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

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ISA Draft 95.00.03, Enterprise-Control System Integration, Part 3: Models of Manufacturing Operations Management

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ISA
67 Alexander Drive
P. O. Box 12277
Research Triangle Park, NC 27709 USA

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Name	Company
Gary Addison	Lyondell - Equistar
William H. Bosler **	Texas Consultants Inc.
Dennis Brandl ***	BR&L Consulting, Inc.
Bernie Brown	DuPont
Yves Carrier	Keops Technologies Inc.
Donald Clark **	Aspentech
Carey Clements	Honeywell Inc.
Chris Conklin	Dow Corning
Dennis Delaney	Accenture
Daniel G. Dziadiw	Schering-Plough
Em delaHostria	Rockwell Automation
David Emerson	Yokogawa
Kevin Harris	Honeywell-Poms
Jay Jeffreys	Wonderware/Invensys
Charlotta Johnsson	University of Lund, Sweden
Baha Korkmaz	Automation Vision Inc.
David Kravitt	Consultant
Richard Martin	Aspentech
Roddy Martin	AMR
Chris Monchinski****	Automated Control Concepts
Paul Moylan	Rockwell Automation
Saroj Patnaik	Emerson Process Automation
Anne Poorman	ABB Inc.
Gary Rathwell	Enterprise Consultants
Leon Steinocher	Fluor Enterprises
John Sutton	ABB Inc
Swarandeep Singh	ABB AS
Keith Unger*	Rockwell Software
Jean Vieille	Consultant
Theodore Williams	Purdue University

* Chairman

** Vice Chairman

*** Editor

**** Secretary

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Part 3: Activity models of manufacturing operations management

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 is informative. The intent is to describe the 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 sections, and to list relevant standards in those areas.

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 Section 9.

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

- Part 1: Models and terminology

- Part 2: Object models and attributes

- Part 3: Activity models of manufacturing operations management

- Part 4: Object models and attributes of manufacturing operations management

INTRODUCTION

This part of the standard shows the activity models and data flows for manufacturing information that enables enterprise/control system integration. These models operate between Level 4 logistics & planning functions and Level 2 manual & automated process control functions. The models are consistent with the Part 1 data models and the Level 3 (Manufacturing Operations and Control) definitions.

The goal of the standard is to reduce the risk, cost, and errors associated with implementing enterprise systems and manufacturing operations systems that inter-operate and easily integrate. The standard may also be used to reduce the effort associated with implementing new product offerings.

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

a) Emphasize good practices of manufacturing operations

b) Can be used to improve existing manufacturing operations systems

c) Can be applied regardless of the degree of automation

Specifically, this standard provides terminology and a consistent set of concepts and models for defining manufacturing operations management activities. Benefits produced will:

a) Reduce the user's time to reach full production levels for new products

b) Enable vendors to supply appropriate tools for manufacturing operations

c) Enable users to better identify their needs

d) Reduce the cost of automating manufacturing processes

e) Optimize supply chains

f) Reduce life-cycle engineering efforts

It is not the intent of this standard to:

a) Suggest that there is only one way of implementing manufacturing operations

b) Force users to abandon their current way of handling manufacturing operations

c) Restrict development in the area of manufacturing operations

d) Restrict its use only to manufacturing industries

ENTERPRISE/CONTROL SYSTEM INTEGRATION

Part 3: Activity Models of Manufacturing Operations Management

1. Scope

This part of the standard defines activity models of manufacturing operations management that enable enterprise system to control system integration. The activities defined in this standard are consistent with the Part 1 data 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 Part 3 is limited to:

- A model of the activities associated with manufacturing operations management, Level 3 functions.
- An identification of some of the data that flows among these activities.

2. Normative references

The following normative documents contain provisions, which through reference in this text constitute provisions of this part 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 part of 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, Enterprise/Control System Integration - Part 1: Models and Terminology

d) ANSI/ISA-S88.01-1995, Batch Control – Part 1: Models and Terminology

e) ISO/IEC 19501-1 Information Technology—Unified Modeling Language (UML)—Part 1: Specification

3. Definitions and abbreviations

For the purposes of this part of this international standard the following apply.

3.1 Definitions

3.1.1

detailed production schedule

collection of production work orders and sequencing involved in production of one or more products, at the level of detail required for manufacturing, including the generation of intermediate material, and references to specific production equipment, classes of production equipment, personnel, or classes of personnel

3.1.2

dispatch list

set of specific production activities to be performed and the time or event to start the activity

Note: 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.

3.1.3

finite capacity scheduling

scheduling methodology where work is scheduled for production equipment, such that no production equipment capacity requirement exceeds the capacity available to the production equipment

3.1.4

inventory operations management

activities of a manufacturing facility which coordinate, direct, control, and track inventory and material movement within manufacturing operations

3.1.6

maintenance operations management

activities of a manufacturing facility which coordinate, direct, and track the functions that maintain the equipment and tools to ensure their availability for manufacturing and ensure scheduling for periodic or preventive maintenance

3.1.6

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

3.1.7

manufacturing operations management

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

Note 1: This part of the 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 model the concept of manufacturing defines the hardware used in production. The manufacturing operations management activities defined in this part relate to the information functions of the PERA model.

3.1.8

manufacturing operations management category

a collection of manufacturing operations management activities corresponding to a particular focus of concern, and to which the generic template of 5.1 can be applied.

Note: Users of this standard may define additional categories provided the generic template of 5.1 is applied.

3.1.9

production operations management

activities of a manufacturing facility which coordinate, direct, and track the functions that convert raw materials, energy, and information into products, with the required quality, safety, and timeliness

3.1.10

production step

unit of operational activity that uses specific production resources to accomplish a physical segment of production

Note: This may include the definition of the personnel resources, equipment resources, and material specifications required to carry out the segment of production

Note: A production step may be composed of nested production steps, such as build, rework, repair, and retest steps in a main production step.

3.1.11

production work order

unit of scheduled work dispatched to a work center and consisting of an ordered sequence of production steps

3.1.12

quality operations management

activities of a manufacturing facility which coordinate, direct, and track the functions that test materials and equipment to measure and verify quality measures

3.1.13

storage module

subordinate entity within a storage zone that contains a location and may also consist of equipment required to hold or contain the material

Note: A storage module is an element of the equipment hierarchy.

3.1.14

storage zone

location for material that may also include the equipment required to hold or contain the material

Note: A storage zone normally has the capability needed for the receipt, storage, retrieval, movement, and shipment of materials.

Note: A storage zone is an element of the equipment hierarchy.

3.1.15

work center

process cell, production unit, production line, inventory storage, or any other equipment element defined as an extension to the equipment hierarchy model

3.2 Abbreviations

For the purposes of this part of the 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
CNC	Computerized Numerical Control
DCS	Distributed Control System
ERP	Enterprise Resource Planning
EWI	Electronic Work Instructions
KPI	Key Performance Indicator
LIMS	Laboratory Information Management System
MES	Manufacturing Execution System
MPS	Master Production Schedule

MRP	Material Resource Planning
PAT	Process Analytical Technology
PDM	Product Data Management
PLC	Programmable Logic Controller
PLM	Product Lifecycle Management
QA	Quality Assurance
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, and material in the conversion of raw materials and/or parts into products. Manufacturing operations management include activities that may be performed by physical equipment, human effort, and information systems. By performing those activities, the facility fulfills the business mission.

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 the manufacturing facility.

The manufacturing operations management activities correspond to the activity set defined in Part 1 of this standard. These are the activities that are 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 of this standard. Manufacturing operations management is subdivided into four areas: 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 Figure 1, but described in Section 4.7 and Section 10.

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

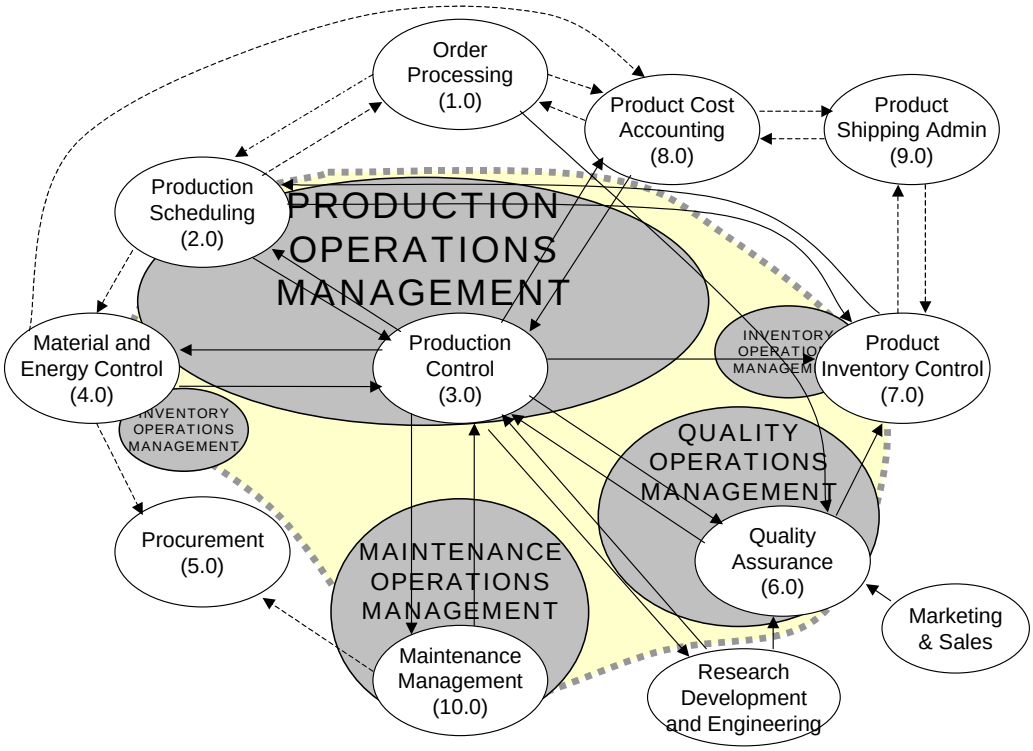


Figure 1 – Manufacturing operations management model

4.2 Manufacturing operations management elements

The shaded areas in Figure 1 represent the manufacturing operations management activities modeled in this part of the 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. Other activities that may be independently managed depending on company policy or organization are also described but not formally modeled.

— The production operations management model includes the activities of production control (3.0) and the subset of the production scheduling (2.0), product inventory control (7.0), and material & energy control activities (4.0) that are defined as operating as Level 3 functions and as shown in Figure 1.

— The maintenance operations management model includes the activities of maintenance management that operate as Level 3 functions.

— The quality operations management model includes the activities of quality assurance that operate as Level 3 functions.

— The inventory operations management model includes the activities of management of inventory and material that operate as Level 3 functions.

4.3 Criteria for defining manufacturing operations management

In this part of the standard an activity is included as a manufacturing operations management activity if it included personnel, equipment, or material directly involved in manufacturing, and meets any of the following conditions:

1. The activity is critical to plant safety.
2. The activity is critical to plant reliability
3. The activity is critical to plant efficiency.
4. The activity is critical to product quality.
5. The activity is critical to maintaining regulatory compliance.

Note: This includes such factors as safety, environmental, and cGMP compliance

Example: Maintaining FDA, EPA, USDA, OSHA, TÜV, EU, EMEA, and other agency compliance.

Note 1: This list is a clarification of the criteria for inclusion of an activity in the manufacturing operations management domain defined in Part 1 of this 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 by these criteria.

4.4 Level 3 activities

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

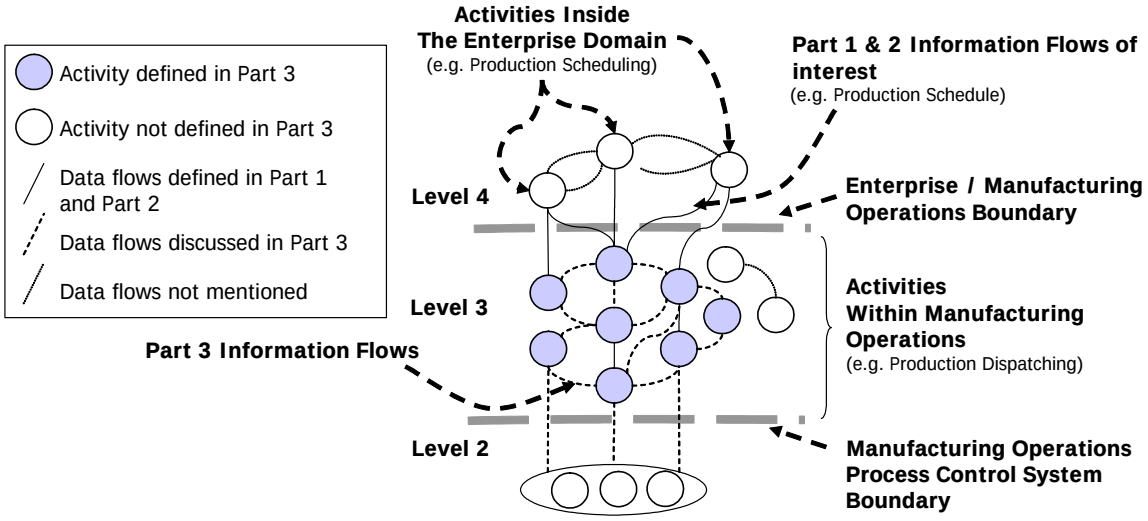


Figure 2 - Activity models in level 3

4.5 Expanded categories of information

Part 1 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, splitting *Production information* into the schedule and performance components: *Production schedule information* and *Production performance information*. See Figure 3.

