed to Level 4 may have economic value.

EXAMPLE:

Property values may be used to determine the cost or price of the final materials, or permit a material to be used in an alternate form or for an alternate use.

In case of a failed test, test responses may be directed to the activities that generated the test request. Typically, these activities analyze the test response and trigger appropriate business rules for disposition of a production work order. The production work order disposition may include recommended corrective action responses such as:

— Continuing production with corrective adjustments.

— Reworking the material following specific work instructions.

— Scrapping or discarding the WIP material and rescheduling the production work order(s).

— Placing quarantine or hold on production work order(s) to conduct further analysis.

— Discarding the test sample and acquiring a new sample.

— Recalibrating the testing equipment.

8.3.5 Quality parameters and procedures

Quality parameters and procedures shall be defined as specific instructions sent to Level 2 and Level 1. Quality parameters and procedures may include the test SOP (Standard Operating Procedures) and calculations to be used.

8.3.6 Test commands

Test commands shall be defined as request information sent to Level 2 or Level 1. Test commands may include context on the test to be executed (e.g., sample context as, e.g., lot number) and commands to start the instrument.

8.3.7 Test responses

Test responses shall be defined as information received from Level 2 or Level 1 as a response to test commands. Test responses may include the test results, or messages such as “instrument is not available.”

8.3.8 Quality-specific data

Quality-specific data shall be defined as information received from Level 2 or Level 1. This information may include in-line or at-line data typically sent in aggregated form with the appropriate context.

EXAMPLE:

Appropriate content may be process data, material, timeframe, and location.

EXAMPLE:

Aggregated form may be the number of measurements, minimum, maximum, average, and standard deviation.

8.4 Quality test definition management

Quality test definition management shall be defined as the collection of activities that define and manage personnel qualifications, quality test procedures, and work instructions needed to perform quality tests.

Quality test definition covers the required test procedures, frequencies (sample plan), and specifications (including tolerances) for materials and resources. Test definition frequencies for suppliers may cover different frequencies for certified and non-certified suppliers.

EXAMPLE:

Always test non-certified suppliers, and test certified suppliers only every tenth delivery except when the last delivery was non-compliant.

The definition of the required tests may include such items as the methodology (e.g., near infrared for moisture test), calculations, and work instructions in terms of standard operational procedures. Quality test definition management also coordinates version numbers, effective dates, material disposition, approval(s), approval history, and release status of quality tests definitions.

EXAMPLE:

Release status could be “in development,” “ready for use,” or “obsolete.”

Quality test definition management tasks may include:

a) Managing new quality test definitions.

b) Managing changes to quality test definitions. This may include the ability to route changes through an appropriate approval process, management of definition versions, tracking of modifications, and security control of the definitions.

c) Providing quality test definitions to other applications, personnel, or activities.

d) Managing the exchange of quality test definition information with Level 4 functions, at the level of detail required by the business operations.

e) Optimizing quality test definitions based on quality test analysis.

f) Generating and maintaining quality test definitions not related to product, such as for test equipment validation and standard sample validation.

g) Managing the key performance indicator (KPI) definitions associated with quality tests.

8.5 Quality test resource management

Quality test resource management shall be defined as the collection of activities that manage the personnel materials and equipment needed to perform quality tests.

NOTE — The scope of the quality test resource management activities may be at site level, area level, or lower levels.

Quality test resource management tasks may include:

a) Providing quality personnel, material, and equipment resource definitions. The information may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities. These resources include:

— Test material – includes material that is consumed during the execution of a test.

— Test equipment – includes equipment used for on-line, off-line, and at-line testing.

— Personnel – includes management of such attributes as skill sets, certifications, authorizations, and security clearances.

b) Providing information on resource capability (committed, available, or unattainable). The information is based on the current statuses, future reservations, and future needs, and is specific for resources and for defined time spans. It may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities.

EXAMPLE:

A qualified scanning electron microscope may be unattainable for third shift in January due to planned maintenance on the equipment.

c) Ensuring that requests for acquisition of resources to meet future test capabilities are initiated.

d) Ensuring that equipment is available for the assigned tasks, and that job titles are correct and training is current for personnel assigned to tasks.

e) Providing information on the location of resources and assignment of resources to areas.

EXAMPLE:

Providing a location for a mobile test machine that can be used in multiple locations.

f) Collecting information on the current state of personnel, equipment, and material resources and on the capacity and capability of the resources. Information may be collected based on events, on demand and/or on a defined schedule, and may be collected from equipment, people and/or applications.

g) Collecting future needs such as the production plan, current production, maintenance schedules, or vacation schedules.

h) Maintaining test personnel qualification test information.

i) Maintaining test equipment capability test information.

j) Managing reservations for future use of quality test resources.

8.6 Detailed quality test scheduling

Detailed quality test scheduling shall be defined as the collection of activities that plan and schedule resources for quality tasks. Detailed quality test scheduling takes into account local situations and resource availability as well as possible preparations needed for the tests.

Detailed quality test scheduling tasks include:

a) Creating and maintaining a detailed quality test schedule.

Tests may be regularly scheduled, initiated by events generated by Level 1-2 activities, initiated by Level 3 activities, or initiated by Level 4 activities.

EXAMPLE:

A regularly scheduled test may be a raw material test run every month.

EXAMPLE:

An event-initiated test may occur when a material arrives and a sample is pulled and sent to the lab.

EXAMPLE:

A Level 4 activity-initiated test may occur when there is a new delivery from a non-certified supplier and samples need to be tested.

A quality test request may result in a new test request to be conducted by another laboratory department inside or external to a plant; for example, testing a raw material may require results from several labs.

The priorities given to the quality test requests are often given in terms of a category (such as high, medium, and low) or time (such as a due date).

NOTE — Unlimited quality test capacity is often assumed in production planning, and this results in quality testing becoming a production constraint.

b) Comparing actual test execution to planned test execution.

c) Determining the committed capacity of each resource for use by the quality test management function.

8.7 Quality test dispatching

Quality test dispatching shall be defined as the collection of activities that assign and send quality work orders to the appropriate resources as identified by the schedule and test definition. Dispatching communicates the test to be run and the resources to be used, and may include sending material to the testing resource for testing.

Resources not assigned as part of the detailed quality test schedule may be assigned by the quality test dispatching activity.

Quality work orders define the specific work order elements to be performed by quality operations.

8.8 Quality test execution management

8.8.1 Introduction

Quality test execution management shall be defined as the collection of activities that direct the performance of testing. Quality test execution management ensures that the correct resources (equipment, materials, and personnel) are used. It also includes the confirmation that the quality test is performed according to the accepted quality standards and that the product can be released (within specified conditions).

8.8.2 Testing

8.8.2.1 In-line testing

In-line tests are inspections that constitute an integral part of production. In-line tests are often performed by a machine or device integrated in the production equipment. The results from in-line tests may be available immediately.

Many in-line analyzers are considered part of process control, but some may be under the responsibility of quality test operations if they are designated as "quality critical instruments." These are instruments used to test product for release quality and are also audited off-line by the quality laboratories.

8.8.2.2 At-line testing

At-line tests are tests in which the item to be tested is taken out of the production stream and where the production operator at the production line performs the inspection. At-line tests may take a limited amount of time (such as seconds or minutes), allowing the process to quickly continue.

8.8.2.3 Off-line testing

Off-line tests are tests where the item to be tested is taken out of the production execution and where the inspection is performed in the laboratory by a lab analyst. The results of an off-line test might take longer to generate (minutes, hours, days) than at-line tests.

Off-line tests are typically under the direction of quality test operations.

> NOTE — Because of initiatives such as “first time right” and the U.S. FDA’s PAT (Process Analytical Technology) initiative, there is an industry shift from off-line inspections on final products to in-line or at-line tests on intermediate products.

8.8.2.4 Pass/fail testing

A pass/fail test only tells if the result of the test is acceptable (pass) or not acceptable (fail).

> EXAMPLE:
>
> Pass/fail tests of microbiological contamination as in present or absent, or as in packaging with OK or not OK.

8.8.2.5 Measurement testing

A measurement test determines a measured value for one or more properties.

8.8.2.6 Retesting

There are often procedures in place for failed tests. Depending on the tests involved, there may be procedures that dictate whether or not there must be a re-test, a re-sample, or some other verification that the test was performed correctly and on the right sample. When re-tests are performed, there is typically the requirement to document all tests, the reason for the retest, and the final results.

8.8.2.7 Blind sample testing

Quality requests are often performed on known reference samples, or on “blind samples,” which are materials with known characteristics. Blind samples are typically analyzed without knowledge that the samples are tests in order to validate test instruments and test procedures, and as a test of test-personnel performance and consistency. Tests on reference samples and blind samples are a common method for testing the quality of quality assurance operations.

8.9 Quality test data collection

Quality test data collection shall be defined as the collection of activities that collect test results and making these results available for other use. The test data may include manually entered data or data coming directly from equipment.

Quality test data collection includes providing standardized or on-demand reports for manufacturing personnel. In these reports, the status of the data has to be indicated clearly. The status of the data can be final or intermediate. Final data is approved and ready for distribution, intermediate data is non-approved. Intermediate data may be for internal distribution, or may still require additional tests.

8.10 Quality test tracking

Quality test tracking shall be defined as the collection of activities that assemble test results into test responses, send the responses, and manage the information about the utilization of resources required to perform tests.

Quality test tracking provides feedback about quality to Level 3 and Level 4 systems. Such information may be provided on a scheduled basis, it may be provided at the end of production runs or batches, or it may be provided on demand.

Quality test tracking includes the activities of tracking of tests that may be done at different times and at different parts of the plant.

8.11 Quality performance analysis

8.11.1 Introduction

Quality performance analysis shall be defined as the collection of activities that analyze quality test results and testing performance in order to determine how to improve product quality. Quality performance analysis includes the analysis of quality variability, quality department cycle times, resource utilization, equipment utilization, and procedure efficiencies. Quality performance analysis is often a continuous business process.

EXAMPLE:

Quality variability may be reported on non-compliance reports, KPI reports, and quality indicator reports.

Quality performance analysis activities may include:

a) Analyzing production data for trends of critical quality indicators.

   EXAMPLE:

   Critical quality indicators may be SPC and SQC analysis over time or across lots.

b) Determining the accuracy of the quality tests execution. This includes evaluation of repeatability, suitability, and efficiency of test methods.

c) Determining the cause of quality analysis problems.

d) Recommending actions to correct identified problems, including correlating the symptoms, actions, and results.

e) Providing information for use in supplier evaluations.

8.11.2 Quality resource traceability analysis

Quality performance analysis also includes resource traceability analysis, which traces the history of all resources in terms of the quality actions and events that dealt with the resources. This includes:

a) Which materials were used in quality activities.

b) Which equipment was used in quality activities.

c) Which personnel were involved in quality activities.

8.11.3 Quality indicators

One of the activities within quality performance analysis is the generation of quality indicators. This information may be used internally within manufacturing operations for improvements and optimization, or if there is a receiving business process that requires the information, it may be sent to higher-level business processes for further analysis and decisions. Within Level 4 quality indicators are often combined with financial information. Cost-based quality indicators can also be provided within Level 3 using Level 4 financial information.

EXAMPLE:

Examples of quality indicators include (used with permission from APQC; © APQC 2005, *www.apqc.org*):

- Percentage error in reliability projections
- Percentage of lots going directly to stock
- Percentage of product that meets customer expectations
- Percentage of quality assurance personnel to total personnel
- Percentage of quality engineers to product and manufacturing engineers
- Receiving inspection cycle time
- Time required to process a request for corrective action
- Time to answer customer complaints
- Time to correct a problem
- Variations between inspectors doing the same job

8.12 Supported activities

Other quality operations activities directly support the following production operations management activities defined in Clause 6.

a) Production resource management

   – This is a source of quality status/attributes information of process segments and resources (such as cleaning status, equipment availability, qualified persons).

b) Product definition management

   – Quality assurance of master data including items utilized in production operations, including the BOM.

   – Management of quality attributes for master data including approval, modification, and substitution of appropriate materials.

   – Approval and modification of work instructions and master recipes.

c) Production execution management

   – This is a destination of information about quality approval and signoff for critical quality checkpoints.

   – Quality actions for out-of-spec conditions and re-work.

   – In-line testing.

d) Production data collection

   – Statistical quality control (i.e., process analysis technology).

   – Data analysis for quality investigations (i.e., system of record).

e) Production performance analysis

   – Quality analysis of production data for trends of critical quality indicators (across batches versus for each batch).

The following production operations activities directly benefit from quality operations:

— Production tracking – tracking WIP and associated quality status.

— Production dispatching – quality attributes and status.

— Production detailed scheduling – information provided by production resource management provides input into available resources based on quality status.

— Production execution management – immediate feedback of quality status towards production can steer corrective actions during production, reducing drastically the total amount of scrap/rework.

EXAMPLE 1:

LIFO (last in, first out) checking at a pack out operation

EXAMPLE 2:

pH check at batch reactor

9 Inventory operations management

9.1 General activities in inventory operations management

The general activities in inventory operations management include:

a) Managing and tracking the inventory of product and/or material.

NOTE — Material may be production materials, maintenance materials, quality materials, or any other material that needs to be tracked and managed.

b) Performing periodic and/or on-demand inventory cycle counts.

c) Managing the transfer of material between work centers.

d) Measuring and reporting on inventory and material transfer capabilities.

e) Coordinating and controlling the personnel and equipment used in material transfer.

f) Directing and monitoring the transfer of material to and from production, quality, or maintenance.

g) Reporting on inventory to production, quality, maintenance operations management, and/or Level 4 activities.

h) Routing raw material to and from storage.

i) Identifying pack out schedules.

j) Staging and monitoring the movement of material in storage.

There are other aspects of inventory operations management not defined in this Part 3 standard, such as coordination with suppliers and distributors, and negotiation of rates. The model presumes these are Level 4 functions.

Inventory transfer activities may be under the control of manufacturing operations, if these activities meet the criteria defined in Clause 4.4.

In some industries and operations, inventory transfer activities may be handled as part of other manufacturing operations activities (see Clauses 6, 7, and 8). In the other cases they are handled as separate inventory transfer activities.

Functions that affect material can be grouped into six functional categories: receipt of material, storage of material, movement of material, processing or conversion of material, testing of material, and shipment of material. Processing and testing of material are discussed in previous clauses. The movement and storage of material functions are defined in this clause.

NOTE — Movement and storage of materials use physical equipment and manual or automated control that is likely to be similar to the equipment and control required for processing of material within production units, production lines, and process cells.

9.2 Inventory operations management activity model

The model shown in Figure 26 defines the activities of inventory operations management as they relate to the transfer of materials between and within work centers. The model defines what transfer activities may be done and the relative sequencing of the activities, but not how they should be performed in a specific organizational structure. Different companies may have different organization of roles and assignments of roles to personnel or systems.

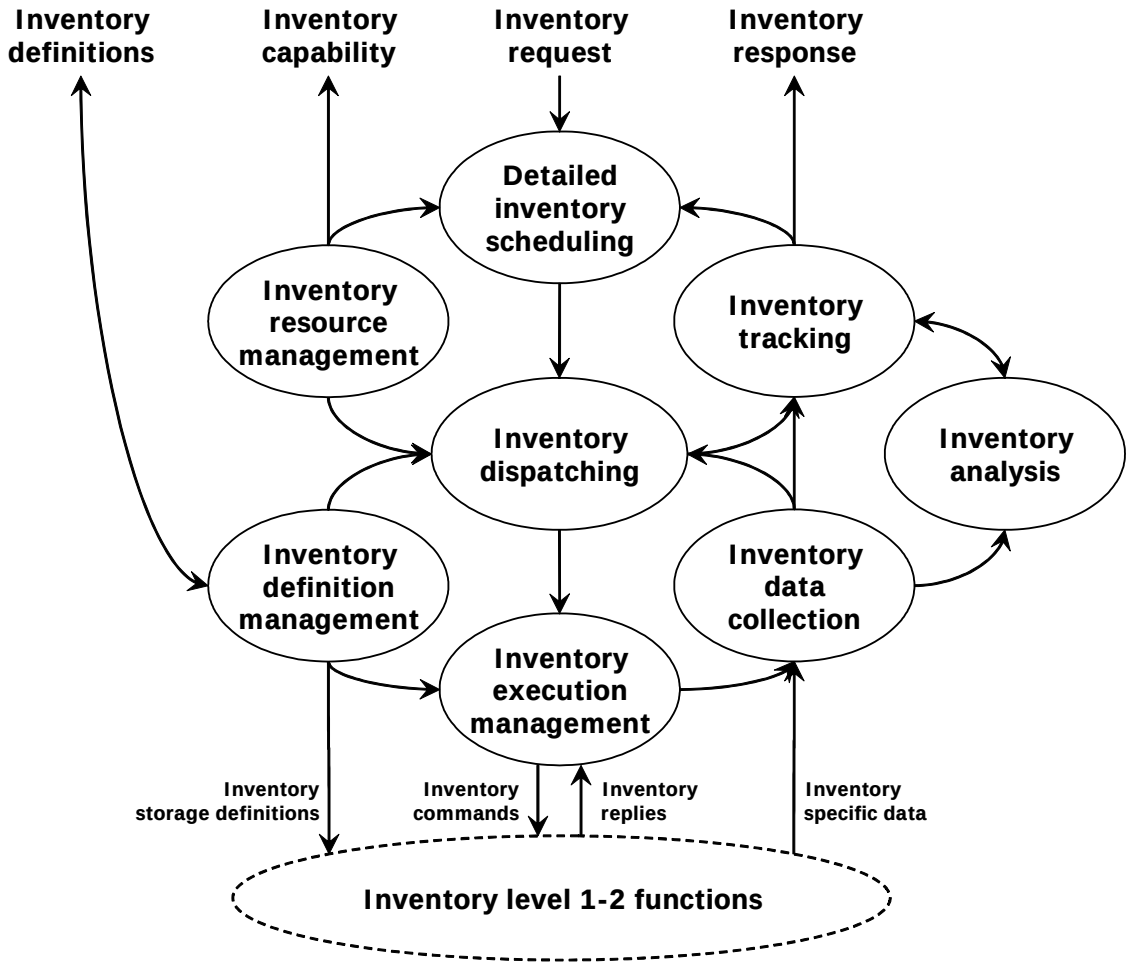

Figure 26 - Activity model of inventory operations management

The ovals in the inventory operations management model indicate collections of activities, identified as the main functions. Lines with arrowheads indicate an important information flow between the activities. Not all information flows are depicted in the inventory operations diagram. In any specific implementation, information from any activity may be needed by any other activity. Figure 26 only illustrates some major information flows between activities.

9.3 Information exchanged in inventory operations management

9.3.1 Inventory definitions

Inventory definitions shall be defined as the rules and information associated with movement and storage of materials. The rules may be location specific, equipment specific, or material specific.

EXAMPLE:

Inventory movement definitions may include environmental requirements for specific material types, rules for locations of storage, rules for containers-material selection, criteria for necessary material environmental parameters, and shelf life constraints for materials.

Inventory definitions information may cross the boundary between Level 3 and Level 4 systems. Alternately, inventory definition information may be entirely contained within Level 3 systems.

9.3.2 Inventory capability

Inventory capability shall be defined as a capability measure of the ability to handle materials, typically for specific time horizons. Inventory capability may be characterized by the type of material, storage space (or volume) available, and type of storage.

EXAMPLE:

Type of storage may include temperature, hazard classification, chemical classification, clean room requirements, or humidity controlled.

Inventory capability information may cross the boundary between Level 3 and Level 4 systems. Alternately, inventory capability information may be entirely contained within Level 3 systems. The inventory capability includes the capacity of the resources. Inventory capability is based on the capability in:

a) Personnel – typically based on qualification, training, experience, and discipline. May also be based on device or equipment-specific proficiencies.

b) Equipment – such as movement equipment, trucks, and carts

c) Material – such as packing materials consumed in material movement or storage

9.3.3 Inventory requests

An inventory request shall be defined as a request to transfer materials between work centers.

Inventory requests may be generated from Level 3 or Level 4 activities, based on the business and operations processes in place.

EXAMPLE:

Inventory requests may be generated internally within manufacturing operations to move material between work centers.

Inventory requests may be exchanged individually or as sets. An organized set of inventory requests can be considered an inventory schedule.