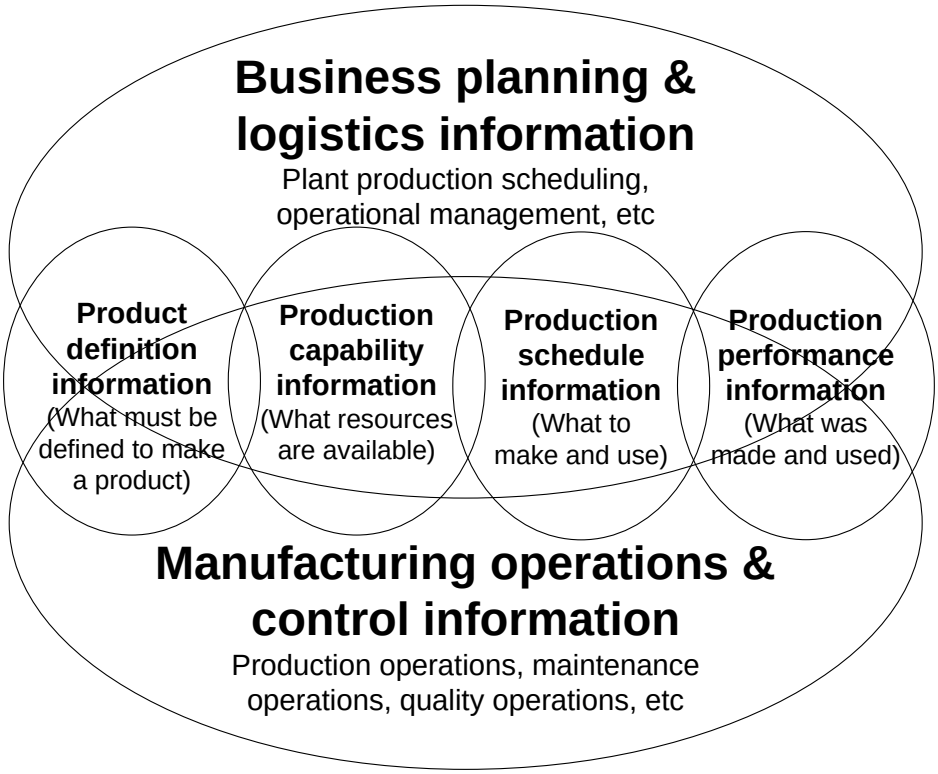


Figure 3 - Areas of information exchange

4.6 Manufacturing operations information

The structure of the production information defined in Part 1, provides a structure that can be applied to maintenance information, quality test information, and inventory transfer information as depicted in Figure 4. The production schedule, production performance, product definition management, production capability, maintenance request, and maintenance response, shown in Figure 4 as bold and underlined text, are defined in Part 1 of this standard. There are equivalent information structures for maintenance, quality test, and inventory management that are of importance for manufacturing operations which are discussed but which are not defined in detail in this part of the standard.

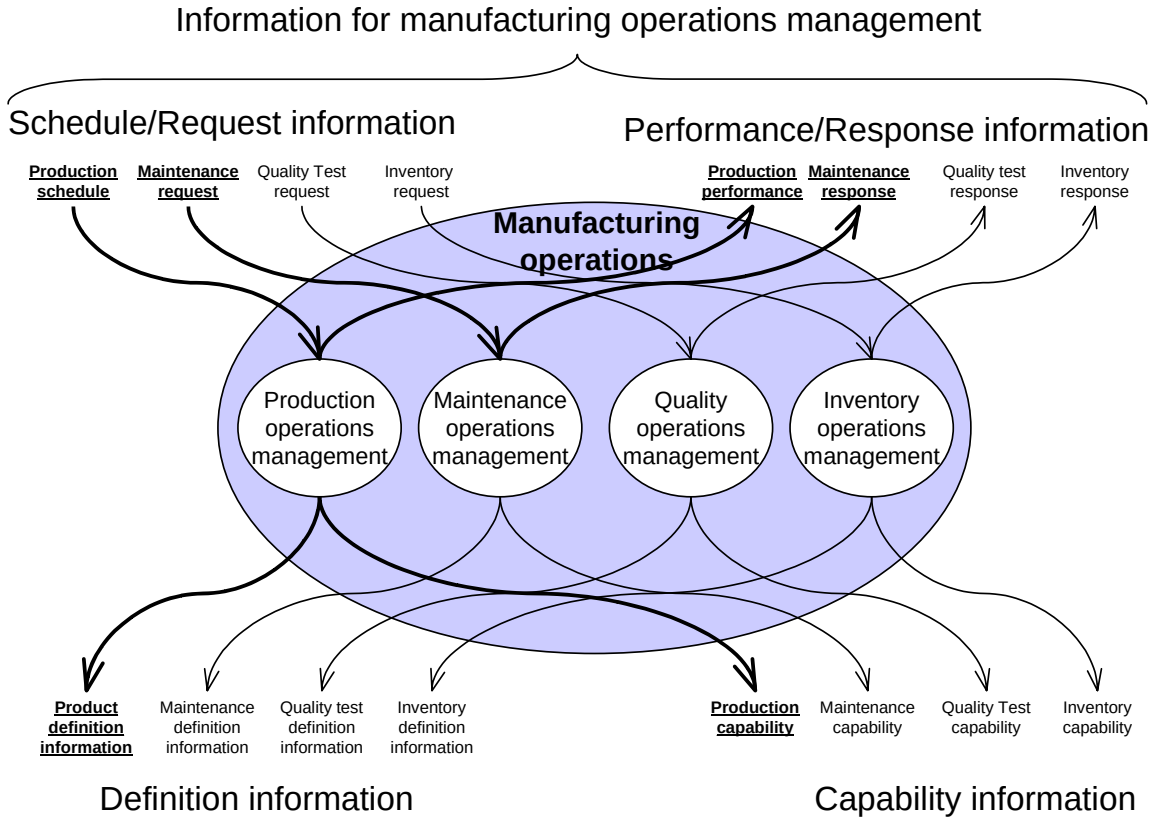


Figure 4 - Manufacturing operations information

4.7 Other enterprise activities within manufacturing operations

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

These supporting activities include:

— Management of security within manufacturing operations.

— Management of information within manufacturing operations.

— Management of configurations within manufacturing operations.

— Management of documents within manufacturing operations.

— Management of regulatory compliance within manufacturing operations.

The definition of the supporting activities is not within the scope of this standard, because they often are enterprise wide, however requirements for the activities as they relate to manufacturing operations are briefly described in Section 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 5. This generic model is extended for each specific area in later sections.

Note: The fine details of the generic model are different for each of the operations management areas.

5.1.2 Use of the generic model

The generic model is instantiated for four management operations categories, however this same template could be instantiated for other manufacturing operations categories, or for other operations areas within the enterprise.

Example: In some companies the model could be applied to receiving operations management and shipping operations management where these are separately managed. In other companies the model could be applied to cleaning and sterilization operations management, these are separately managed.

Note: This section is normative so that companies which apply the generic model to areas other than the 4 detailed in this standard can determine and document their degree of conformance to the model.

5.1.3 Generic model

The generic 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, executes the work, collects data, and converts the collected data back into responses. This request-response cycle is supported with:

— Analysis of the work that was done to allow improvements or corrections

— Management of the resources used in execution of the work to be done.

— Management of the definitions of the work to be done.

The generic activity model and the specific 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 an important information flow between the activities.

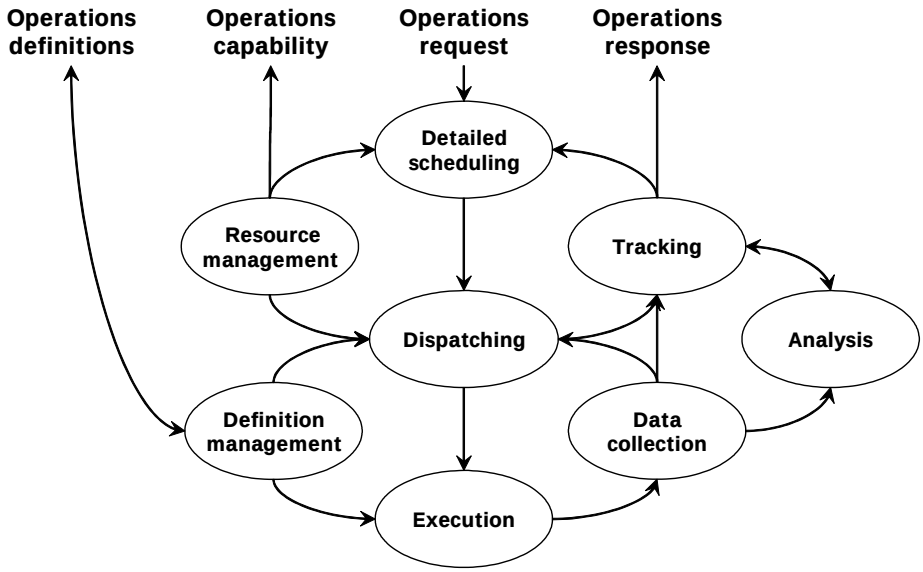


Figure 5- Generic activity model of manufacturing operations management

Not all information flows are depicted in Figure 5, 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.

Note: There is a hierarchy used in this standard that starts at a category of operations management, each category is composed of a set of activities, and each activity is composed of a set of tasks.

5.2 Expanded equipment hierarchy model

5.2.1 Equipment hierarchy model

The equipment hierarchy model, defined in Part 1 of this standard is extended in this part of the standard to the model shown in Figure 6. 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. Specific rules for collapsing and expanding these models are not covered in this standard.

Note: Collapsing - Elements in the models may be omitted as long as the model remains consistent, and the functions of the element removed are taken into account.

Note: Expanding - Elements may be added to the modules. When they are added between related elements, the integrity of the original relationship should be maintained.

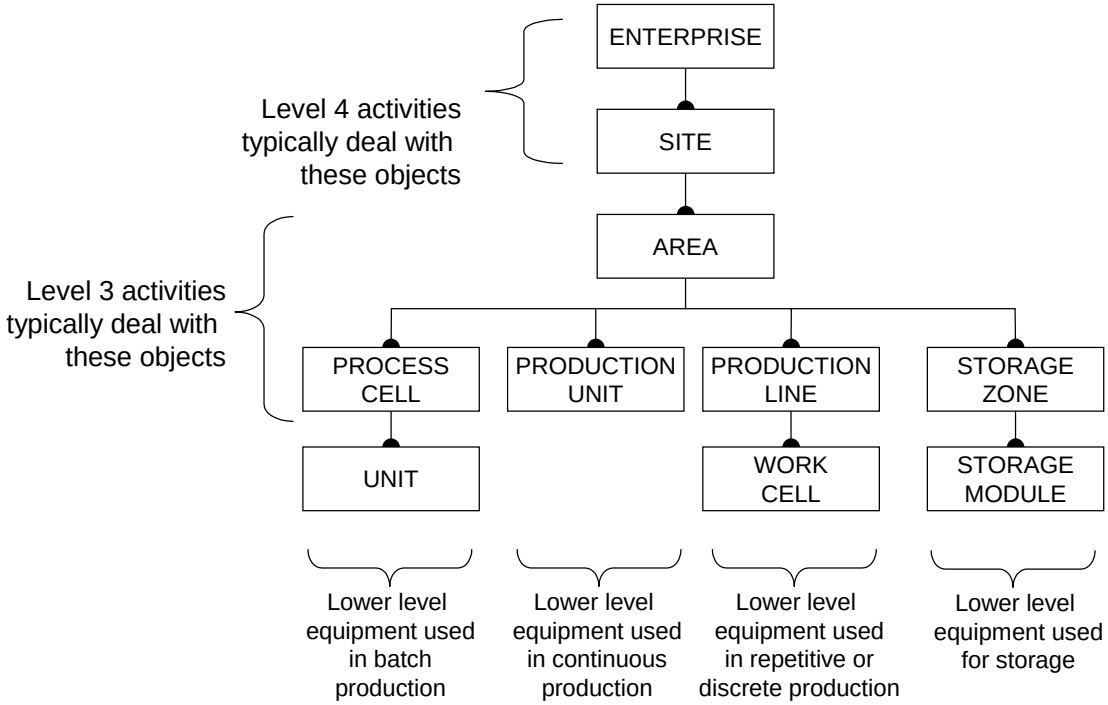


Figure 6 - Expanded equipment hierarchy

Storage zones and storage modules 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 may be considered WIP (Work In Process) and is usually distinct from inventory managed materials.

Storage zones and storage modules are the lowest levels of equipment typically scheduled by the Level 4 or Level 3 functions for continuous, batch, and discrete manufacturing. Storage zones and storage modules 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.

5.2.2 Storage zone

A storage zone provides a location for material. A storage zone normally has the capability needed for the receipt, storage, retrieval, movement, and shipment of materials. The major activity identifying a storage zone or storage module is the need to store material before, after, or in between processing by process cells, production units, or production lines.

5.2.3 Storage module

Storage modules are subordinate entities within a storage zone. Storage modules are usually of interest to business systems only when business functions maintain inventory locations to a finer level of detail than a storage zone.

Storage modules may be dedicated to a given material, group of materials or method of storage. Storage modules may be composed of other storage modules, but a complete definition of this hierarchy is outside the scope of this document. The storage modules hierarchy is needed to map to the actual use of business to manufacturing information exchange regarding inventory locations. For example, a rack within a warehouse may be a storage module, a bin within a rack may be a storage module, and a slot within a bin may be a storage module.

5.2.4 Storage zone and storage module examples

Table 1 lists examples of storage zones and the associated storage modules.

Table 1 - Storage zone and storage module examples

Storage Zone	Storage Module
Warehouse	Zone/Rack/Bin/Slot
Trailer Yard	Trailer, Container
Tank Farm	Tank
Silo Farm	Silo
Ship	Container, Barrel, Tank
Rail Yard	Railcar
Pipeline	Pipe Section
Holding Area	Pallet, Barrel
Conveyor System	Conveyor/Lift/Zone

5.2.5 Work center

The term *work center* may be used to identify an element of the equipment hierarchy under an area. This term 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, inventory storage, or any other equipment element that may be defined by the user in an extension to the equipment hierarchy model.

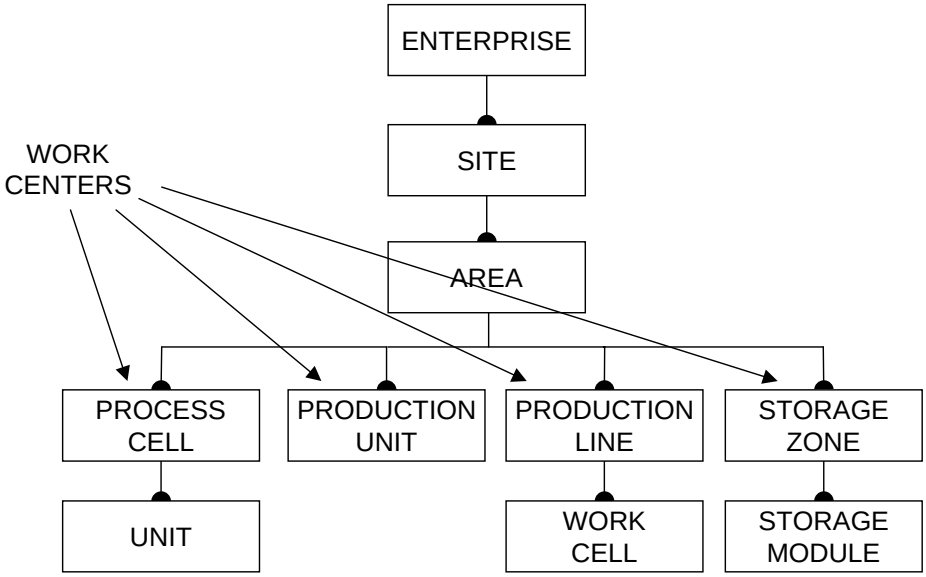


Figure 7 - Work centers

6. Production operations management

6.1 General activities in production operations management

The general activities in production operations management are listed in Part 1 of this standard and include:

a) Reporting on area production including variable manufacturing costs;

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

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

d) Carrying out 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 including maintenance, transportation and other production-related needs;

f) Locally optimizing the costs for its individual production area while carrying out the production schedule established by the Level 4 functions;

g) Modification of 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 8. The four elements of information, *product definition, production capability, production schedule,* and *production performance*, correspond to the exchanged information that is defined in Part 1, and illustrated in Figure 3. The *Level 0-1-2 process control* oval represents Level 2 control functions. Level 2 is labeled process control, as defined in the ANSI/ISA-88.00.01 and IEC 61512-1 standards. 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 organization of roles and assignment of roles to personnel or systems.

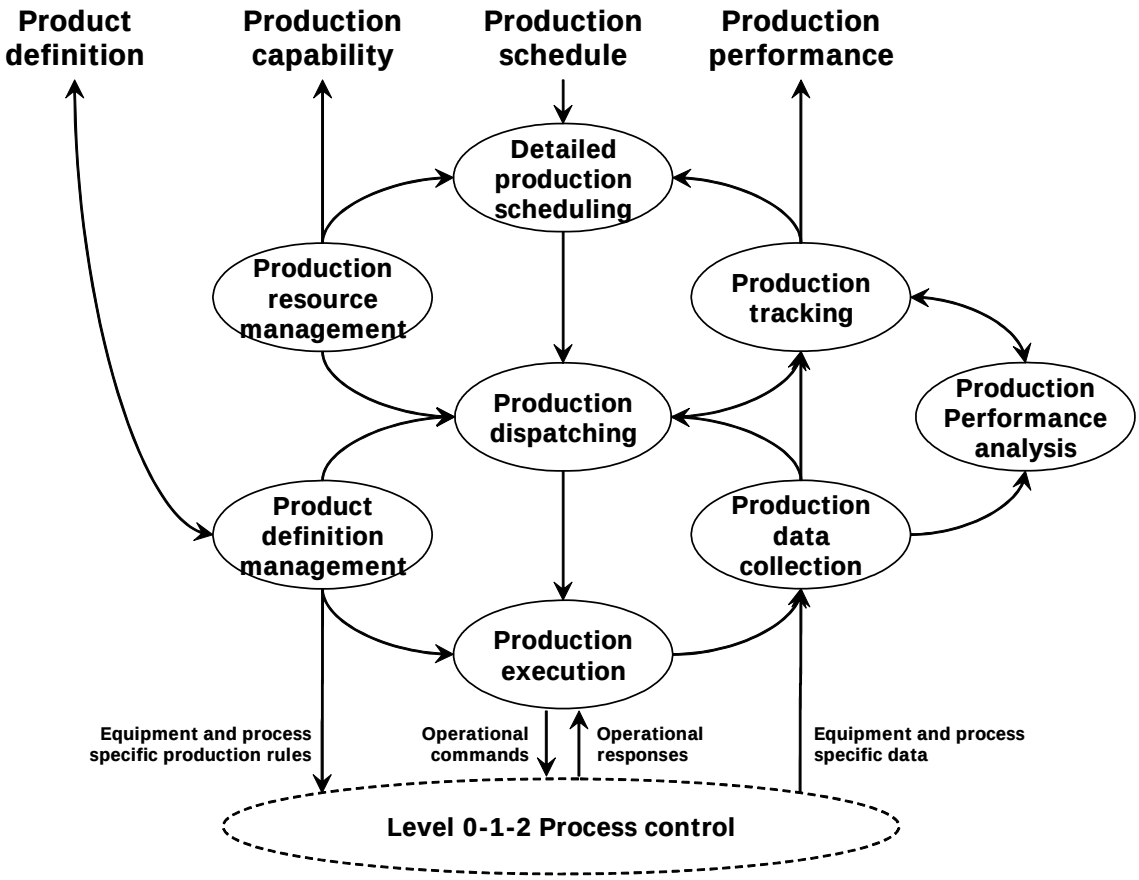


Figure 8 - Activity model of production operations management

Not all production requests and production responses have to 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.

6.3 Information exchange in production operations management

6.3.1 Equipment and process specific production rules

Equipment and process specific production rules are the specific instructions to equipment that are downloaded to the equipment based on the specific tasks assigned to the equipment. Examples of this include 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 1 equipment.

Note: See IEC 61131-3 for examples of this type of data.

6.3.2 Operational commands

Operational commands are information that is sent to Level 2 and Level 1 process control personnel and equipment, usually commands to start or complete production steps. This information may also be SOPs that are displayed or given to operators, such as procedures for setting up machines or cleaning of machines. This information exchange corresponds to the recipe-equipment interface defined in IEC 61512-1.

6.3.3 Operational responses

Operational responses are information that is received from Level 2 production equipment, usually corresponding to the completion or status of production steps. This information exchange corresponds to the recipe-equipment interface defined in IEC 61512-1.

6.3.4 Equipment and process specific data

Equipment and process specific data is information that is received from Level 2 production equipment about the equipment performing the production functions.

6.4 Product definition management

6.4.1 Activity definition

Product definition management is the collection of activities that manage all of the site or area information about the product required for manufacturing, including the product production rules. The 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-S88.01-1995 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 & 1 equipment. When that is the case, downloads of this information will usually be coordinated with other manufacturing operations management functions, so as to avoid affecting production. This information may be included as part of operational commands when the download is done as part of a production execution coordination activity.

6.4.2 Activity model

Figure 9 illustrates some of the interfaces to product definition management.

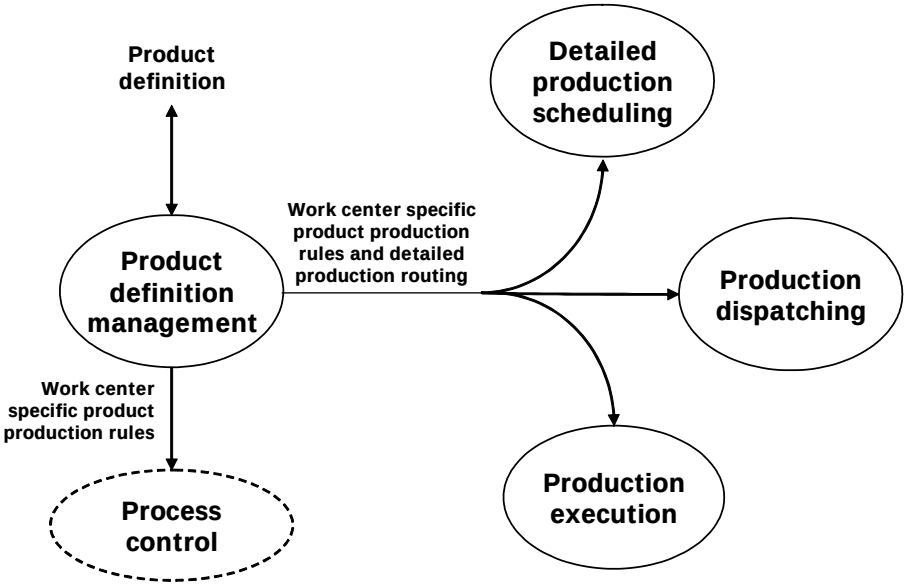


Figure 9 - Product definition management activity model interfaces

6.4.3 Tasks in product definition management

Product definition management tasks 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 other applications, personnel or activities, in the form of manufacturing steps, master recipes, machine setup rules, and process flowsheets.

e) Maintaining the detailed production routing for the product.

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 not related to product, such as for cleaning, startup, and shutdown.

j) Managing the Key Performance Indicator (KPI) definitions associated with 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 involve translation to production steps such as: master recipes, machine setup rules, and process flowsheets.

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 to get the work done and interacts with research development and engineering to obtain the *product production rules* for executing the work. For instance the production dispatching activities may need to refer to *production dependencies* to identify when a specific resource will be required.

The Product Production Rule identifies production steps and establishes relationships between them. Each production step 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 production step dependencies. These are sometimes called a production route, master business system route, master route, or business route. Detailed production step routing may be a finer granularity of definition than what is visible to business systems, but which is required for routing of work between work centers (process cells, production lines, and production units). Detailed production step routing is organized by the physical production process, and not by the view of business processes using product segments and process segments.

6.5 Production resource management

6.5.1 Activity definition

Production resource management is the collection of activities that manage the information about resources required by production operations. These 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 of information about segments of production is also an activity in resource management.

The scope of the production resource management activities may be at a site level, area level, or at work center levels.

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

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 10 illustrates some of the interfaces to production resource management.

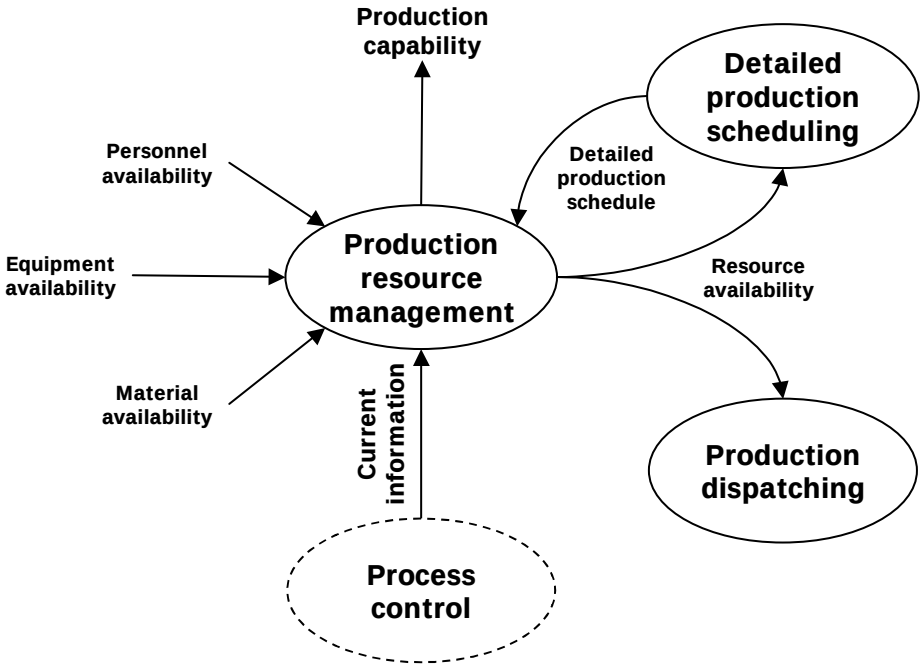


Figure 10 – Production resource management activity model interfaces

6.5.3 Tasks in production resource management

Production resource management tasks 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 information.

j) Maintaining equipment capability test information.

k) Managing reservations for future use of resources.

6.5.4 Resource availability

Resource availability provides time specific definitions that are 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 11 illustrates the types of information about the capacity of a single resource that may be provided by resource management.

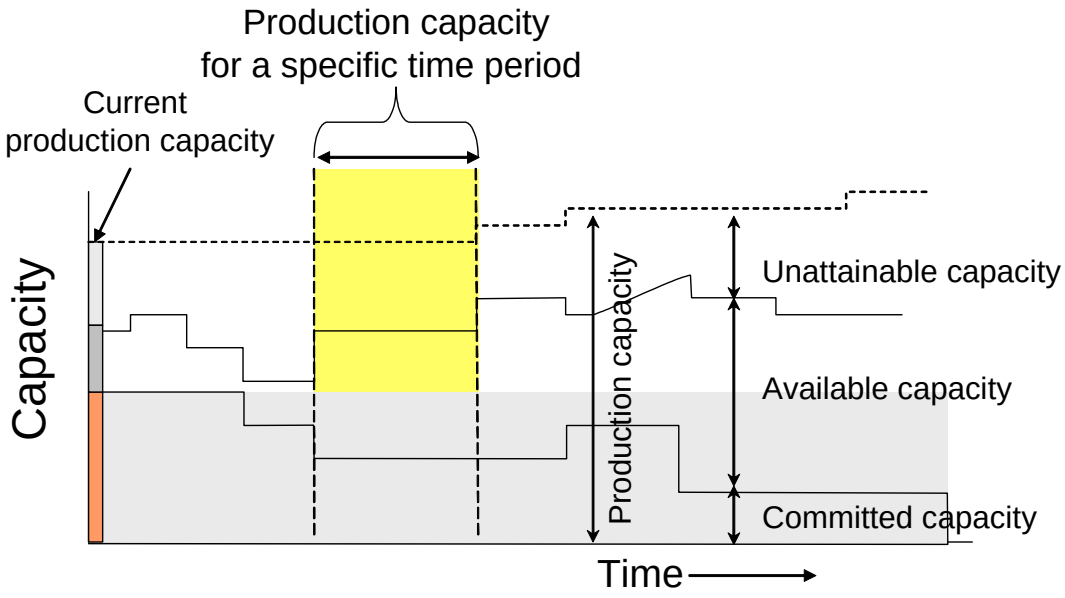


Figure 11 - Resource management capacity reporting

6.5.5 Collecting future committed resource information

Production resource management must manage committed resource availability based on the detailed production schedule. An assigned resource will change from being available to being committed for the period of time defined by the production plan, or until signaled by the completion of the scheduled task.

Note: Once the schedule window requiring the resource is completed, the resource is usually taken back to the available state, unless it is 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 will relay 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 an activity in 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 will prevent 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 management level. Each member of the personnel may have recognized skills through qualification tests results. This will define a skill profile that production resource management must be aware of in order 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 an activity in resource management.

Maintenance operations will 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. This test result will determine 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 an activity in 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 usually indicated from *QA test results*.

Example: A material lot may change from “dry” to “wet”, with a ph change from 7.0 to ph 7.1, or available electrical power may change from 300KW to 280KW.

6.6 Detailed production scheduling

6.6.1 Activity definition

An activity of manufacturing operations includes local planning and scheduling of production and resources. Enterprise-level planning systems often do not have the detailed information required to schedule specific work centers, work center elements, or personnel. Detailed production scheduling takes into account local situations and resource availability.

Detailed production scheduling takes the production schedule and determines the optimal use of local resources to meet the schedule requirements. This can 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.

6.6.2 Activity model

Figure 12 illustrates some of the interfaces to detailed production scheduling.