9.3.4 Inventory response

An inventory response shall be defined as the response to an inventory request, indicating the completion status (successful or unsuccessful) of the request.

Inventory responses may, but do not always, cross the boundary between Level 3 and Level 4 systems.

Inventory responses may be exchanged individually or as sets. An organized set of responses can be considered an inventory performance.

9.3.5 Inventory storage definitions

Inventory storage definitions shall be defined as storage definition information sent to Level 2 associated with movement and control.

EXAMPLE:

This may be routing rules implemented by automated sorting equipment or the human operators of forklift trucks; or load patterns for automated truck loading equipment.

9.3.6 Inventory commands

Inventory commands shall be defined as request information sent to Level 2, typically commands to move or transfer materials.

9.3.7 Inventory replies

Inventory replies shall be defined as information received from Level 2 as a response to an inventory command.

9.3.8 Inventory-specific data

Inventory-specific data shall be defined as information received from Level 2 inventory equipment about the equipment performing the inventory functions, information about the environment of the material, and/or about the material (such as quantity and location).

9.4 Inventory definition management

Inventory definition management tasks shall include:

a) Managing information about transfer criteria for materials.

EXAMPLE:

This could be handling instructions and warehouse storage restrictions. For example, there may be specific handling instructions on how to handle specific toxic materials during material transfers, how to handle traceability, or specific handling restrictions for controlled or regulated substances.

b) Managing new inventory definitions.

c) Managing changes to inventory definitions. This may include the requirement to route changes through an appropriate approval process, management of definition versions, tracking of modifications, and security control of the definitions.

d) Providing inventory definitions to other applications, personnel, or activities.

EXAMPLE:

Managing information about locations where materials may be stored, appropriate range of volume of the storage material, and other material inventory operations constraints that are sent to dispatching or detailed scheduling activities.

e) Managing the exchange of inventory definition information with Level 4 functions, at the level of detail required by the business operations.

f) Optimizing inventory definitions based on quality test analysis.

g) Managing the Key Performance Indicator (KPI) definitions associated with inventory tests.

9.5 Inventory resource management

Inventory resource management shall be defined as the collection of activities that manage resources used in material storage and movement. Inventory resource management tasks may include:

a) Providing personnel, material, and equipment resource definitions. The information may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities. These resources include:

— Transfer Equipment – This includes equipment such as conveyors, fork lifts, trucks, railcars, valve arrays, pipes, ASRS (Automated Storage and Retrieval Systems), containers, and AGV

(Automated Guided Vehicles). Transfer equipment also includes storage location control equipment, such as heating or cooling control, positive or negative pressure control, ventilation (flow rate, humidity, and particulate level) control, and electrostatic grounding.

— Storage Equipment – This includes tanks, silos, containers, pallets, stock area of stocker machines, shelves, and so forth. Some equipment has specific ranges of capacity in terms of physical constraint and/or operational efficiency.

— Personnel – This includes management of such attributes as skill sets, certifications, authorizations, and security clearances.

— Material and energy used in the movement, such as disposable consumables like gloves, gowns, masks, and ink.

b) Providing information on resource capability (committed, available, or unattainable). The information is based on the current statuses, future reservations, and future needs and is specific for resources and for defined time spans. It may be provided on demand or on a defined schedule, and may be provided to people, to applications, or to other activities.

c) Managing stock sizes and using other means to control the amount of inventory required to meet business requirements and production requirements.

d) Ensuring that requests for acquisition of resources to meet future capabilities are initiated.

e) Ensuring that equipment is available for the assigned tasks, and that job titles are correct and training is current for personnel assigned to tasks.

f) Providing information on the location of resources and assignment of resources to areas.

EXAMPLE:

Providing a location for a fork lift truck and its assignment to a movement work order.

g) Collecting information on the current state of personnel, equipment, and material resources and on the capacity and capability of the resources. Information may be collected based on events, on demand, and/or on a defined schedule, and may be collected from equipment, people, and/or applications.

h) Collecting future needs such as the production plan, current production, maintenance schedules, or vacation schedules.

i) Maintaining personnel qualification test information.

j) Maintaining equipment capability test information.

k) Managing reservations for future use of resources.

Inventory resource management includes management of the distribution of inventory definitions. Some of the inventory definitions may exist in Level 2 and 1 equipment. When that is the case, downloads of this information shall be coordinated with other manufacturing operations management functions, so as to avoid affecting production. This information may be included as part of inventory commands when the download is performed as part of an inventory execution management activity.

9.6 Detailed inventory scheduling

Detailed inventory scheduling shall be defined as the collection of activities that take inventory requests and generate detailed inventory schedules. Detailed inventory scheduling tasks may include:

a) Creating and maintaining a detailed inventory schedule.

This may include such activities as scheduling and optimization of pallet loading, optimizing pick order from a warehouse, scheduling material movement equipment (fork lift trucks), or determining pumping and valve arrangements.

Detailed inventory scheduling may define movement schedules to avoid exceeding storage capacity, and to avoid exceeding environmental capabilities and capacities of storage locations.

b) Comparing actual movements to planned movements.

c) Determining the committed capacity of each resource for use by the inventory resource management function. This information may include location of empty storage, time, and route to move to the location.

d) Creating inventory work orders in accordance with inventory requests from Level 4 functions.

e) Determining future assignment of inventory work orders to storage zones and storage units. This task may include a decision of location of material.

f) Determining start time and completion time of inventory work orders with respect to future capacity of storage resource, future availability of transfer resources, and future amount of available inventory material.

g) Determining lot size of each inventory transfer order by splitting or merging inventory transfer requests with respect to constraints of the transfer resources. Constraints may include cost, capacity, and due time of the corresponding inventory movement.

9.7 Inventory dispatching

Inventory dispatching shall be defined as the collection of activities that assign and send inventory work orders to the appropriate inventory resources as identified by the inventory schedule and inventory definitions.

EXAMPLE:

This may take the form of move orders to fork lift truck operators, transfer commands to tank farm systems, pumping schedules to pipelines, movement commands to an ASRS system, or location pickup commands to an AGV.

Resources not assigned as part of the detailed inventory schedule may be assigned by the inventory dispatching activity.

9.8 Inventory execution management

Inventory execution management shall be defined as the collection of activities that directs the performance of work, as specified by the contents of the inventory dispatch list elements.

Inventory execution management may include:

a) Directing the performance of work, including executing the work order and initiating Level 2 activities.

NOTE — When material movement is performed manually, inventory execution management activities include displaying specific work instructions to inventory personnel.

b) Ensuring that the correct resources (equipment, material, and personnel) are used in inventory operations.

c) Ensuring that work order procedures and regulations are followed during the transfer operations.

d) Documenting the status and results of the work performed.

e) Informing transfer dispatching and/or detailed transfer scheduling when unanticipated events result in the inability to meet the work requirements.

f) Confirming that the work was accomplished according to the accepted quality standards.

g) Verifying that equipment and personnel certifications are valid for the assigned tasks.

h) Verifying the actual volume or quantity of particular items of inventory materials, by means of special equipment or manual operations. This task may be performed on demand or on a defined schedule provided by accounting activities as well as the detailed inventory scheduling.

9.9 Inventory data collection

Inventory data collection shall be defined as the collection of activities that gather and report data on inventory operations and materials manipulated. Figure 27 illustrates some of the interfaces to inventory data collection.

Inventory data collection may include maintaining information for product tracking such as tracking storage used, storage conditions, equipment used in storage, and operators involved in storage and transfer.

Inventory data collection includes maintaining information for quality tracking such as samples or reference materials produced.

Inventory data collection also includes maintaining information for maintenance tracking such as spare parts consumed.

This information may be required for regulatory control and may have to be integrated with production data.

EXAMPLES:

- Silo or tank inventory and movement data collection
- Lot and sublot location and amount data collection
- Material balances and reconciled data
- Location of WIP
- Records of positive pressure in a storage building

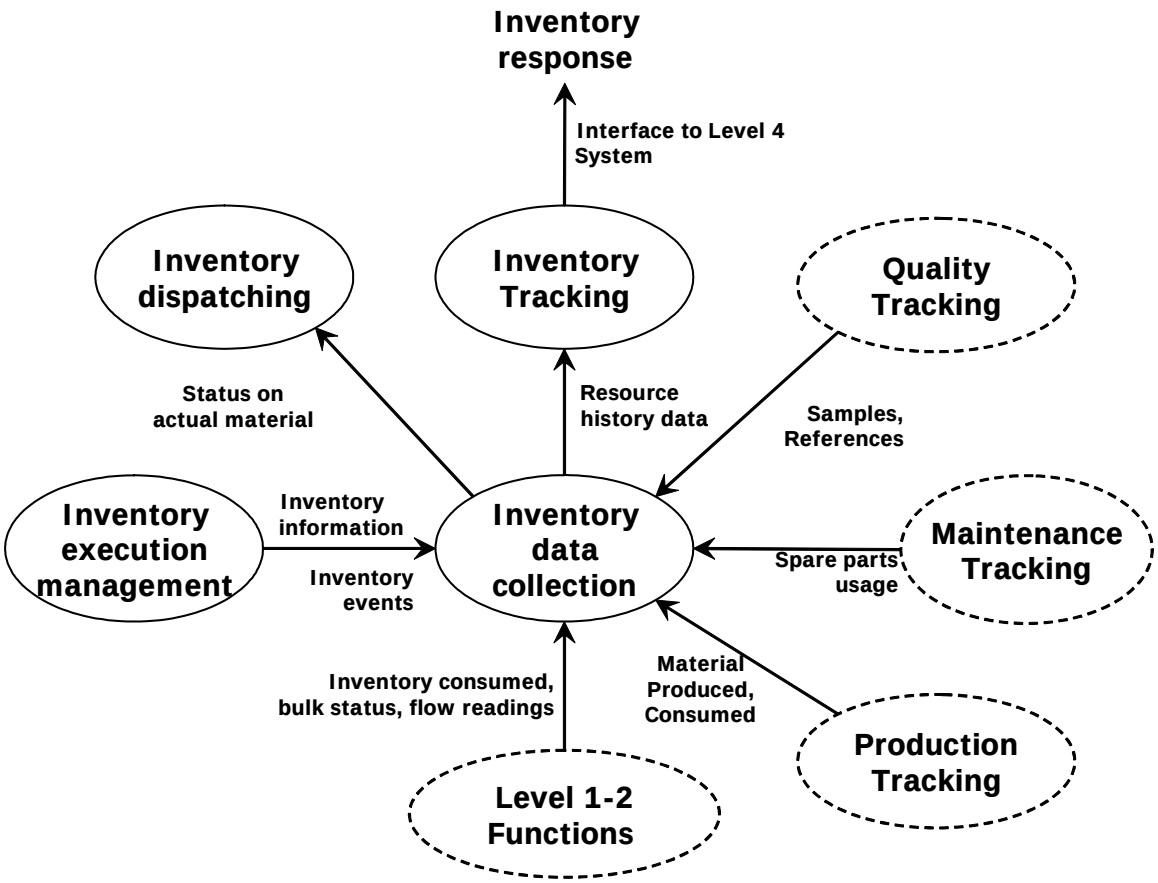

Figure 27 – Inventory data collection activity model

9.10 Inventory tracking

Inventory tracking shall be defined as the collection of activities that manage information about inventory requests and report on inventory operations. The activities may include reporting on relative transfer efficiencies and utilization of the resources used in inventory. This may include recording the start and end of movements and collecting updates to lot and sublot quantities and locations as they occur.