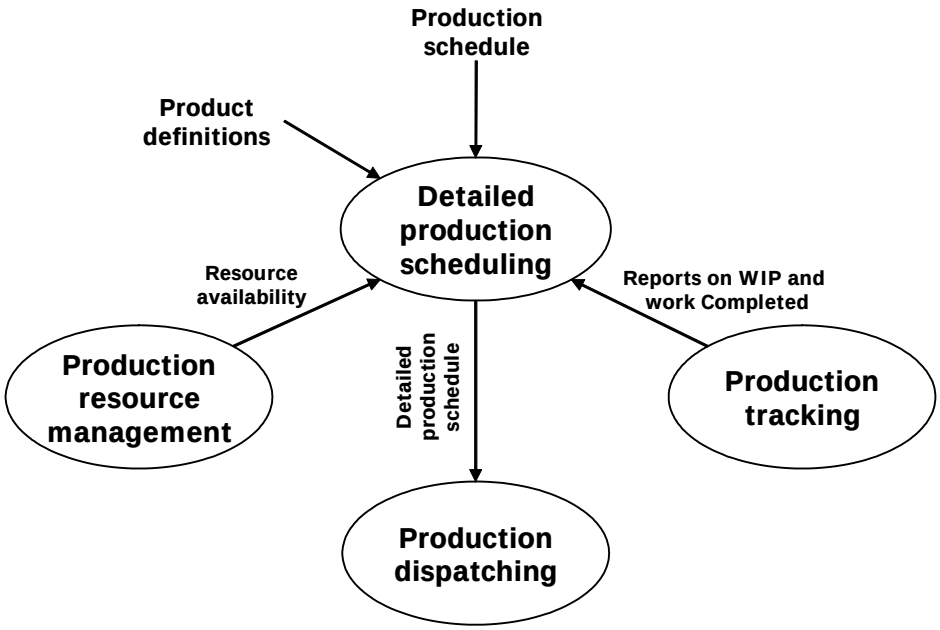


Figure 12 - Detailed production scheduling activity model interfaces

6.6.3 Tasks in detailed production scheduling

Detailed production scheduling tasks 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.

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.

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 equipment, such that no production requirement exceeds the capacity available to the production equipment

Finite capacity scheduling is usually 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 13 illustrates how a single production schedule can be split into multiple detailed schedules that are sent to dispatching. The left side of Figure 13 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 days of production.

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

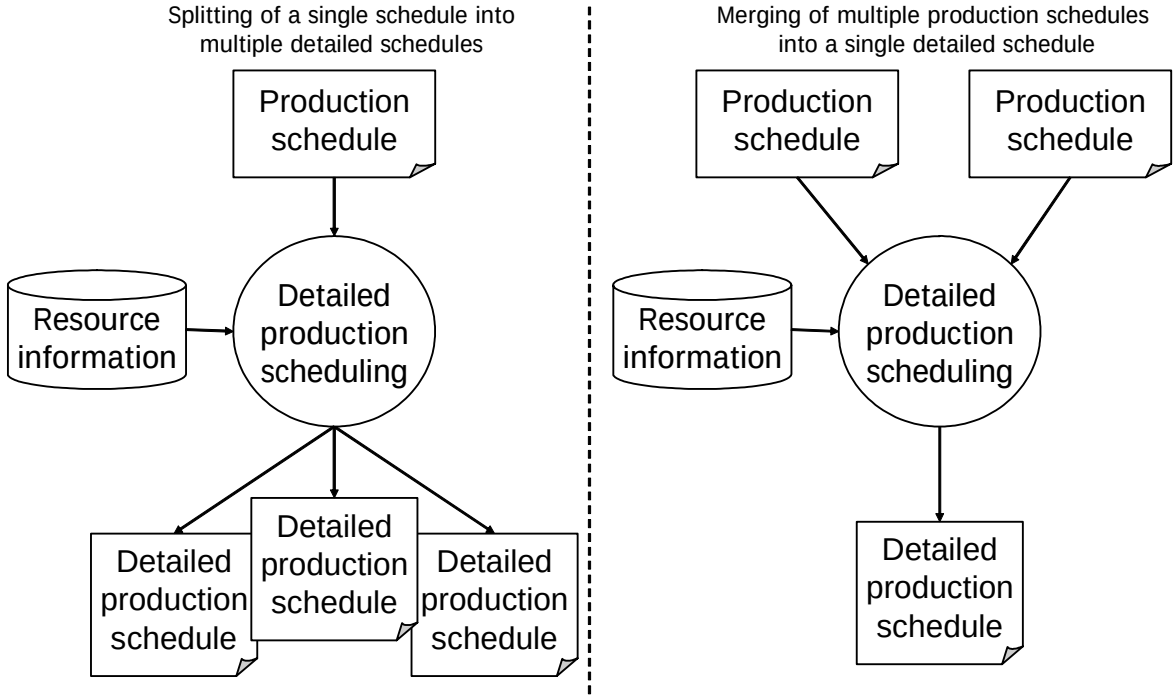


Figure 13 - Splitting and merging production schedules to detailed production schedules

One common function of detailed production scheduling involves merging production requests into single elements of work for purposes of reducing startup and switch over 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 determination of campaigns, 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.

6.6.6 Detailed production schedule

A detailed production schedule is a collection of *production work orders* and their sequencing involved in production of one or more products, organized as required for manufacturing. It may define the generation of intermediate material that may not be included as part of higher level scheduling definitions. A detailed production schedule ties physical and/or chemical *production steps* to specific production equipment or classes of production equipment, with specific starting times or starting events, through production work orders.

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 production steps. For example the detailed production schedule may define the various sub-levels of “operations oriented” *production steps* 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 14 illustrates an example detailed production schedule for equipment that is represented in a GANTT chart format. Each of the colored polygons in the figure represents a *production step* and each color represents a work order or job.

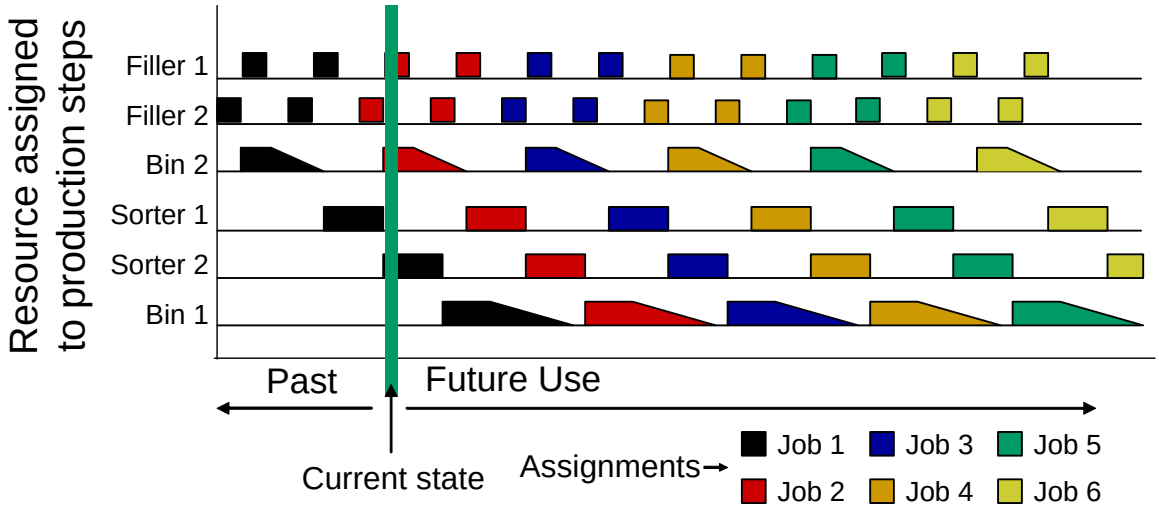


Figure 14 - Detailed production schedule

6.7 Production dispatching

6.7.1 Activity definition

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

– Scheduling batches to start in a batch control system

– Scheduling production runs to start in production lines

– Specifying operating conditions in production units.

– Sending work orders to work cells

The dispatching may take the form of starting procedures for manual operations.

Example: The procedures can be for such activities as machine setup, grade change switchovers, equipment cleaning, run rate setup, or production flow setup.

6.7.2 Activity model

Figure 15 illustrates some of the interfaces to production dispatching.

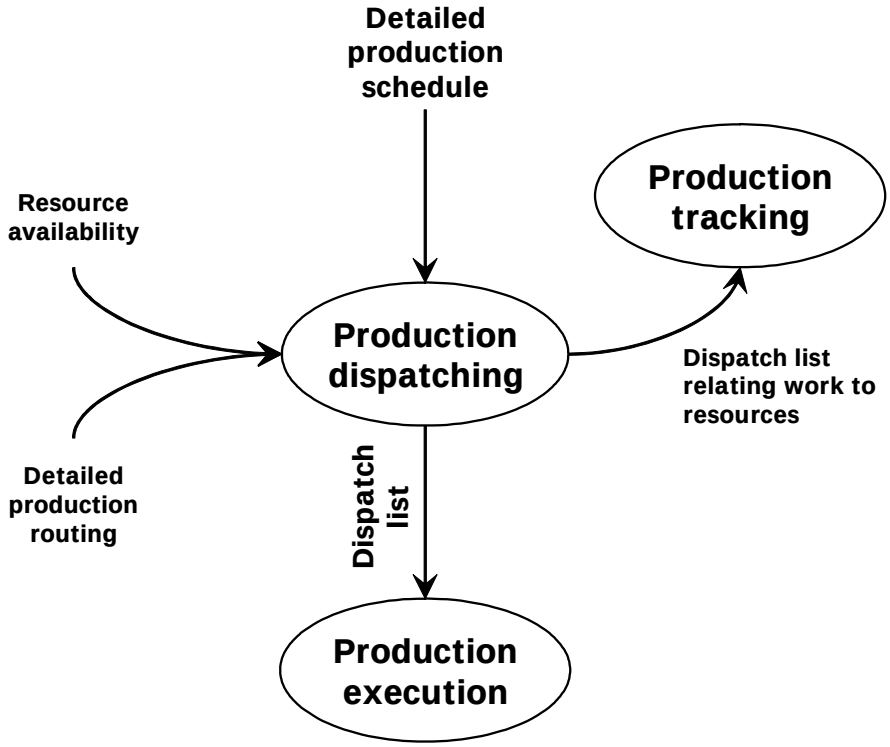


Figure 15 – Production dispatching activity model interfaces

6.7.3 Tasks in production dispatching

Production dispatching tasks include:

a) Initiating the execution of the detailed production schedule elements, at the times identified by the schedule.

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

c) Handling conditions that were 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.

d) 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.

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

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

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

The production dispatching activities send, or make available, the dispatch list specifying the production activities to be performed.

6.7.4 Dispatch list

A dispatch list is the set of production work orders that are ready to be executed. They define the specific production activities to be performed at production lines, production units, process cells, or storage zones (when inventory is managed by production). Each dispatch list includes the time or event to start the activity that is specified in the detailed production schedule.

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

Note: The detailed production schedule might include visibility into customer orders from the business systems. For example, production dispatching would translate the list of active customer orders the business decided to make this week or this shift into a lot dispatch list or a list of shop floor work orders. At the individual manufacturing cell level, then, the line supervisor would decide which lot to start first and begin its execution, transacting it through a series of operations as defined in the manufacturing route for the particular item to be made.

6.7.5 Assigning work

Production dispatching includes:

– Assigning material to work

– Assigning work to equipment

– Assigning work to personnel

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.

Figure 16 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, dispatch lists would specify setup for a continuous premix operation, including any initial charging. The 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.

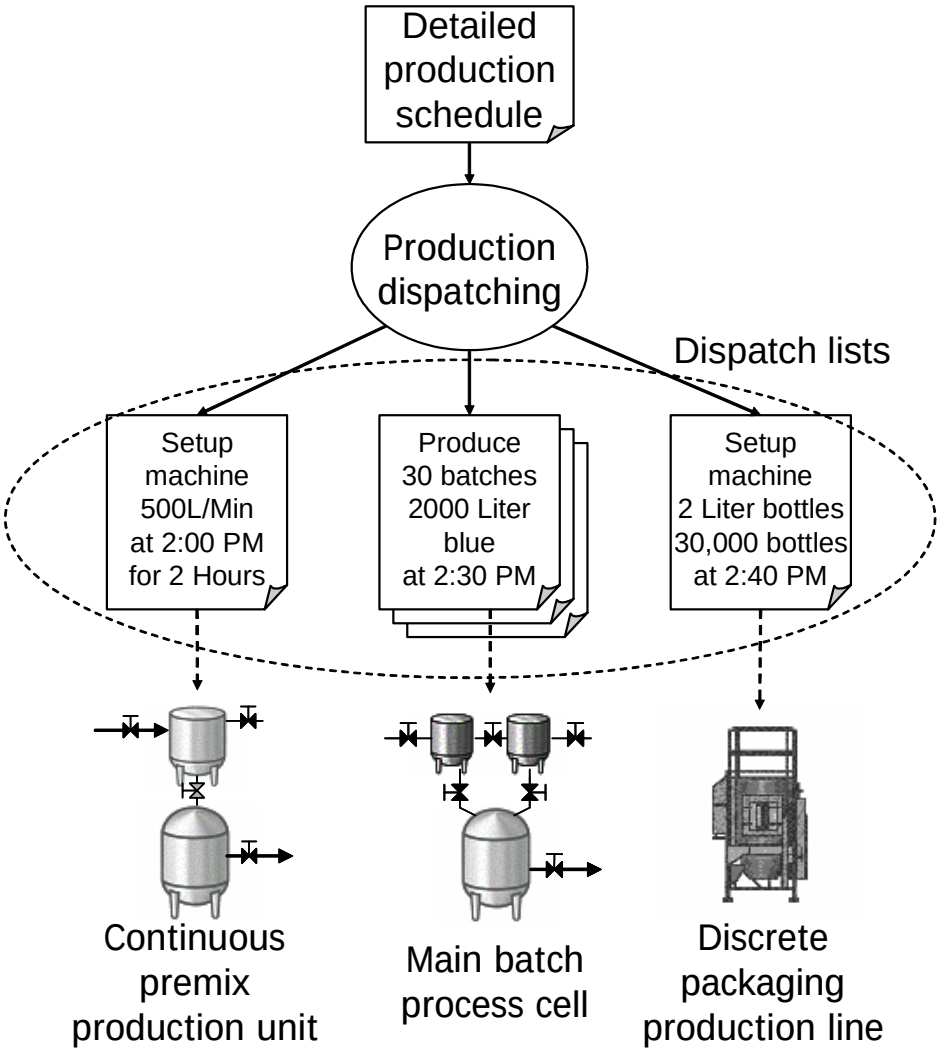


Figure 16 - Work dispatching for mixed process facility

6.8 Production execution

6.8.1 Activity definition

Production execution is the set of activities that direct the performance of work, as specified by the contents of the dispatch list elements. The production execution activity takes care of 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 that is 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.

The information flow from Production Execution to Process Control, for a discrete assembly operation, might take the form of a kanban signal to a machine operator to start work, or an event signal to start a part through a machine cell. It represents the signal to perform actual operations such as metal cutting, combining chemicals, or causing some direct physical change in material.

Production execution 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 17 illustrates some of the interfaces to production execution.

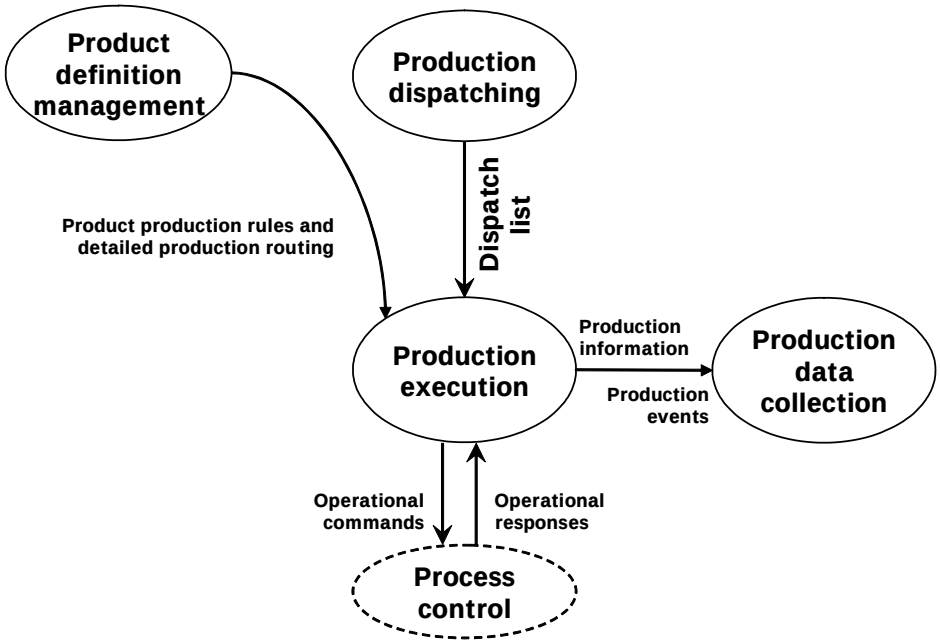


Figure 17 - Production execution activity model interfaces

6.8.3 Tasks in production execution

The production execution 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 tasks include:

a) Direct the performance of work.

Note: When production is performed manually, production execution activities include displaying specific work instructions to manufacturing personnel. The display of specific work instructions may be done in an automated manner.

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

c) Confirming that the work is done according to the accepted quality standards. This may involve receiving information from quality that indicates an unanticipated condition.

d) Ensuring that equipment certifications, personnel certifications and materials statuses 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).

e) Ensuring the dynamic allocation of resources under local run time control.

Example: The allocation 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, 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

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 sensor and actuator statuses. The manufacturing operations activities include collecting and managing this data for specific work processes or specific production requests. 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 signals or event signals added to give context to the collected information.

6.9.2 Activity model

Figure 18 illustrates some of the interfaces to production data collection.

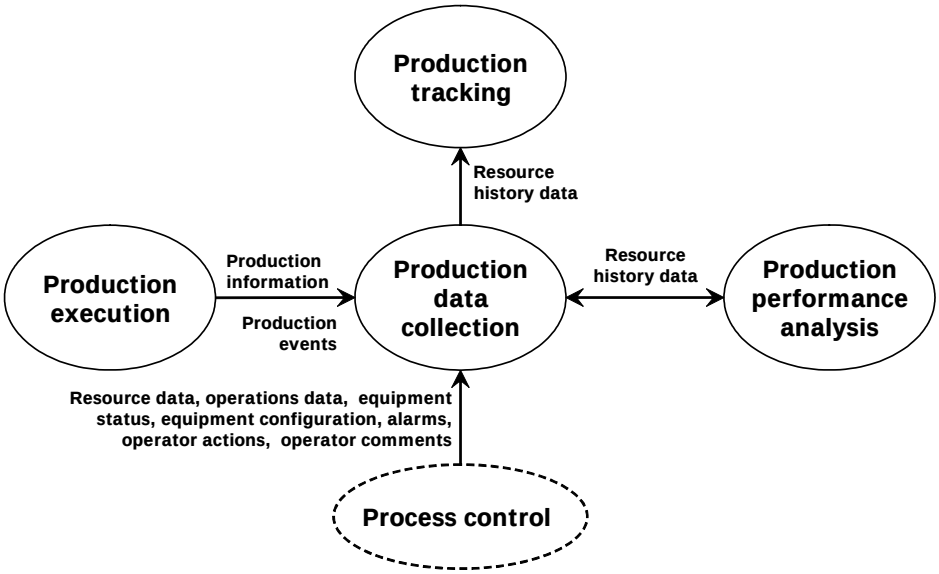


Figure 18 - Production data collection activity model interfaces

6.9.3 Tasks in production data collection

Production data collection tasks include:

a) Collecting, retrieving and archiving information related to the execution of production equipment and 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 standardized or on-demand reports for operations and manufacturing personnel.

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 product genealogy 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 product quality information for comparison against specifications.

6.10 Production tracking

6.10.1 Activity definition

Production tracking is the activity that prepares the *production response* for Level 4 as defined in Part 1 of this standard. This response includes summarizing and reporting information about personnel and equipment actually used to produce product, material consumed, material produced, as well as other relevant production data such as genealogy, costs and performance analysis results. This activity 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 19 illustrates some of the interfaces to production tracking.

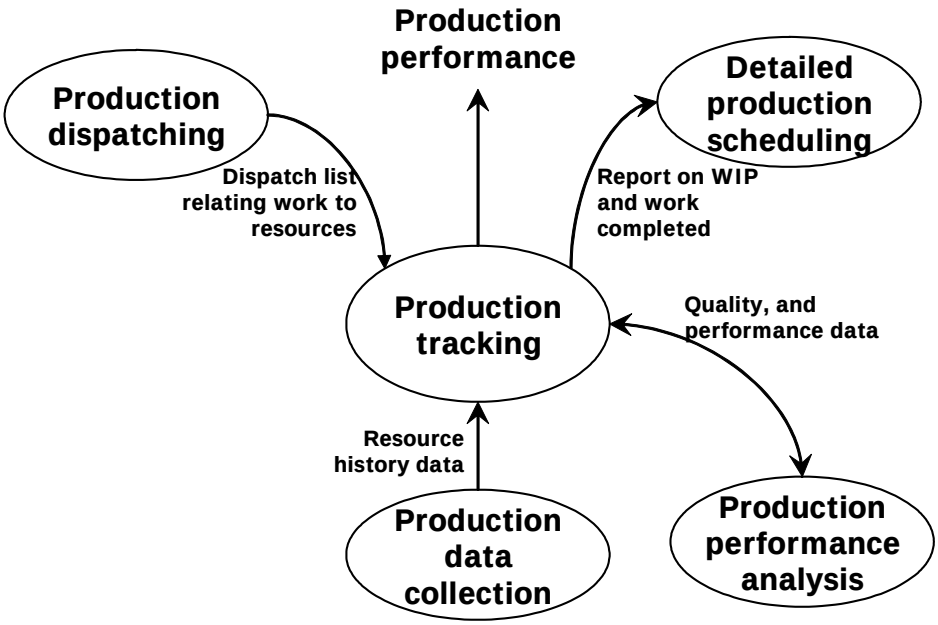


Figure 19 - Production tracking activity model interfaces

6.10.3 Tasks in production tracking

The essential elements of production tracking are movements and segments.

Production tracking tasks 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 from the point of production to the shipping dock.

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 genealogy) and information on plant environmental conditions during the production of the lot.

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

e) Providing information for genealogy analysis.

f) Generation of production performance and production responses. 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) Generation of electronic 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. This 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 20.

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.

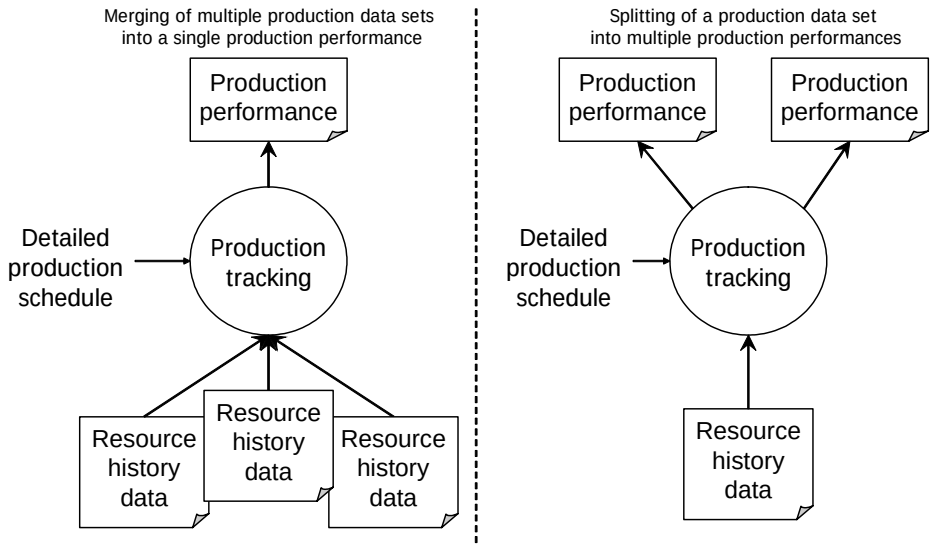


Figure 20 - Merging and splitting production tracking information

6.11 Production performance analysis

6.11.1 Activity definition

Production performance analysis provides feedback about production back to enterprise logistic systems. Such information may be provided on a scheduled basis, it may only be provided at the end of production runs or batches, or it may be provided on demand.

Production performance analysis also includes the analysis of information of production unit cycle times, resource utilization, equipment utilization, procedure efficiencies, and production variability. This information is normally used to optimize production and resources.

Production performance analysis is a continuing process. 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 reexamine throughput and policies under current and expected conditions in order to maximize system throughput.

6.11.2 Activity model

Figure 21 illustrates some of the interfaces to production performance analysis.

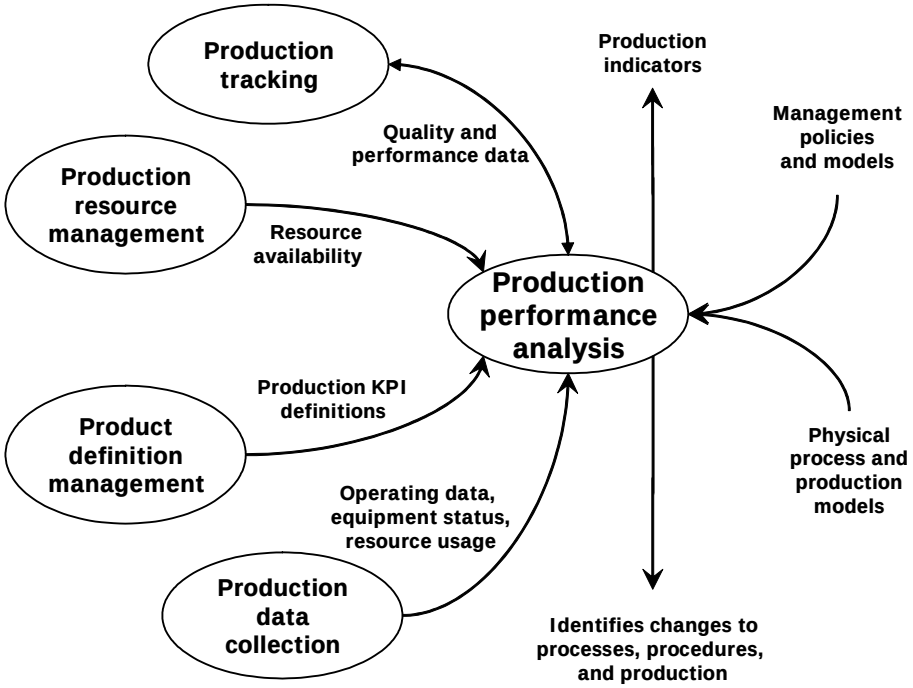


Figure 21 - Production performance analysis activity model interfaces

6.11.3 Tasks in production performance analysis

Production performance analysis tasks typically 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) Determine 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) Predict 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 production steps, product segments, and process segments, 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 set points were used, which procedure,...), where it happened, when it happened, and who performed it?".

Note: In addition to this main question, questions related to resource tracking 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 traces the history of all resources (material, equipment, and personnel) in terms of the process actions and events that dealt with the resources in production. This includes:

— Which materials were produced, consumed, stored, and moved.

— Which equipment was used in production, testing and storage.

— Which personnel were 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 so on. 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 section 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.

Traceability has two components, tracking and tracing.

1. Tracking involves monitoring a resource and all its inputs through all steps and agents
2. Tracing involves following a resource from any point, forward or backward, using the tracking information.

Note 4: For example material tracing may be characterized as:

a) Forward material tracing - Which shows the upstream history of the material as inputs to manufacturing processes and the equipment used to transfer the material

b) Backward 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-process or off line. In process testing involves real time measurements collected to assure proper product quality and identify problems requiring attention. Product analysis also includes the off line analysis typically performed in laboratories and the

management of quality test procedures. The activities associated with off line product analysis are defined in Section 7.11.

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 the 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 will flow through the plant and evaluate how the process will respond 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, track change affects and for operator training. Simulation can provide the following benefits to production:

- Cost Avoidance - Adding additional capacity without significant addition of new equipment, machinery, or labor
- Optimized Performance - Increasing the efficiency and effectiveness of an existing system
- Discovering Hidden Value - Eliminating bottlenecks, using existing assets better
- Continuous Improvement programs - evaluating possibilities for quality and throughput improvements or cost reductions
- Improved ability to meet deadlines, customer commitment, and changing customer requirements
- Operator Training – Simulation systems are used to 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 Part 1 and Part 2 of this standard 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.

Examples of Production Indicators include (*from the APQC site* (*www.apqc.org*)):

- Actual versus planned volume
- Average machine availability rate or machine uptime
- Capacity utilization
- Defective lots, sublots, or items (ppm)
- Finished product first-pass yield
- Hours lost due to equipment downtime
- Major component first-pass yield
- Manufacturing cycle time for a typical product
- Number of items exceeding shelf life
- Number of line stops
- Number of process changes per operation due to errors
- Number of processes with yields at six sigma
- Percentage of assembly steps automated
- Percentage increase in output per employee
- Percentage reduction in component lot sizes
- Percentage error in yield projections
- 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 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 effort
- Scrap and rework percentage reduction
- Scrap material value - total material value
- Standard order-to-shipment lead time for major products
- Supplier parts scrapped due to engineering changes
- Time line is down due to sub-assembly shortage
- Time required to incorporate engineering changes
- Total scrap and rework as a percentage of sales
- Units produced per square foot or meter of manufacturing and storage space
- Warranty effort reduction
- Warranty repair costs/sales
- Yield improvement

6.11.9 Performance Management

Performance management is the systemic capture, management, and presentation of information in a consistent framework that is combined with 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 Key Performance Indicators (KPIs)

— Ability to roll-up KPI information in a model

— Root Cause Analysis

— Prediction of future KPI values

— Capability to enact control based on KPI values

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

Example: This could be the ability to roll-up all inventory along product families down to the individual product stock-keeping unit (SKU). A simple model could just be a summation of all child node values of an indicator.