Inventory tracking includes the activity of generating or updating of records related to the transfer of material and management of the material stored. This may include records required for regulatory or quality management purposes.

Inventory tracking provides an inventory response to Level 4 activities requesting inventory information.

9.11 Inventory analysis

Inventory analysis shall be defined as the collection of activities that analyze inventory efficiencies and resource usage in order to improve operations. Inventory analysis may provide information on received material quality and time for use in supplier evaluations, may provide information on waste due to improper storage, or may provide information on movement by location, equipment, or shift.

EXAMPLE:

Analysis may be used to detect resource bottlenecks such as the number of forklift trucks or pallets, or counts of AGV delays due to aisle contention.

Inventory analysis also includes resource traceability analysis, which traces the history of all resources in terms of the inventory actions and events that dealt with the resources. This includes:

a) Which materials were used in inventory activities

b) Which equipment was used in inventory activities

c) Which personnel were involved in inventory activities

There is information about inventory movement and control that provides summaries of past performance and indications of future performance or potential future problems. Collectively this information is defined as "inventory indicators". One of the activities within inventory analysis is the generation of inventory indicators. This information may be used internally within manufacturing operations for improvements and optimization, or if there is a receiving business process that requires the information, it may be sent to higher-level business processes for further analysis and decisions. Inventory indicators may be combined at Level 4 with financial information, or at Level 3 using Level 4 financial information to provide cost-based indicators.

EXAMPLE:

Examples of inventory indicators include (used with permission from APQC; © APQC 2005, *www.apqc.org*):

- Annual inventory turns
- Annual lines shipped per SKU
- Annual work-in-process (WIP) turns
- Cases per hour
- Customer order cycle time in days
- Dock-to-stock cycle time
- Finished goods inventory turns
- Gross inventory as a percentage of sales dollars
- Inventory accuracy
- Inventory carrying cost
- Inventory reliability: line items filled on first try per total line items ordered
- Line items processed per employee/hour
- Lines shipped per person per hour
- Order fill rate
- Order line fill rate
- Pallets shipped per person per hour
- Percentage error in cases shipped
- Percentage error in lines shipped
- Percentage error in orders shipped
- Percentage of orders expedited
- Percentage of orders shipped complete and on-time
- Percentage of sales order lines items not fulfilled due to stock outs
- Percentage of sales orders delivered on time
- Percentage of supplier orders delivered on time
- Picking error rate
- Pick-to-ship cycle time for customer orders (hours)
- Pilferage reduction
- Raw material inventory turns
- Stock turns per year
- Vendor lead time

10 Other enterprise activities affecting manufacturing operations

10.1 Other areas

In addition to the major activities already described, there are other activities that are used within manufacturing operations, but are not necessarily unique to the manufacturing element of a company. These supporting activities include, but are not limited to:

a) Management of security within manufacturing operations

b) Management of information within manufacturing operations

c) Management of configurations within manufacturing operations

d) Management of documents within manufacturing operations

e) Management of regulatory compliance within manufacturing operations

f) Management of incidents and deviations within manufacturing operations

Figure 28 illustrates the concept of the supporting activities, and their relationship with the major manufacturing operations activities. For example, there may be an aspect of management of information used in production data collection, production resource management, production tracking, production definition management, maintenance definition management, and quality test data collection.

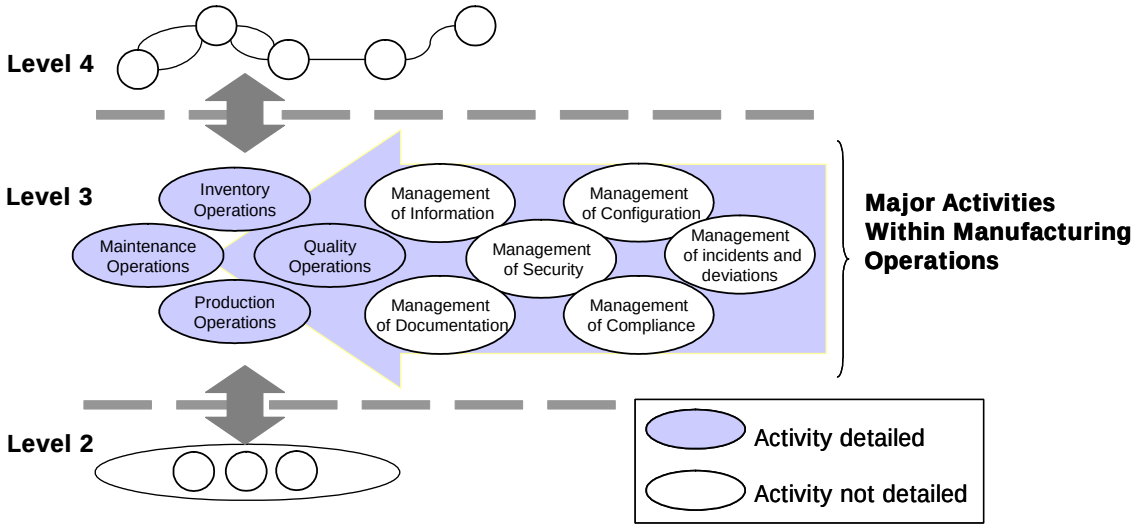

Figure 28- Other enterprise activities affecting manufacturing operations

10.2 Management of security

Management of security is an enterprise function and is not defined in this standard, but does impact manufacturing operations management. Security management functions include physical (site and area) security, information security, and computer security. The basic role of security in manufacturing operations is to make sure that only authorized personnel may make changes or affect manufacturing in allowed ways. This typically involves physical security to limit access to facilities, control of information flows out of a facility to protect intellectual property, and control of communications to ensure that unauthorized remote access does not affect operations.

NOTE — Management of security is often combined with management of networks. The current recommend practice is to ensure that networks used in production operations, especially those involved in physical control of processes, are separate

from non-real time networks. This separation may be physical, through different networks or network standards, or virtual through protocols, firewalls and routers. Real-time control requires predictable network responsiveness and latency, which is best accomplished through the separation of networks.

When policies and procedures for management of security do not exist on a company wide basis, then security control can be considered a manufacturing operations activity, for manufacturing security.

Potentially relevant standards for security relating to communications and computer systems are listed in Annex C.

10.3 Management of information

Management of information is an enterprise function and not defined in this standard, but does impact manufacturing operations management. In fact, most of the manufacturing operations activities consume and generate information as part of their function. Many functions must exchange information with other functions that are not listed in Clauses 6, 7, 8, and 9 of this standard.

When policies and procedures for management of information do not exist on a company-wide basis, then information control can be considered a manufacturing operations activity, for manufacturing information.

Management of information involves management of information storage, transmission, backup, recovery, and redundancy. These are often corporate-level functions that follow corporate, industry, national, or international standards.

10.4 Management of configuration

Management of configuration is often an enterprise function and is not defined in this standard, but does impact manufacturing operations management. Management of configuration includes configuration management and change control procedures that should be considered in manufacturing operations. This function may be required any place there is a semi-permanent data storage and actions can be taken based on the stored data. Often audit trails and revision management procedures are required.

EXAMPLE:

This may include product definitions, work instruction, standard operating procedures, product and process definitions, resource class definitions.

EXAMPLE:

This may include management of Level 2 information such as PLC programs and DCS configurations.

When policies and procedures for management of configurations do not exist on a company wide basis, then configuration control can be considered a manufacturing operations activity, for manufacturing configurations.

One aspect of configuration management involves the processes and procedures necessary to implement changes to configuration elements that may comprise the production operations. This includes identification, surveillance, and control of changes to these configurable items. This includes but is not limited to:

a) Equipment hardware identification and change procedures

b) Level 2 and Level 3 software identification and change procedures

c) Data and record management for Level 2 and Level 3 records

d) Version control of the configuration elements

One aspect of change control involves processes or procedures by which changes are initiated and managed. These procedures often include the following:

e) Requests for change

f) Analysis of the change request

g) Impact analysis of the change

h) Approval of the change

i) Implementation of the change

j) Review and approval of the change implementation

k) Monitoring of the change

Potentially relevant standards for management of configuration include are listed in Annex C.

10.5 Management of documents

Management of documents is often an enterprise function and is not defined in this standard, but does impact manufacturing operations management. Manufacturing operations need to manage a wide range of documents. These include items such as SOPs (Standard Operating Procedures), work instructions, recipes, control system programs, drawings, batch records, engineering change notices, alarm logs, and exception reports. Management of this information is often required for regulatory, environmental, health and safety, or certification reasons. Generally companies have a set of procedures, policies, and software tools in place to manage all corporate documents.

When policies and procedures for management of documents do not exist on a company-wide basis, then document control can be considered a manufacturing operations activity, for manufacturing documentation.