Performance indicators that are not visible significantly decrease the value of the performance management system. This can be compared with typical traditional report systems 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: A typical 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 typically indicate an indicator has exceeded acceptable ranges. White lights typically represent 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: This could include the ability to drill out of the performance management system an indication of *First Pass First Quality* yield to the 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 estimating future values.

Example: An example might be to take the historical mean time between failure (MTBF) values and develop a slope to predict the next MTBF for a piece of equipment.

Performance management includes the ability to take a control action based on an out-of-specification indicator. Automated workflow engines can be used to ensure consistent action and timing.

Example: An automatic reduction 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

7.1.1 Maintenance activity categories

Maintenance operations management are the collection of activities that ensure the availability of equipment and tools for both manufacturing operations and manufacturing operations management. There are four main categories of maintenance activities:

a) Providing corrective maintenance responses to immediate equipment problems.

b) Scheduling and performing preventive maintenance, such as on a periodic cycle.

c) Providing condition based maintenance based on information obtained from the equipment or which can be inferred about the equipment. This includes predictive maintenance based on a prognosis of expected future failure.

d) In some industries maintenance activates also include optimizing equipment operating performance and efficiencies, functions that could also be considered as production and process analysis.

7.1.2 General maintenance activities

General maintenance activities typically include:

— Providing corrective, preventive, and condition based maintenance

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

— Developing maintenance cost and performance reports

— Coordinating and monitoring outside contract work effort

— Supervision of requested maintenance

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

— Coordinating planned work with operators and plant supervision

— Making performance verifications of production equipment

— Calibrating production equipment and/or sensors/actuators

— Assisting with product changeover needs that involves equipment changes

— Monitoring and updating maintenance history files

7.1.3 Repair and improvement

All maintenance activities also often fall into two broad categories for accounting purposes: repair and improvement. The activities performed in these two categories are often identical, but are segregated for purposes of reporting, accounting and asset management.

— "Repair" is associated with re-establishing the status quo of existing assets and is viewed as an expense cost.

— "Improvement" is associated with adding asset value to the existing asset base and is a capitalized cost.

7.2 Maintenance operations management activity model

The model shown in Figure 22 defines the activities of maintenance in manufacturing operations. The model defines what maintenance activities should be done and the relative sequencing of those activities, not how they should be performed in a specific organization structure. Different companies may have a different organization of roles and assignment of roles to personnel or systems.

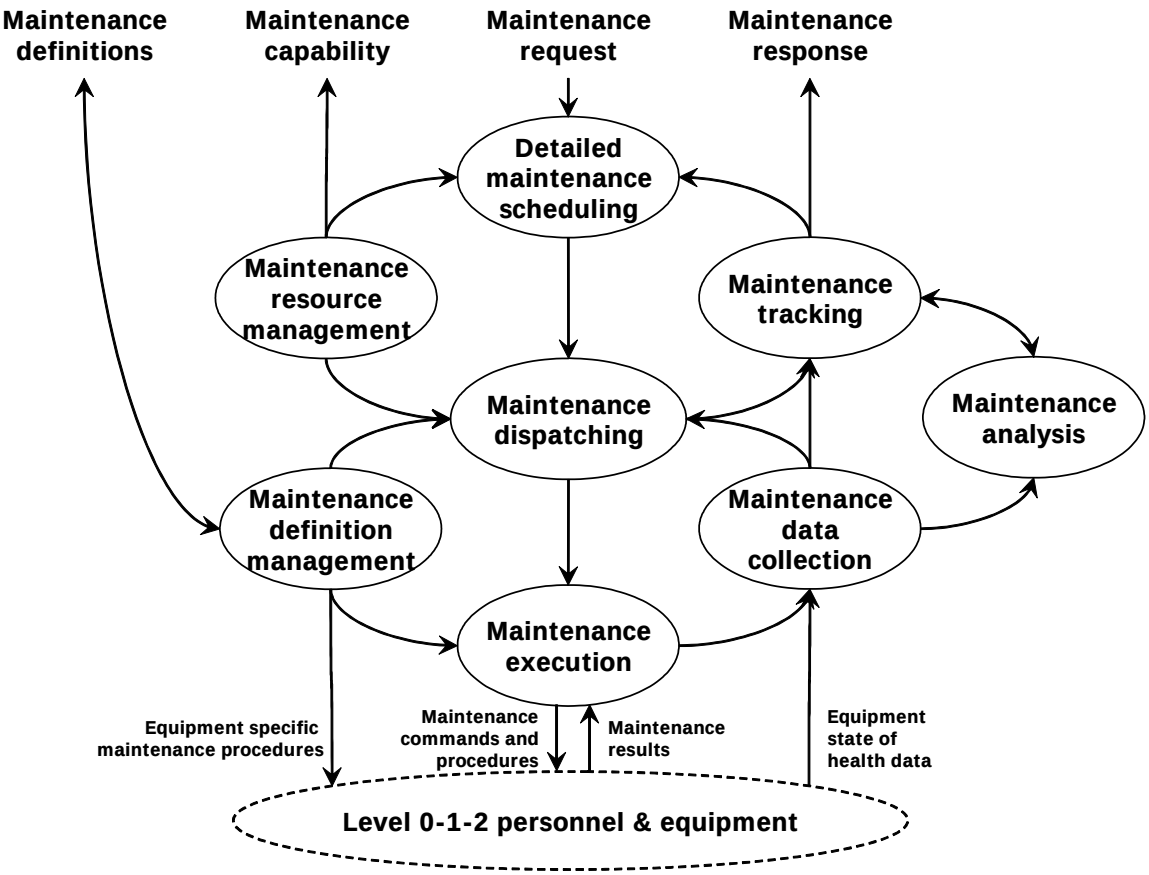


Figure 22 - Activity model of maintenance operations management

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 22 only illustrates some major information flows between activities.

7.3 Information exchanged in maintenance operations management

7.3.1 Maintenance information

Maintenance requests and maintenance responses do not always cross the boundary between Level 3 and Level 4 systems. Maintenance requests and maintenance responses are often generated internally within manufacturing operations. Maintenance requests and maintenance responses may be exchanged individually or as sets. An organized set of requests can be considered a maintenance schedule.

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 are the documentation sets for the manufacturing assets under maintenance. These include equipment and system drawings (with maintenance additions and deletions), engineering documentation, specifications, vendor's handbooks, 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 what 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 sub-activity, 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 is the expected future available, committed, and unattainable maintenance capacity. Maintenance capability is based on the capability in:

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

— Equipment – Such as calibration equipment and special tools.

— Material – Such as maintenance consumable materials and spare parts.

7.3.4 Maintenance request

Maintenance requests are requests for maintenance services. These may be for corrective maintenance, preventive maintenance, and condition based maintenance. *Maintenance requests* may be generated from Level 3 or Level 4 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 is often done with significant coordination with production and process analysis activities to perform tests and implement improvements or changes.

7.3.5 Maintenance response

Maintenance responses are the documented 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 are the specific instructions for equipment that are downloaded to the equipment based on specific tasks assigned.

Examples: 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 preventative or predictive maintenance.

7.3.7 Maintenance commands and procedures

Maintenance commands and procedures are information for Level 2 and Level 1 personnel and equipment 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 for relevant maintenance information.

7.3.8 Maintenance results

Maintenance results are information that is received from Level 2 and Level 1 personnel and equipment, usually corresponding to the completion of maintenance commands and procedures. This may include detailed data on maintenance activities that were determined 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" clearance gap, and put back into service."

7.3.9 Equipment state of health data

Equipment state of health data is information that is collected from equipment, usually on a regular basis, which indicates the health of the equipment. This information is 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 when the rate of change of a valve's time-to-close rate of change exceeds a specified limit

Note: See ISO 13374-1 *Condition monitoring and diagnostics of machines — Data processing, communication and presentation* for examples of this type of data.

7.4 Maintenance definition management

Maintenance definition management is the activity of defining, managing, and maintaining the information and instructions necessary to complete maintenance tasks. The information is used to provide direction for executing maintenance and includes the activity of managing all of the maintenance definitions and the associated bill of material and bill of resource.

Maintenance definition management includes:

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

b) Managing new 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, 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 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 Key Performance Indicator (KPI) definitions associated with maintenance.

Maintenance definition management includes management of the distribution of maintenance definitions. Some of the maintenance definitions may exist in Level 2 and Level 1 equipment. When that is the case, downloads of this information will usually be coordinated with other manufacturing operations management functions, so as to avoid affecting production. This information may be included as part of maintenance commands and procedures when the download is done as part of a maintenance execution coordination activity.

Note: Maintenance definition management must address all aspects of process safety management, including "replacement in kind" part substitutability, if allowed by the corporation and permitted within the process safety management regulations.

7.5 Maintenance resource management

Maintenance resource management is defined as the collection of activities that manage the information about the state of the resources used within the sphere of control of maintenance.

The resources 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 includes:

— The maintenance of the information about maintenance personal, including qualification information, such as qualification status and qualification test results, as defined in the Part 1 and Part 2 personnel model.

— The maintenance of information about equipment used in maintenance and equipment capability tests, as defined in the Part 1 equipment model.

— The maintenance of information about maintenance supplies, defined as consumable materials, as described in the Part 1 material model.

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

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 is the collection of activities for:

— Reviewing maintenance requests.

— Confirming or denying the maintenance request.

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

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

A detailed maintenance schedule is generated for each site or area, based on the required maintenance work orders and available resources (personnel, equipment, and materials). A detailed maintenance schedule maintains the requirements and develops the necessary time series 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 is the activity that assigns and sends maintenance work orders to the appropriate maintenance resources as identified by the 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 that are not assigned as part of the detailed maintenance schedule may be assigned by the maintenance dispatching activity.

7.8 Maintenance execution

Maintenance execution is the set of activities that execute the dispatched maintenance work. Maintenance Execution has the:

— Responsibility to perform the assigned work

— Responsibility to ensure that maintenance procedures and regulations are followed during maintenance activities.

— Responsibility to document the status and results of the work done.

— Has the responsibility to inform maintenance dispatching and/or detailed maintenance scheduling when unanticipated events result in the inability to meet the work requirements.

— Confirming that the work was done according to the accepted quality standards. This may involve receiving information from quality operations that indicated an unanticipated condition.

— Responsibility to ensure that the correct resources are used in maintenance.

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

7.9 Maintenance data collection

This activity summarizes and reports the information and events surrounding the disposition of the maintenance work order. Information includes 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

The maintenance tracking activity is 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 generation or updating of electronic records related to the maintained equipment condition (e.g. dirty or clean) and usability (e.g. qualified for use or unqualified for use). This may include records required for regulatory or quality management purposes.

Maintenance tracking includes the activity of tracking the state of the equipment used to perform the maintenance (e.g. handheld sensor calibration tool, voltmeters, and oscilloscope).

7.11 Maintenance analysis

Besides the tasks performed within each of the other maintenance operations activities, *maintenance analysis* includes activities that examines the equipment history to identify the "top ten" problem areas by level of effort, economic impact on the manufacturing facility, frequency of repair, cost of repair, etc.

Maintenance analysis functions 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 can routine preventive maintenance activities be reduced

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

Maintenance analysis also assists 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 risk of successfully producing X amount of product next week

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

— 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.

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. 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.

Examples of Maintenance Indicators include (from the APQC site (www.apqc.org)):

- Labor hours spent on preventive maintenance per area and/or per workcenter
- Maintenance cost/equipment cost ratio
- Maintenance cost/output unit ratio

- Number of unscheduled maintenance calls per area and/or per workcenter
- Production time lost because of unscheduled maintenance activities
- Percentage of equipment maintained on schedule
- Waste caused by equipment problems

8. Quality operations management

8.1 General activities in quality operations management

8.1.1 Quality operations management activities

Quality operations management is the collection of activities related to measuring and reporting on quality. Typical quality operations include: testing and verifying the quality of materials (raw, final, and intermediate), measuring and reporting the capability of the equipment to meet quality goals, and certifying product quality.

8.1.2 Types of testing

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

— Tests of material, suppliers, equipment, or other resources - Testing of material, suppliers, equipment, and other resources is commonly a subject for quality testing.

— 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.

— Reference analyses tests - Reference analysis consists of sending known samples to various laboratories in order to check the performance of a specific laboratory (e.g., is the lab able to produce correct results).

8.1.3 When testing occurs

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

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

— 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.

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

8.1.4 Other quality operations

Quality operations may be required in any of the activities shown in Figure 1 to ensure that quality goals are met. This part of the standard focuses on quality test operations. There are other aspects of quality operations that are not defined in this part of the standard, such as:

— Conducting periodic quality evaluations

— Setting standards for material quality

— Setting standards for product specifications

— Creating and reviewing procedures and processes to ensure that quality is defined and maintained

8.1.5 Quality systems

Multiple different systems may support quality operations. Typically these may include Laboratory Information Management Systems (LIMS), historian systems, batch management systems, or SPC (Statistic Process Control) or SQC (Statistic Quality Control) systems.

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

8.2 Quality test operations activity model

The model shown in Figure 23 defines the activities of quality test operations in manufacturing operations, 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.