Document management also involves an aspect of disaster recovery. Many manufacturing systems are based on confidence in the delivery systems. However, natural or man-made disasters can delay delivery of raw materials, delivery of final products, and make manufacturing facilities temporarily or permanently unavailable. Companies with significant operations typically develop a disaster-recovery plan that includes information about production. It should also contain documentation on core manufacturing processes. Aside from recovering data, entire processes may have to be recreated that must map to machine, automated systems, physical layout, production sequences, and part inventory systems. The information should be available after disasters so that operators can physically recreate production lines in the event of unforeseen disasters.

Potentially relevant standards for document management are defined in Annex C.

10.6 Management of regulatory compliance

The broad footprint of management of regulatory compliance means that many areas of the enterprise can be significantly affected. Failures in regulatory compliance can stop production, force product recalls, and potentially cause safety problems. Where management of regulatory compliance activities involves the quality and safety of production, then the activities are in the scope of production operations.

When policies and procedures for management of regulatory compliance do not exist on a company-wide basis, then compliance control can be considered a manufacturing operations activity, for manufacturing compliance.

Figure 29 illustrates some of the aspects of regulatory compliance and general activities associated with each aspect.

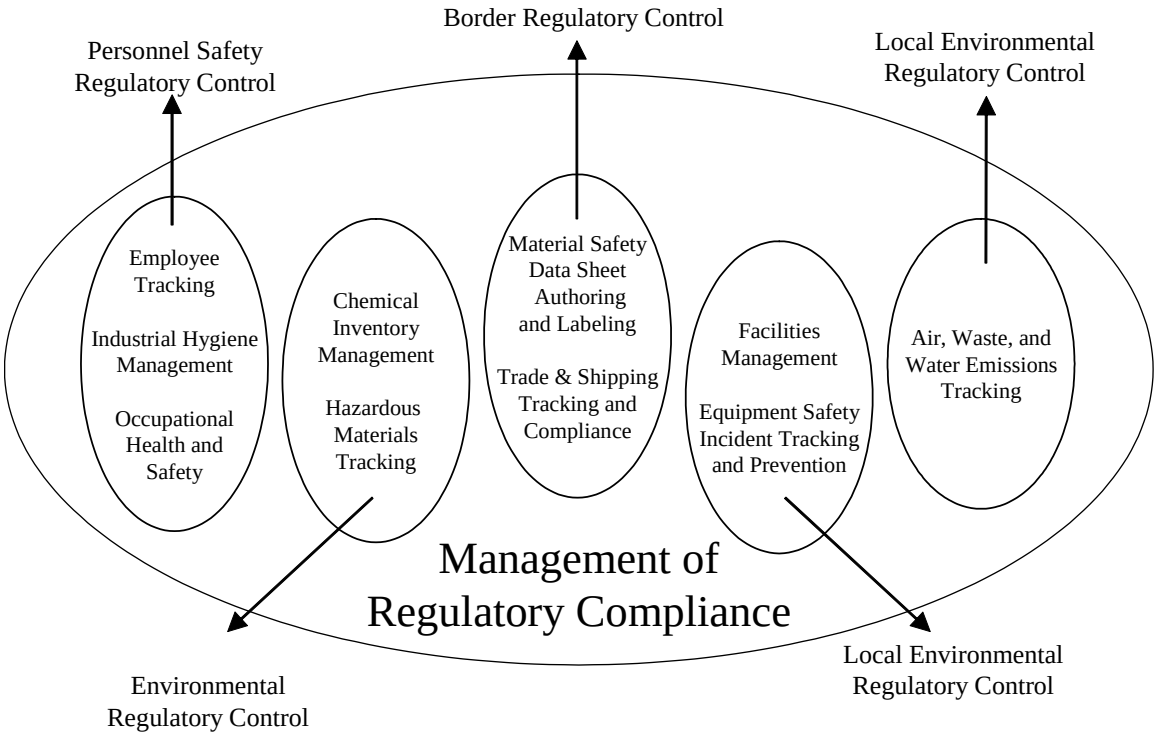

Figure 29 - Functions in management of regulatory compliance

Typical environmental activities include:

a) Permit requirements related to planning/construction and operations.

b) Air pollution control including emissions limitation/control and permits.

c) Water pollution control including wastewater and effluent discharges and storm water runoff.

d) Waste management of solids, hazardous material, and packaging.

e) Notification, classification, packaging, and labeling of hazardous materials. This also includes storage of such material.

EXAMPLE:

Special handling of asbestos, PCBs, and pesticides.

f) Liability and management practices including civil and criminal liability and contaminated land liability.

Typical health and safety activities include:

g) Handling, classification, packaging, and labeling of hazardous substances including safety data sheets.

h) Disaster planning including emergency planning and response, and fire safety.

i) Hazard communication in the form of warning signs, training, and advice.

j) Occupational health surveillance in the form of occupational exposure controls (including chemical, physical, biological agents, and noise).

k) Medical surveillance of personnel.

l) Process safety in the form of machinery safety, lifting equipment, pressure systems, confined space entry/work permits/access control.

m) Management of functional safety

n) Electrical safety

o) Ergonomics including office work, manual handling of loads, and the like.

p) First aid

Potentially relevant standards related to regulatory compliance are defined in Annex C.

10.7 Management of incidents and deviations

Management of incidents, deviations, corrective actions, and preventative actions is often an enterprise function and is not defined in this standard, but does impact manufacturing operations management. Management of incidents, deviations, corrective actions, and preventative actions is often associated with maintenance of regulatory compliance or with continuous improvement processes. These activities are also often performed in conjunction with other manufacturing operations management activities.

Management of incidents: Maintaining plant operation often requires that unexpected events, called incidents, are recorded and that the response to the incident is recorded. Incidents are typically unexpected events related to maintaining plant operations, safety, regulatory compliance, or security. Incident management typically involves investigation to determine the root cause of the incident and may lead to preventive actions to prevent future incidents.

EXAMPLE:

An unexpected release of a chemical into the environment may generate an incident, and the incident report may have to be sent to the appropriate regulatory agency, such as the US EPA.

EXAMPLE:

An unexpected pump failure from a newly installed pump may generate an incident, and the incident response may be to investigate and potentially change the supplier.

Management of deviations: Maintaining plant operations often requires that deviations that have been detected because of normal conditions are recorded and that the response to the deviation is recorded. Deviations are typically measured differences between an observed value and an expected or normal value, or an anomaly from a documented standard or process. Deviation management typically involves determination of the root cause of the deviation and may lead to corrective actions to remove the source of the deviation.

Management of corrective actions and preventive actions: Maintaining plant operations often requires that corrective actions, typically in response to an incident, deviation, or failure, are recorded and managed, and that the results of the corrective action are recorded. Clear, appropriate, and implementable corrective actions should be identified at the conclusion of any investigation. Tracking and follow-up should be managed to ensure that the corrective actions are implemented and verified.

EXAMPLE:

Corrective actions may include improving procedures, adding maintenance procedures for equipment, or implementing retest or revalidation procedures.

Preventative actions are typically managed in a similar fashion, in order to prevent possible future incidents or deviations.

EXAMPLE:

Batch cycle times on a process cell may not meet the rated value and this is identified as a deviation; then, a preventive action is created to reduce the batch cycle time.

Recommended actions are managed in a similar function. Recommended actions are predefined sets of actions to occur in the event of an incident or deviation.

11 Completeness, compliance, and conformance

11.1 Completeness

The number of models supported, as defined in Clauses 5 through 9, shall determine the degree of completeness of a specification or application.

11.2 Compliance

Any assessment of the degree of compliance of a specification shall be qualified by the following.

a) The use of the structuring models of Clause 5 and the terminology defined in Clauses 5 through 9.

b) A statement of the degree to which they then conform partially or totally to definitions.

In the event of partial compliance, areas of non-compliance shall be explicitly identified.

11.3 Conformance

Any assessment of the degree of conformance of an application shall be qualified by the documentation to which the models conform.

In the event of partial conformance, areas of non-conformance shall be explicitly identified.

Annex A (Informative) – Technical and responsibility boundaries

A.1 **Introduction**

The models shown in Figure 9, Figure 24, Figure 25, and Figure 26 define a large collection of activities, only some of which have been traditionally identified with operations management. One reason for this is because the boundary between what is done by Level 3 operations (production, maintenance, quality, and inventory) personnel and by Level 4 personnel is not invariant. There may be three different boundaries, one that defines the scope of required responsibilities, one that defines the scope of actual organizational responsibilities, and one related to areas of technical integration.

A.2 **Scope of responsibility**

There are several questions that should be asked to determine the scope of responsibility of production operations (Level 3, 2, and 1 functions). These are defined in Clause 4.4 and include:

1) Is the function or activity critical to product quality? If yes, then it should be part of manufacturing operations.
2) Is the function or activity critical to maintaining regulatory compliance, such as FDA, EPA, USDA, OSHA, TÜV, EC, EU, EMEA, and other agency regulations? If yes, then it should be part of manufacturing operations.
3) Is the function or activity critical to plant safety? If yes, then it should be part of manufacturing operations.
4) Is the function or activity critical to plant reliability? If yes, then it should be part of manufacturing operations.
5) Is the function or activity critical to plant efficiency? If yes, then it should be part of manufacturing operations.

Different environments will give different answers for activities. For example, if quality, safety, compliance, reliability, and efficiency are only determined at the lowest level activities and not related to scheduling or dispatching, then the manufacturing operations boundary may be defined by dotted line “A” in Figure 30. If in the previous example the collection of production data is also required for regulatory compliance, then the boundary may be defined by line “B.” Lines “C” and “D” provide other possible boundaries of responsibility. Line “E” defines the level of manufacturing operations management responsibility assumed in this Part 3 standard.

> NOTE — This defines the activity boundaries, but not the organizational boundaries. For example, in some regulated industries the quality organization is required by laws to be independent of the manufacturing operations organization.

This same partitioning of responsibility can occur in maintenance operations management, quality operations management, and in inventory operations management. The decisions on responsibility are based on industry type, regulatory control, and physical properties of production.

This complexity is one reason for the inability of the Level 3 functions to have a simple and clean definition. There is no simple and clean definition, because there are so many possible solutions. For example, in a hypothetical regulated drug manufacturing company:

— The detailed production schedule generates schedules for intermediate material production and is critical to product quality.

— The batch record for regulatory compliance is critical to regulatory compliance.

— Material and personnel resource management is critical to regulatory compliance.

— Maintenance of the equipment and of the quality measurement equipment is critical to product quality, plant safety, and regulatory compliance.