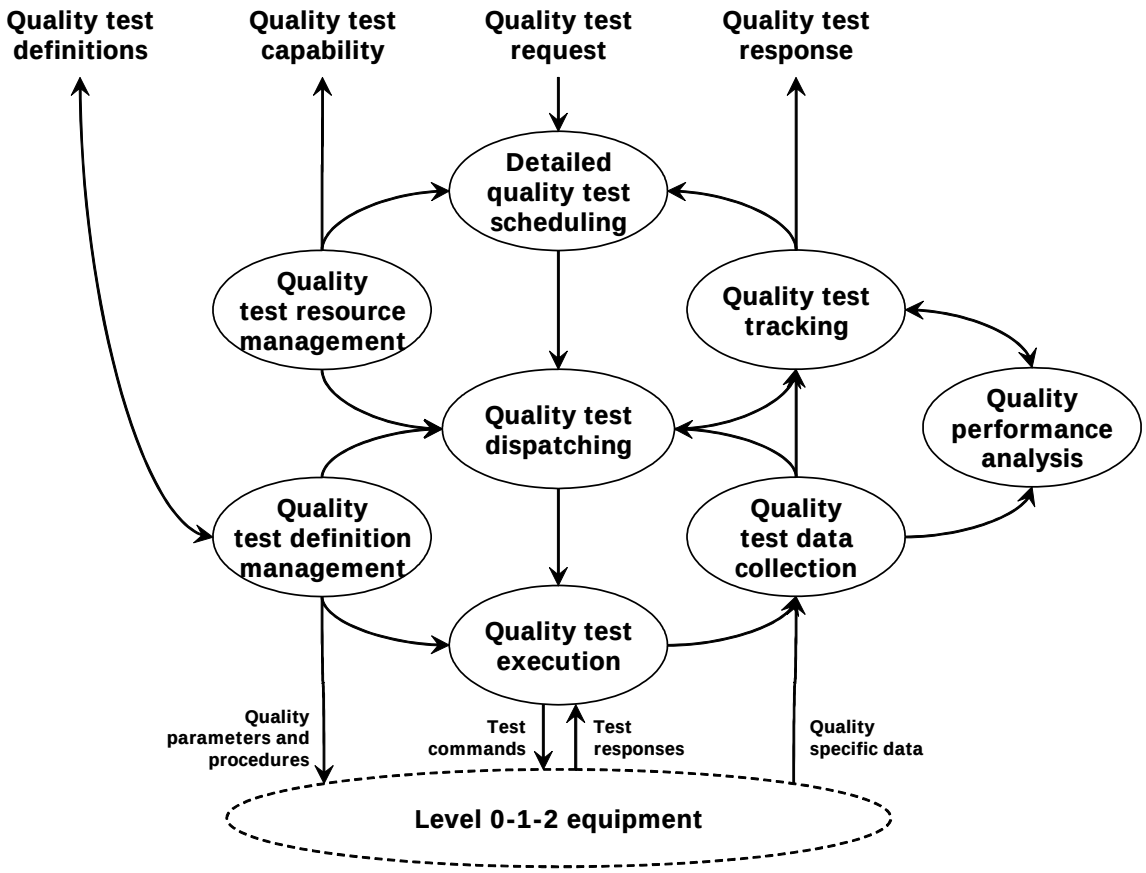


Figure 23 – Activity model of quality test operations management

The ovals in the quality test operations activity model indicate of 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 23 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 are test specifications for testing of materials, environment, and equipment. Quality test definitions are often downloaded to Level 3 from a Level 4 system e.g., 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. There may be significant interaction with maintenance operations in these control methods.

8.3.2 Quality test capability

Quality test capability is a combination of required resources and contains information about its status e.g., committed, available or unattainable.

8.3.3 Quality test request

Quality test requests are 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 are the result of 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 (typically due to the sample characteristics exceeding specification limits), test responses will typically include recommended corrective action responses such as continue the production execution with corrective adjustments, rework the operation, discard the material, discard the sample and acquire a new sample, or recalibrate the testing equipment.

8.3.5 Quality parameters and procedures

Quality parameters and procedures sent from Level 3 to Level 1-2 may include the test SOP (Standard Operating Procedures), calculations to be used, etc.

8.3.6 Test commands

Test commands sent from Level 3 to Level 1-2 may include context on the test to be executed (e.g. sample context as e.g. lot#), commands to start the instrument, etc.

8.3.7 Test responses

Test responses sent from Level 1-2 to Level 3 may include the test results, or messages such as “instrument is not available”, etc.

8.3.8 Quality specific data

Quality specific data sent from Level 1-2 to Level 3 may include in-line or at-line data usually sent in aggregated form (e.g. # measurements, minimum, maximum, average, standard deviation, etc.) with the appropriate context (process data, material, timeframe, location, etc.)

8.4 Quality test definition management

Quality test definition management is the activity that defines and manages 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 can cover different frequencies for certified vs. non-certified suppliers, e.g. always test non-certified suppliers vs. test certified suppliers only every 10^{th} deliveries except when the last delivery was non-compliant. The definition of the required tests covers the methodology (e.g. near infrared for moisture test), calculations, work instructions in terms of standard operational procedures (SOPs), etc. Quality test definition management also coordinates the version number, the effective dates, the disposition of materials, the approval(s), approval history and release status of quality tests definitions (e.g., in development, ready for use, obsolete, etc), and work instructions.

Quality test definition management tasks 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 is the activity that manages 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 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 – This includes material which is consumed during the execution of a test.

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

— Personnel – This 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.

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 includes planning and scheduling of resources to quality tasks, taking into account local situations and resource availability. Detailed quality test scheduling also takes into account 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 schedule 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 3 activity initiated test may occur when recipe system triggers a sample to be taken and the next production step waits for the laboratory results

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

Detailed quality test scheduling schedules test that may be regularly scheduled (for example, each raw material must be tested every month), or event generated by Level 1-2 activities

(for example, material arrives and a sample is pulled and sent to the lab), Level 3 activities (for example a recipe system triggers a sample to be taken and the next production step waits for the laboratory results) or Level 4 activities (for example 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 effected by another laboratory department inside or external to the 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, 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 is the activity that assigns and sends 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 the sending of the material to be tested to the testing resource.

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

8.8 Quality test execution

8.8.1 Introduction

Quality test execution is the collection of activities that directs the performance of testing. The quality test execution activity takes care of obtaining test samples, performing the test, and obtaining the results. Quality test execution ensures that the correct resources (equipment, materials and personnel) are used. It also includes the confirmation that the quality test is done according to the accepted quality standards and that the product can be released (under certain conditions).

8.8.2 Testing

8.8.2.1 In line testing

In-line tests are inspections that constitute an integral part of the production execution, they 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 control of quality test operations if they are designated as "quality critical instruments." These are

instruments that are 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 where the item to be tested is taken out of the production execution 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 results (minutes, hours, days) than at-line tests.

Off-line tests are usually under the control of quality test operations.

Note: Because of initiatives such as "First time right" and the FDA's PAT (Process Analytical Technology) initiative, there is a 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). Examples of pass/fail tests can be e.g., microbiological contamination present/absent, packaging OK/NOK, etc.

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 done correctly and done on the right sample. When re-tests are performed, there is usually the requirement to document all tests done, 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 usually 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 is the activity of collecting 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 only be for internal distribution, or may still require additional tests.

8.10 Quality test tracking

A typical lifecycle for a quality test may include: generate test request ID, assign test(s), generate sample ID, obtain samples, perform tests, assemble responses, and send responses. Quality test tracking is the activity that records the movement of the tests and timestamps through this lifecycle. The data tracked must be in accordance with relevant regulatory or policy definitions.

Quality test tracking includes the generation or updating of electronic records related to product quality. This may include records required for regulatory or quality management purposes.

Quality test tracking needs to support the tracking of tests that may be done at different times and at different parts of the plant.

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

8.11 Quality performance analysis

8.11.1 Introduction

Quality performance analysis includes the functions of analyzing quality test results and testing performance in order to determine how to improve product quality. These include the analysis of quality variability (e.g., non-compliance reports, KPIs and Quality indicators), quality department cycle times, resource utilization, equipment utilization and procedure efficiencies. Quality performance analysis is often a continuous business process. Quality performance analysis activities may include:

— Analyzing production data for trends of critical quality indicators (for example SPC and SQC analysis over time or across lots).

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

— Determining the cause of quality analysis problems.

— Recommending actions to correct identified problems, including correlating the symptoms, actions and results

— Providing information for use in supplier evaluations.

8.11.2 Quality resource traceability analysis

Quality 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:

— Which materials were used in quality activities.

— Which equipment was used in quality activities.

— 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. Examples of Quality Indicators include (from the APQC site (www.apqc.org)):

- Number of tests performed on schedule
- Number of complaints from manufacturing regarding test timing
- Number of customer complaints of defects not discovered in testing
- Number of manufacturing interruptions caused by supplier parts
- Number of requests for corrective action being processed
- 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 Other quality operations activities

Other quality operations activities directly support the following production operations:

— 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)

— Product Definition Management

- Quality assurance of Master Data including items utilized in production operations including items, 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.

— Production Execution

- 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

— Production Data Collection

- Statistical Quality Control (i.e. Process Analysis Technology)
- Data analysis for Quality Investigations (i.e. system of record)

— 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 (work-in-progress) and associated quality status.

— Production Dispatching - Based on input from scheduling, resource management, definition management and scheduling, quality attributes and status will impact on the implementation dispatching of resources.

— Production Detailed Scheduling - Information provided by Production Resource Management provides input into available resources based on quality status.

9. Inventory operations management

9.1 General activities in inventory operations management

Inventory movement and control operations is the collection of activities that manage the inventory of material, manage the transfer of material, measure and report on inventory and material transfer capabilities, and coordinate and control the personnel and equipment used in material transfer. There are other aspects of inventory operations that are not defined in this part of the standard, such as coordination with suppliers and distributors.

Inventory transfer activities may be under the control of manufacturing operations, if these activities meet the criteria defined in Section 4.3. In some industries and operations these

functions may be handled as part of the manufacturing operations activities (see Sections 6.10, 7.5, and 8.5), in other cases they may be handled as separate inventory transfer activities.

Functions that effect 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 sections. The movement and storage of material are functions that call for 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 24 defines the activities of inventory operations management as they relate to the transfer of materials between 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.

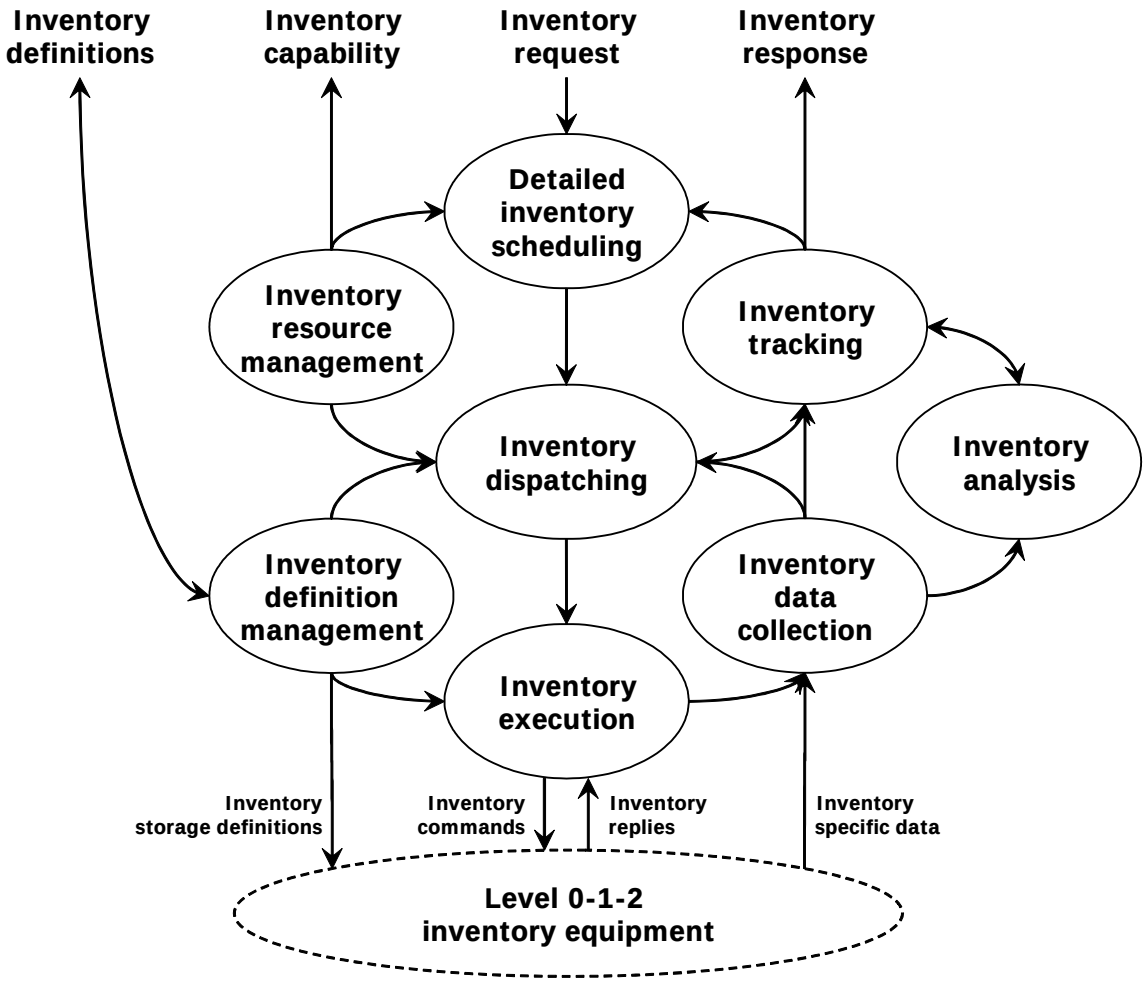


Figure 24 - Activity model of inventory operations management

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 24 only illustrates some major information flows between activities.

9.3 Information exchanged in inventory operations management

9.3.1 Inventory definitions

Inventory definitions are definitions of the rules associated with movement and storage of materials. The rules may be location specific and material specific.

Example: Inventory movement definitions may include environmental requirements for specific material types, rules for locations of storage (oils not stored above water), rules for containers-material selection, 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 is a capability measure of the ability to handle materials, usually for specific time horizons. Inventory capability may be characterized by the type of material, storage space (or volume) available, and type of storage (e.g. temperature 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.

9.3.3 Inventory requests

An inventory request is a request to transfer materials between storage locations in 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 is 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 definitions

Inventory definitions are information that is needed by Level 2 inventory equipment associated with movement and control.

Example: This may be routing rules implemented by automated sorting equipment, or load patterns for automated truck loading equipment.

9.3.6 Inventory commands

Inventory commands are information that is sent to Level 2 inventory equipment, usually commands to move or transfer materials.

9.3.7 Inventory replies

Inventory replies are information that is received from Level 2 inventory equipment, usually as a response to an inventory command.

9.3.8 Inventory specific data

Inventory specific data is information that is 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 include:

a) Managing information about how to transfer 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, or specific handling restrictions for controlled or regulated substances.

b) Managing new inventory definitions.

c) Managing changes to inventory 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 inventory definitions to other applications, personnel or 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 is the activity that manages resources used in material movement. Inventory resource management tasks 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).

   — 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 & 1 equipment. When that is the case, downloads of this information will usually 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 done as part of an inventory execution coordination activity.

9.6 Detailed inventory scheduling

Detailed inventory scheduling is the activity that takes inventory requests and generates a detailed inventory schedule. Detailed inventory scheduling tasks 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 also have to take into account the limited physical space available for material, and define movement schedules to avoid exceeding storage capacity.

b) Comparing actual movements to planned movements.

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

9.7 Inventory dispatching

Inventory dispatching is the activity that assigns and sends inventory movement 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 that are not assigned as part of the detailed inventory schedule may be assigned by the inventory dispatching activity.

9.8 Inventory execution

Inventory execution is the activity of executing material movements, or initiating transfers. Where the transfer is accomplished by automated equipment it is performed by Level 2 systems.

Transfer execution:

- Directs the performance of work.

  Note: When material movement is performed manually, inventory execution activities include displaying specific work instructions to inventory personnel.