In this hypothetical situation all of the activities of production, maintenance, and quality could be under the scope of control of production, shown as Line E in Figure 30. In this situation the manufacturing operations management layer would be significant and cover all of the defined aspects of production.

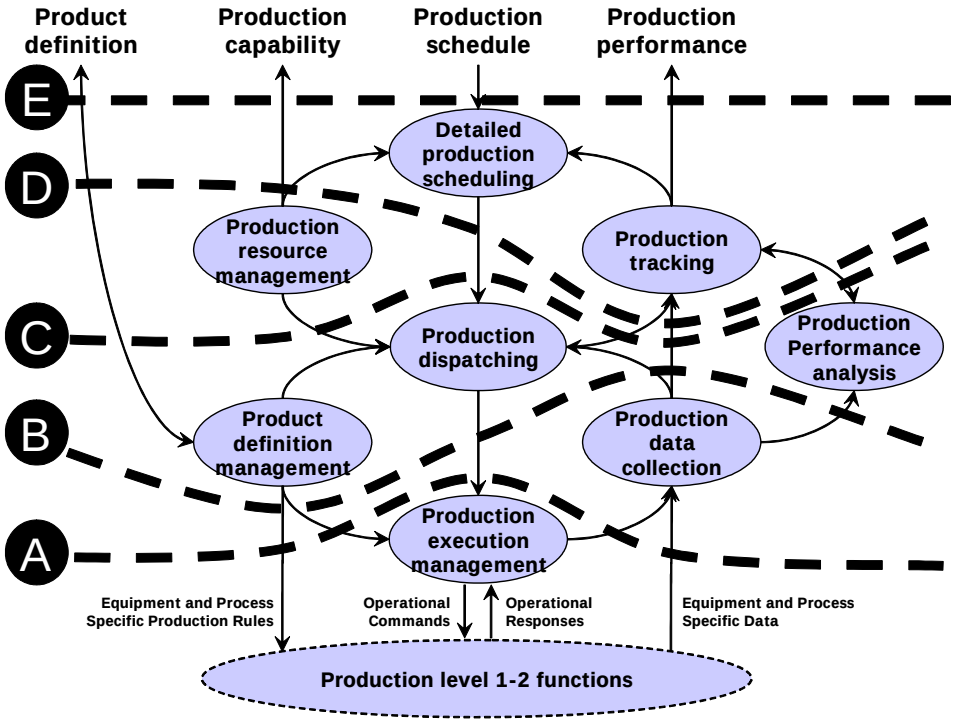

Figure 30 - Different boundaries of responsibility

At the other end of the spectrum of solutions, assume a hypothetical electronic board assembly facility. In this case:

— Quality is only determined by production execution management. The production paths are fixed and production scheduling does not affect quality, safety, or compliance.

— Production safety is managed at the Level 2 function through safety interlocks, PC, and PLC programs.

— Maintenance, quality, and inventory are not critical to product safety or product quality, although they are important for effective and efficient production.

In this situation perhaps only production execution management is within the scope of control of production operations management. This is shown in Line A in Figure 30.

A.3 **Actual responsibility**

The five questions in Clause 4.4 define the required boundary of responsibility, but there may be an actual boundary of responsibility different from the required responsibility. Usually this occurs due to business reasons, such as local site management of activities and local accountability. In these cases the line of actual responsibility should be the same or higher than the required responsibility.

For example, a company may decide that even though detailed production scheduling and production resource management are not required for safety, quality, reliability, or regulatory compliance issues, they are still under the control of manufacturing operations. When decisions are made to include activities under the control of manufacturing operations, the reason for the decision should be clearly understood.

A.4 **Technical integration**

Many of the functions illustrated in Figure 9, Figure 24, Figure 25, and Figure 26 may be implemented in Level 3 or Level 4 systems.

EXAMPLE:

The functions may be implemented by systems such as ERP (Enterprise Resource Planning) systems, MES (Manufacturing Execution Systems) systems, LIMS (Laboratory Information Management Systems), AMS (Asset Management Systems), WMS (Warehouse Management Systems), or DCS (Distributed Control System) systems.

The lines of technical integration might not be determined by the same rules as the lines of responsibility. The lines of technical integration are based on technical decisions, including the availability of installed systems, the cost of new systems, and integration of existing systems. The line of technical integration may include several systems in the maintenance, quality, production, and inventory area, as well as several systems in the business logistics area. Figure 31 illustrates one possible line of integration (“X”) for a hypothetical company with some maintenance activities, some quality activities, and most inventory activities supported by ERP systems.

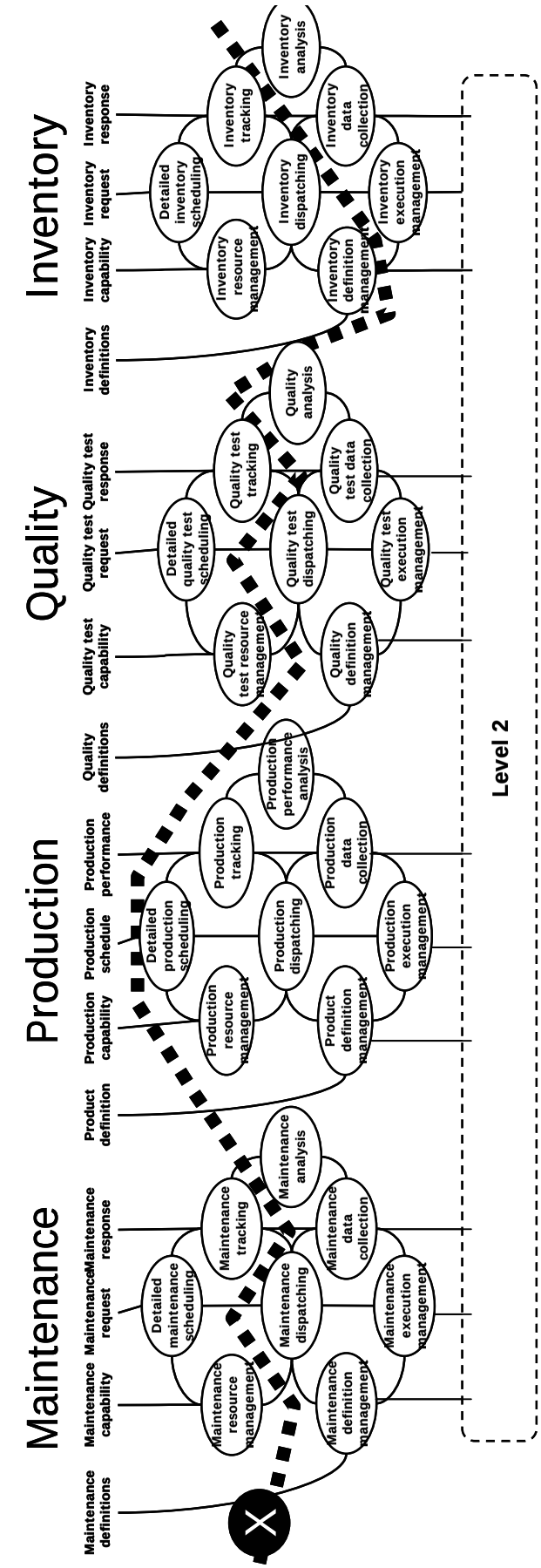

Figure 31 - Lines of technical integration

A.5 **Defining solutions**

The combination of lines of management responsibility and lines of technical integration preclude any simple definition of the manufacturing operations management layer. Even companies in the same industry may have different solutions. However, the models defined in this standard define a systematic way to approach the problem, segment it, and define solutions. These allow both concise and formal documentation of the lines of responsibility and the lines of technical integration. The two do not need to be the same. This may involve manufacturing personnel using ERP systems to automate their processes and activities. For example, an ERP scheduling system may be used by manufacturing operations for detailed production scheduling, detailed maintenance scheduling, and detailed quality scheduling. The important points are:

— There are four main categories to consider in manufacturing operations management: maintenance, production, quality, and inventory.

— There are three lines of integration to be considered: the line of required responsibility, the line of actual organizational responsibility, and the line of technical integration.

— There are four criteria for determining if an activity should be under the scope of control of manufacturing operations. (See Clause 4.4.

— There is no single definition of the manufacturing operations management layer; the determination of what activities are covered and where the system must integrate with business logistics may be different for every company.

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Annex B (Informative) - Scheduling hierarchy

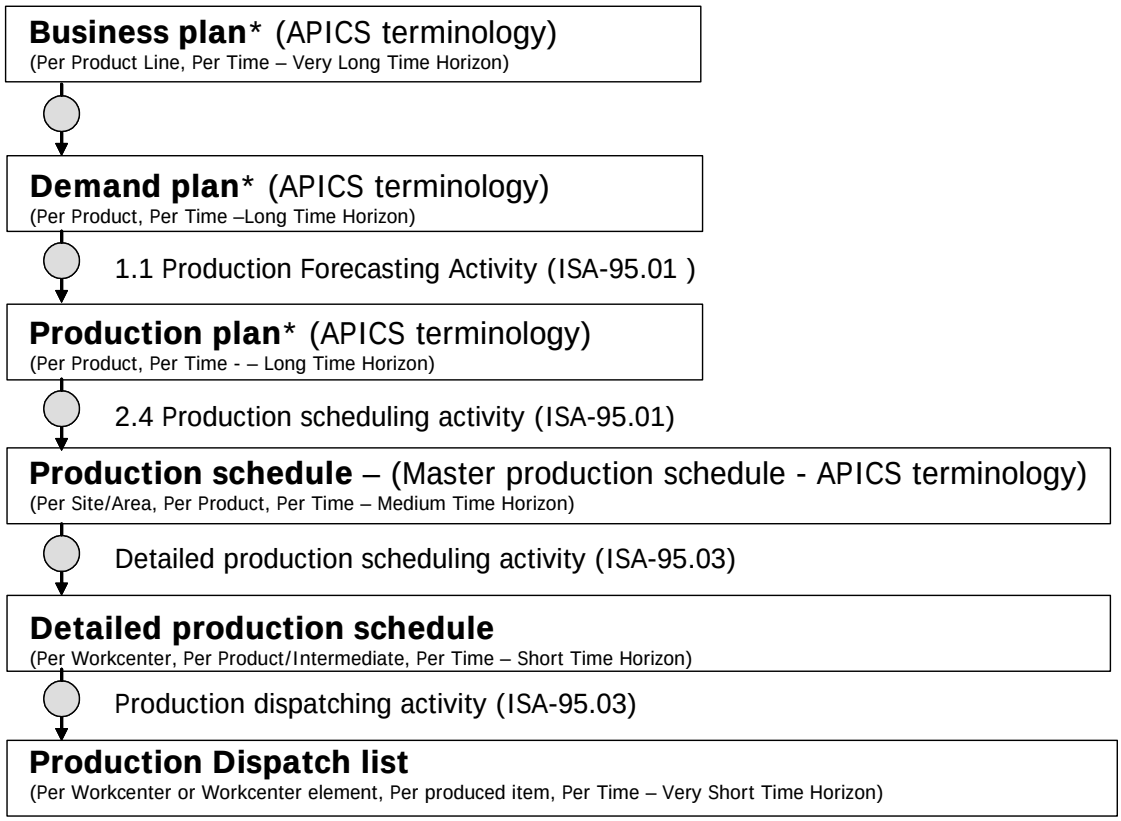
There is a hierarchy of scheduling within many companies. Many companies start with a company-wide plan that balances market demand with company capabilities using constraints such as manufacturing capacity, distribution capacity, and capital capacity.

In a multi-site company this plan is often divided among the facilities and results in a Master Production Schedule (MPS) for each facility. Depending on how the organization defines demand, the MPS may be used to create the production schedules through a Material Resource Planning (MRP) activity or Enterprise Resources Planning (ERP) activity. Alternatively, a company may use the MPS to reconcile customer orders and forecast to drive the ERP/MRP Planning function to create the production schedules.

Companies may also run on a “pull” system, where immediate demand, such as direct input from sales channels, is used to generate production requests. In all of these cases, production schedules (and production requests) are sent to manufacturing operations and cross the Enterprise-Control System boundary.

Most enterprises, even those with advanced planning and scheduling tools, have at least two and often three levels of planning activities. The lowest level is a local site or area scheduling activity that generates a detailed production schedule. This schedule defines the allocation of resources and people that production executes against. There may also be an even lower level of scheduling at the process cell, production line, or process unit level, handled in production execution management functions activities such as batch management systems.

Figure 32 illustrates a hierarchy of scheduling, combining the terminology of APICS and this standard. This hierarchy is only an example of a possible scheduling and planning hierarchy within a company. It illustrates how the APICS-defined elements and the elements in this standard fit together. The hierarchy starts with a business plan and ends with a production dispatch list. There may be additional levels of scheduling and planning below the production dispatch list based on the specific control strategy selected. The top levels of the hierarchy have longer time scales than the lower levels of the hierarchy, the top levels of the hierarchy usually have a broader scope than the lower levels of the hierarchy, and the top levels of the hierarchy usually have less detail than the lower levels of the hierarchy.



* Not in the scope of this standard

Figure 32 - Sample hierarchy of schedules and scheduling activities.

The top levels of the hierarchy are defined and used by business processes. A business plan, as defined in the APICS (the Association for Operations Management) Dictionary, 11th ed., is a statement of long-range strategy and revenue, cost, and profit objectives. A business plan is usually stated in terms of money and grouped by product family. A business activity, not defined in this standard, uses information in the business plan plus other information to generate a demand plan.

The demand plan is one of a set of inputs used to forecast demand and results in the generation of a production plan. Demand can be immediate, such as from sales channels, or forecast from sales plans and marketing plans. A production plan is the overall level of manufacturing output, sometimes stated as a monthly rate for each product family. An approved production plan is management's authorization for generation of production schedules (master production schedules in APICS terminology).

Production schedules define what products to build, and they may define segments of production, as seen by the business. Detailed production schedules are generated from these and they define production of products and intermediates, as defined by physical segments of production.

The lowest level of the sample schedule is the production dispatch list, which is the immediate list of activities to perform; however, there may be ordering and prioritization performed at even lower levels.

Annex C (Informative) - Associated Standards

The documents listed in this Annex C were current at the time of publication of ANSI/ISA-95.00.03-2005.

C.1 Management of Security

The following documents may apply to the common enterprise activities of management of security.

a) ANSI/ISA-TR99.00.01, Security Technologies for Manufacturing and Control Systems; and ANSI/ISA-TR99.00.02, Integrating Electronic Security into the Manufacturing and Control Systems Environment

b) ISO/IEC 13335-1Information technology – Security techniques -- Management of information and communications technology security -- Part 1: Concepts and models for information and communications technology security management

c) ISO/IEC WD 13335-2: IT security techniques -- Management of information and communications technology security -- Part 2: Techniques for information and communications technology security risk management

d) ISO/IEC TR 13335-3 Information technology -- Guidelines for the management of IT security -- Part 3: Techniques for the management of IT security

e) ISO/IEC DIS 14980 Information technology -- Code of practice for information security management

f) ISO 7498-2 Information processing systems -- Open Systems Interconnection -- Basic Reference Model -- Part 2: Security Architecture

g) ISO/IEC 10164-7 Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function

h) ISO/IEC 10164-8 Information technology -- Open Systems Interconnection -- Systems Management: Security audit trail function

i) ISO/IEC 10164-9 Information technology -- Open Systems Interconnection -- Systems management: Objects and attributes for access control

j) ISO/IEC 10181-1 Information technology -- Open Systems Interconnection -- Security frameworks for open systems: Overview

k) ISO/IEC 10181-2 Information technology -- Open systems interconnection -- Security frameworks for open systems -- Part 2: Authentication framework

l) ISO/IEC 10181-3 Information technology -- Open Systems Interconnection -- Security frameworks for open systems -- Part 3: Access control framework

m) ISO/IEC 10181-4 Information technology -- Open Systems Interconnection -- Security frameworks for Open Systems -- Part 4: Non-repudiation framework

n) ISO/IEC 10181-5 Information technology -- Security frameworks for open systems: Confidentiality framework

o) ISO/IEC 10181-6 Information technology – Open Systems Interconnection -- Security frameworks for open systems: Integrating frameworks

p) ISO/IEC 10181-7 Information technology -- Open Systems Interconnection -- Security frameworks for open systems: Security audit and alarms framework

q) ISO/IEC 10745 Information technology -- Open Systems Interconnection -- Upper layers security model

r) ISO/IEC 11586-1 Information technology -- Open Systems Interconnection -- Generic upper layers security -- Part 1: Overview, models and notation

s) ISO/IEC 11586-2 Information technology -- Open Systems Interconnection -- Generic upper layers security: Security Exchange Service Element (SESE) Service definition

t) ISO/IEC 11586-3 Information technology -- Open Systems Interconnection -- Generic upper layers security: Security Exchange Service Element (SESE) protocol specification

u) ISO/IEC 11586-4 Information technology -- Open Systems Interconnection -- Generic upper layers security: Protecting transfer syntax specification

v) ISO/IEC 9798-1 Information technology -- Security techniques -- Entity authentication mechanisms -- Part 1: General

C.2 Management of configurations

The following standards may apply to the common enterprise activities of management of configurations:

a) ANSI/EIA-649-A National Consensus Standard for Configuration Management

b) OSHA 29 CFR 1910.119 Process safety management of highly hazardous chemicals

c) FDA 21 CFR Part 11 Electronic records; electronic signatures

C.3 Management of documentation

The following standards may apply to the common enterprise activities of management of documentation:

Potentially relevant standards for document management include:

a) IEC 61355 Ed. 1.0 b – Classification and designation of documents for plants, systems and equipment

b) IEC 61506 Ed. 1.0 b – Industrial-process measurement and control – Documentation of application software

c) IEC 82045-1 Ed. 1.0 b – Document management – Part 1: Principles and methods

d) IEC 62023 Ed. 1.0 b – Structuring of technical information and documentation

e) IEC 61346-1 Ed. 1.0 b – Industrial systems, installations and equipment and industrial products – Structuring principles and reference designations - Part 1: Basic rules

f) IEC 61346-4 Ed. 1.0 b – Industrial systems, installations and equipment and industrial products - Structuring principles and reference designation - Part 4 Discussions of concept

g) IEC 61175 Ed. 1.0 b – Designations for signals and connections

h) IEC 61666 Ed. 1.0 b – Industrial systems, installations and equipment and industrial products – Identification of terminals within a system

i) IEC 60848 Ed. 2.0 b– GRAFCET specification language for sequential function charts

j) IEC 61082-1 Ed. 1.0 b – Preparation of documents used in electrotechnology - Part 1: General requirements

k) IEC 61082-2 Ed. 1.0 b – Preparation of documents used in electrotechnology - Part 2: Function-oriented diagrams

l) IEC 61082-3 Ed. 1.0 b – Preparation of documents used in electrotechnology - Part 3: Connection diagrams, tables and lists

m) IEC 61082-4 Ed. 1.0 b – Preparation of documents used in electrotechnology - Part 4: Location and installation documents

n) IEC/TR 61082-6 Ed. 1.0 b – Preparation of documents used in electrotechnology - Part 6: Index

o) IEC 60617-2 – DB-12M Ed. 1.0 b – Graphical symbols for diagrams - 12-month subscription to online database comprising parts 2 to 13 of IEC 60617 -contains graphical symbols for use in electrotechnical diagrams. Parts 2 to 13 of IEC 60617 have been incorporated into a database that currently includes some 1400 symbols. The database is the official source of IEC 60617. It replaces parts 2 to 13 of the previous published version (edition 2) of IEC 60617.

p) IEC/TR 61734 Ed. 1.0 b – Application of IEC60617-12 and IEC 60617-13 standards

q) ISO 81714-1 – Design of graphical symbols for use in the technical documentation of products. Part 1: Basic rules.

r) IEC 81714-2 Ed. 1.0 b – Design of graphical symbols for use in the technical documentation of products. Part 2: Specification for graphical symbols in a computer sensitive form including graphical symbols for a reference library, and requirements for their interchange.

s) IEC 81714-3 Ed. 2.0 b – Design of graphical symbols for use in the technical documentation of products. Part 3: Classification of connect nodes, networks and their encoding.

t) IEC 61286 Ed. 2.0 b – Information technology – Coded graphic character set for use in the preparation of documents used in electrotechnology and for information interchange

u) IEC 60417 – DB-12M Ed. 1.0 b – Graphical symbols for use on equipment. Index, survey and compilation of the single sheets

v) IEC 60416 Ed. 2.0 – General principles for the formulation of graphical symbols

w) IEC 61360-1 Ed. 2.1 en – Standard data element types with associated classification scheme for electric components - Part 1: Definitions - Principles and methods

x) IEC 61360-2 Ed. 2.1 en – Standard data element types with associated classification scheme for electric components - Part 2: Express dictionary schema.

y) IEC/TR 61360-3 Ed. 1.0 b – Standard data element types with associated classification scheme for electric components - Part 3: Maintenance and validation procedures

z) IEC 61360-4 Ed. 2.0 en – Standard data element types with associated classification scheme for electric components - Part 4: IEC reference collection of standard data element types, and component classes and terms

C.4 Management of regulatory compliance

The following standards may apply to the common enterprise activities of management of regulatory compliance:

a) ISO 14001 Environmental management systems – Specification with guidance for use

b) ISO 14004 Environmental management systems – General guidelines on principles, systems and supporting techniques

c) ISO 14015 Environmental management – Environmental assessment of sites and organizations (EASO)

d) ISO 14020 Environmental labels and declarations – General principles

e) ISO 14021 Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling)

f) ISO 14024 Environmental labels and declarations – Type I environmental labeling - Principles and procedures

g) ISO/TR 14025 Environmental labels and declarations – Type III environmental declarations

h) ISO 14031 Environmental management – Environmental performance evaluation – Guidelines

i) ISO/TR 14032 Environmental management – Examples of environmental performance evaluation (EPE)

j) ISO 14040 Environmental management – Life cycle assessment – Principles and framework

k) ISO 14041 Environmental management – Life cycle assessment – Goal and scope definition and inventory analysis

l) ISO 14042 Environmental management – Life cycle assessment – Life cycle impact assessment

m) ISO 14043 Environmental management – Life cycle assessment – Life cycle interpretation

n) ISO/TR 14047 Environmental management – Life cycle assessment – Examples of application of ISO 14042

o) ISO/TS 14048 Environmental management – Life cycle assessment – Data documentation format

p) ISO/TR 14049 Environmental management – Life cycle assessment – Examples of application of ISO 14041 to goal and scope definition and inventory analysis

q) ISO 14050 Environmental management – Vocabulary

r) ISO/TR 14061 Information to assist forestry organizations in the use of the Environmental Management System standards ISO 14001 and ISO 14004

s) ISO/TR 14062 Environmental management – Integrating environmental aspects into product design and development

t) ISO 19011 Guidelines for quality and/or environmental management systems auditing.

u) 29 CFR 1910 Occupational safety and health standards.

C.5 Related standards on quality

a) ISO 9000 Quality management systems -- Fundamentals and vocabulary

b) ISO 9001 Quality management systems – Requirements

c) ISO 9004 Quality management systems -- Guidelines for performance improvements

d) ISO 10005 Quality management -- Guidelines for quality plans

e) ISO 10006 Quality management systems -- Guidelines for quality management in projects

f) ISO 10007 Quality management systems -- Guidelines for configuration management

g) ISO 10012 Measurement management systems -- Requirements for measurement processes and measuring equipment

h) ISO/TR 10013 Guidelines for quality management system documentation

i) ISO/TR 10014 Guidelines for managing the economics of quality

j) ISO 10015 Quality management -- Guidelines for training

k) ISO/TR 10017 Guidance on statistical techniques for ISO 9001:2000

l) ISO 19011 Guidelines for quality and/or environmental management systems auditing

Annex D (Informative) – Frequently asked questions

D.1 Does this apply to more than just manufacturing applications?

As stated in the Introduction, it is not the intent of this standard to restrict its use only to manufacturing applications. The models defined have been applied in other industries, such as power distribution, oil and gas production, pipelines, warehouse/shipping management, and other industries not identified as manufacturing.

D.2 What are some of the main expected uses of this Part 3 standard?

A main use of this Part 3 standard is in the development of requirements for manufacturing operations management and related systems. The terminology and models defined in this Part 3 standard have been used as the structure for requirement specifications in RFQ (Request For Quote).

This standard has also been used within companies to evaluate and compare operations at different facilities. It has been used to point out where functions have been unassigned or not implemented.

D.3 How does this standard relate to Enterprise - Control System Integration?

Control systems are Level 2 systems and enterprise business systems are Level 4 systems. The scope of this Part 3 standard defines the activities and functions in Level 3 that tie these two together. It defines the activities in Level 3 that are the touch points for integration of the data defined in Part 1. It defines the functions within Level 3 that convert business requirements into actual Level 2 control requirements, and that convert Level 2 information back into business information. This Part 3 standard also describes some of the information that flows between the Level 3 activities and activity categories.

D.4 How does this facilitate connection to ERP systems?

Part 1 and 2 specify the interfaces between enterprise (Level 4) and the control domain (everything below Level 4). Part 3 of the standard does more than facilitate the connection to ERP systems. It provides a common way to specify the interfaces independent of the specific ERP / manufacturing management systems deployed. It also identifies the components (activities) and interfaces of the manufacturing management systems.

D.5 Why is genealogy not discussed?

The terms tracking and tracing are used as the formal definitions of the functions required for genealogy. These terms can be applied to materials, personnel, and equipment, in production, maintenance, quality testing, and inventory operations. The methods for doing genealogy may also be industry specific, while the concepts of tracking and tracing appear to be consistent across industries.

D.6 Why are all data flows not shown?

Any activity may provide information to any other activity, based on the business and production processes. The committee decided to show the ones that they felt were the most common data flows. The data flows are intended to represent the normal flow of information in a large number of cases. In any specific circumstance other data flows may be more important, or normal.

D.7 What industry does the standard apply to?

This Part 3 standard applies to any industry that converts material from one form to another using any combination of batch, continuous, and discrete manufacturing processes. Industries that have a need to improve manufacturing effectiveness to respond to their respective industry supply chains will find benefit in applying this standard. This has been confirmed by a number of industry end users, consultants, and system suppliers.

D.8 What is the relation between this standard and MES?

This standard uses the basic MESA definitions of manufacturing execution systems (MES) and expands them by adding activity detail and tasks, and extends them into additional operational areas as well as into Maintenance, Quality, and Inventory areas.

D.9 How does this Part 3 standard relate to Level 2 of PRM?

This standard defines activities that coordinate and direct PRM Level 2 activities. The levels shown in Figure 33 are defined by the Purdue Reference Model for CIM (Computer Integrated Manufacturing), and are defined in Clause 4.2. The focus of the ANSI/ISA-95 series of standards are also labeled in the figure. Parts 1 and 2 focus on the interfaces between Level 4 enterprise and Level 3 manufacturing control systems. Part 3 focuses on the activities within manufacturing.

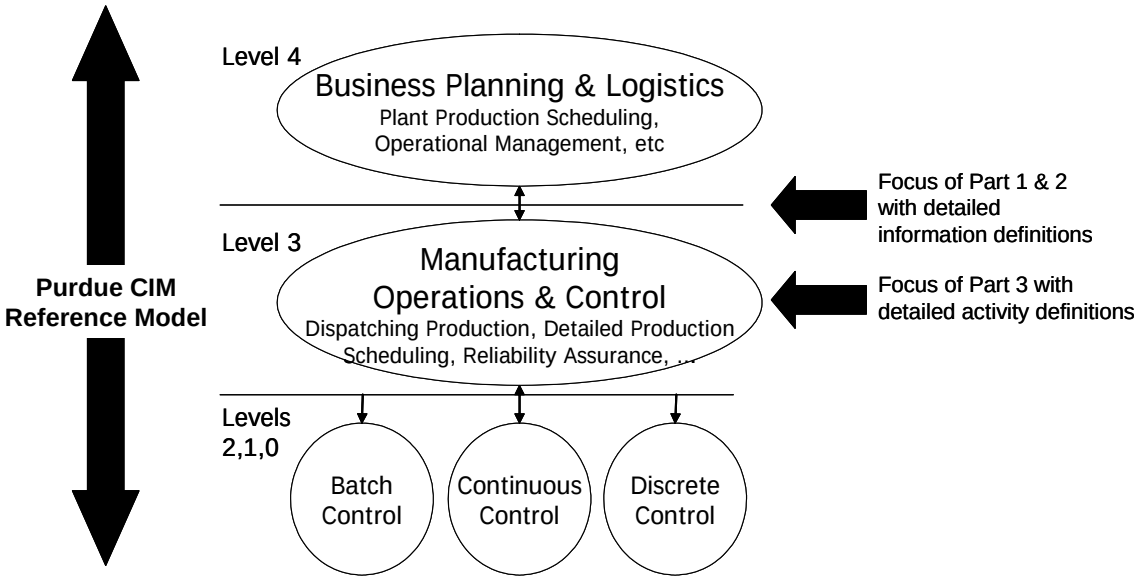


Figure 33 - CIM and standard levels

D.10 How do the ANSI/ISA-88 series of standards and ANSI/ISA-95 series of standards relate?

This topic will be addressed in a separate technical report.

D.11 How does the QA, quality assurance, element in Part 1 relate to Part 3?

The term “quality assurance,” or QA for short, was used in Part 1 and in the referenced documents. QA was been variously defined as:

— the planned and systematic activities implemented within the quality system and demonstrated as needed to provide adequate confidence that an entity will fulfill requirements for quality. (Source: ANSI/ISO/ASQ A8402-1994, Quality Management and Quality Assurance — Vocabulary)

— a program that is intended by its actions to guarantee a standard level of quality

— planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality

— planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality

— result of quality control processes to provide security to the end-user that product is wholesome, meets high quality standards, and is safe

— a system of inspections and/or tests instituted at various stages in a manufacturing or printing process to ensure that the end product will meet predetermined standards

The terminology “quality operations management” has been defined in this Part 3 standard as the activities that include all of the above definitions. The term QA has often been used to indicate either a quality program or a quality department, and has led to confusion in its use in Part 1. The term “quality operations management” replaces this terminology and makes it consistent with the other operations management areas. See Annex C for a list of applicable standards.

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