- Has the responsibility to ensure that the correct resources (equipment, material, and personnel) are used in inventory operations.
- Has the responsibility to ensure that transfer procedures and regulations are followed during the transfer operations.
- Has the responsibility to document the status and results of the work done.
- Has the responsibility to inform transfer dispatching and/or detailed transfer scheduling when unanticipated events result in the inability to meet the work requirements.
- Confirms that the work was done according to the accepted quality standards.
- Verifys that equipment and personnel certifications are valid for the assigned tasks.

9.9 Inventory data collection

Inventory data collection is activity that collects data on inventory operations and may collect data on the materials manipulated.

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

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

Storage location of Work In Progress (WIP) material

9.10 Inventory tracking

Inventory tracking is the activity that manages information about inventory requests and reports 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 generation or updating of electronic records related to the transfer of material and management of the material stored. This may include records required for regulatory or quality management purposes.

9.11 Inventory analysis

Inventory analysis is the activity that analyzes inventory efficiencies and resource usage in order to improve operations. For 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 may include providing information on received material quality and time for use in supplier evaluations.

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:

— Which materials were used in inventory activities.

— Which equipment was used in inventory activities.

— 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.

Examples of Inventory Indicators include (from the APQC site (www.apqc.org)):

- Annual inventory turns
- Annual work-in-process (WIP) turns
- Back orders
- Cost of stores
- Gross inventory as a percentage of sales dollars
- Inventory carrying cost
- Inventory reliability: line items filled on first try per total line items ordered
- Integrated supply contract
- Inventory expenses
- Item usage
- Line items processed per employee/hour
- On time delivery

- Pilferage reduction
- Reduced freight expenses
- Stock turns per year
- Vendor lead time
- Annual lines shipped per SKU
- Cases per hour
- Dock-to-stock cycle time
- Inventory accuracy
- Items on hand
- Lines shipped per person per hour
- Pallets shipped per person per hour
- Percentage error in cases shipped
- Percentage error in lines shipped
- Percentage error in orders shipped
- Picking error rate
- Replacement costs for material handling and storage

10. Other enterprise activities affecting manufacturing operations

10.1 Other areas

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

— Management of security within manufacturing operations.

— Management of information within manufacturing operations.

— Management of configurations within manufacturing operations.

— Management of documents within manufacturing operations.

— Management of regulatory compliance within manufacturing operations.

Figure 25 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 that is used in production data collection, production resource management, production tracking, production definition management, maintenance definition management, and quality test data collection.

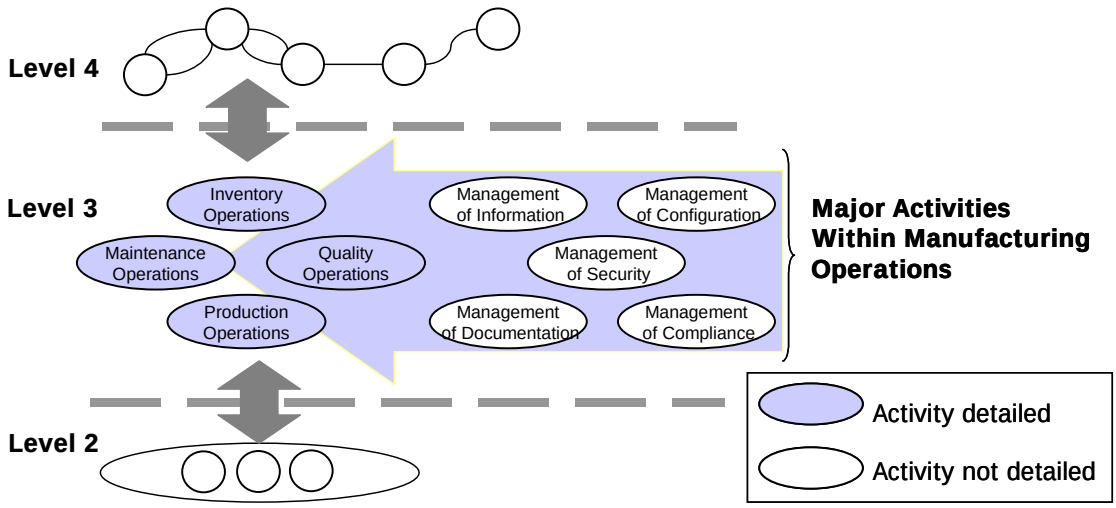


Figure 25- Other enterprise activities affecting manufacturing operations

10.2 Management of security

Management of security is an enterprise function and 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 usually 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 no unauthorized remote access can affect operations.

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 include 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. In addition many functions must exchange information with many functions than are listed in Clauses 5, 6, and 7 of this standard. These functions have an aspect of management of information.

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, redundancy, access control, and security. These are often corporate level functions that follow corporate, industry, national, or international standards.

Note: Management of information 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, protocols or network standards, or virtual through firewalls and routers. Real-time control requires predicable network responsiveness and latency, which is best accomplished through the separation of networks.

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

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 are configuration management and change control procedures that should be considered in manufacturing operations. This function may be required anyplace 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:

— Equipment hardware identification and change procedures

— Level 2 and Level 3 software identification and change procedures

— Data and record management for Level 2 and Level 3 records

— 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 includes the following:

— Requests for change

— Analysis of the change request

— Impact analysis of the change

— Approval of the change

— Implementation of the change

— Review and approval of the change implementation

— 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 will 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 temporally or permanently unavailable. Companies with significant operations usually 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 involve 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 26 illustrates some of the aspects of regulatory compliance and general activities associated with each aspect. The figure also illustrates the USA regulatory agencies involved in compliance with the aspect.

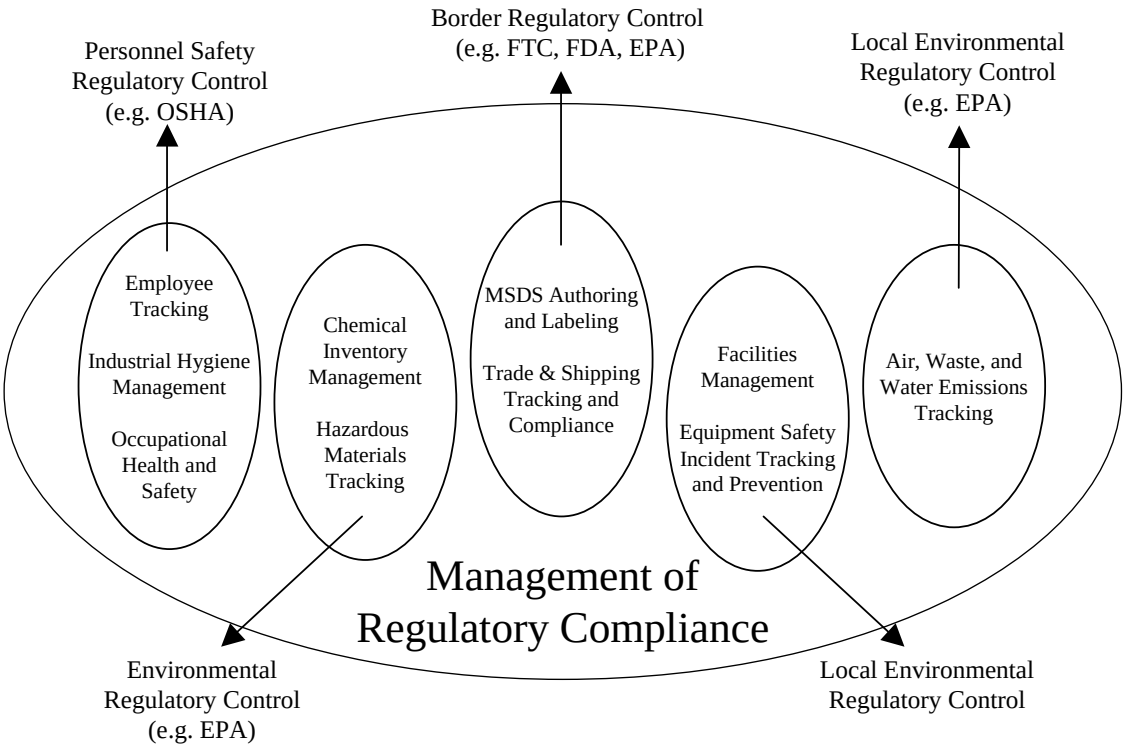


Figure 26 - Functions in management of regulatory compliance

Typical environmental activities include:

- Permit requirements related to planning/construction and operations
- Air Pollution control including emissions limitation/control and permits.
- Water Pollution control including wastewater and effluent discharges and storm water runoff.
- Waste Management of solids, hazardous material and packaging.
- Notification, classification, packaging and labeling of hazardous materials. This also includes storage of such material. Special handling of asbestos, PCBs and pesticides.
- Liability and management practices including civil and criminal liability and contaminated land liability.

Typical health and safety activities include:

- Handling, classification, packaging and labeling of hazardous substances including safety data sheets.
- Disaster planning including emergency planning and response, and fire safety.
- Hazard communication in the form of warning signs, training and advice.
- Occupational health surveillance in the form of occupational exposure controls (including chemical, physical, biological agents and noise).
- Medical surveillance of personnel, such as identifying and monitoring the activities of pregnant workers.
- Process safety in the form of machinery safety, lifting equipment, pressure systems, confined space entry/ work permits/access control.
- Electrical safety
- Ergonomics including office work, manual handling of loads, etc.
- First Aid

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

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 – Technical and responsibility boundaries

A.1 Introduction

The models shown in Figure 8, Figure 22, Figure 23, and Figure 24 define a large set 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. These are defined in Clause 4.3 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, 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 27. 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 of the 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 operation 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 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 27. In this situation the manufacturing operations management layer would be significant and cover all of the defined aspects of production.

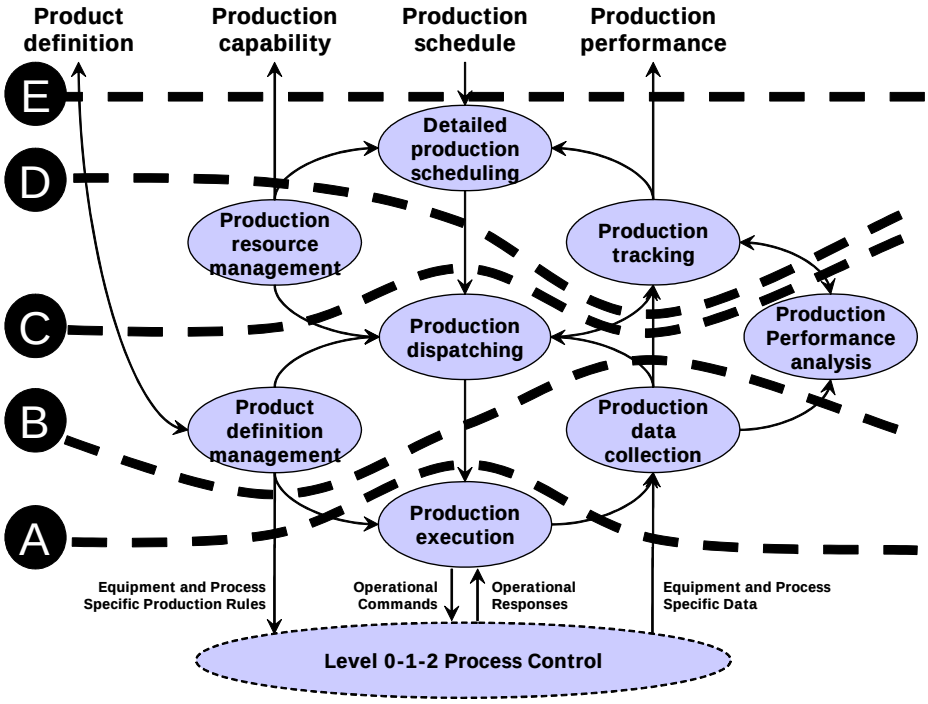


Figure 27 - Different boundaries of responsibility

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. 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 is within the scope of control of production operations management. This is shown in Line A in Figure 27

A.3 Actual responsibility

The four questions in Clause 4.3 define the required boundary of responsibility, but there may be an actual boundary of responsibility that is 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 8, Figure 22, Figure 23, and Figure 24 may be implemented in ERP (Enterprise Resource Planning) systems. Likewise the functions may be implemented by MES (Manufacturing Execution Systems) systems, by LIMS (Laboratory Information Management Systems), by AMS (Asset Management Systems), by WMS (Warehouse Management Systems), by DCS (Distributed Control System), or by SCADA (Supervisory Control and Data Acquisition) systems. The lines of technical integration may 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 28 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.

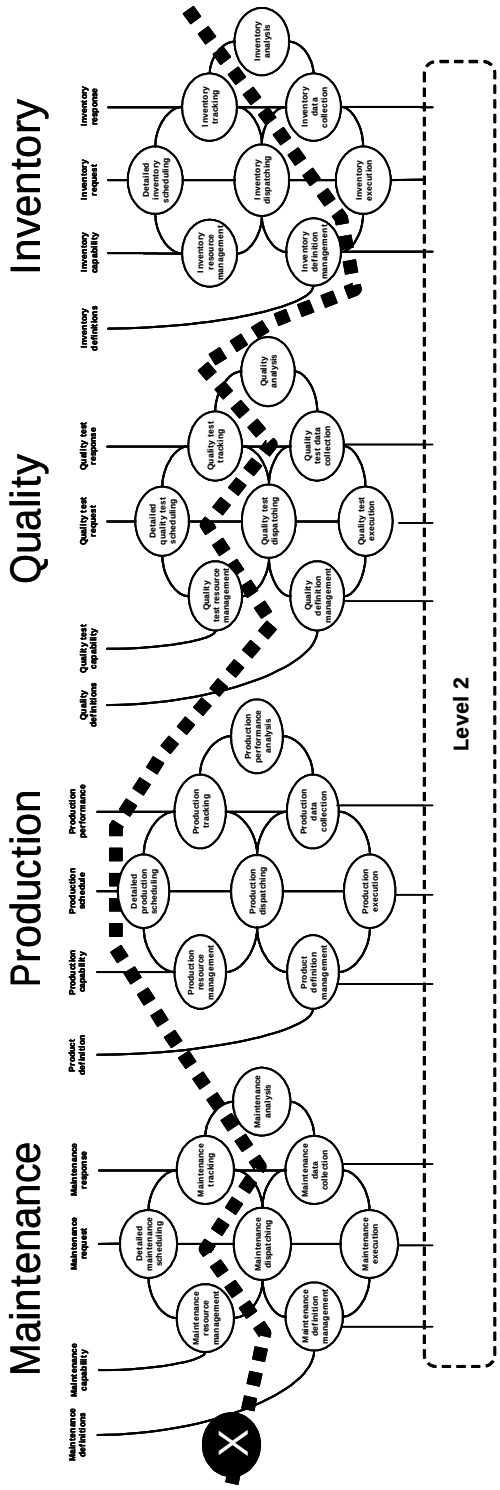


Figure 28 - Lines of technical integration

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 areas 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.
- 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.

B - Scheduling hierarchy

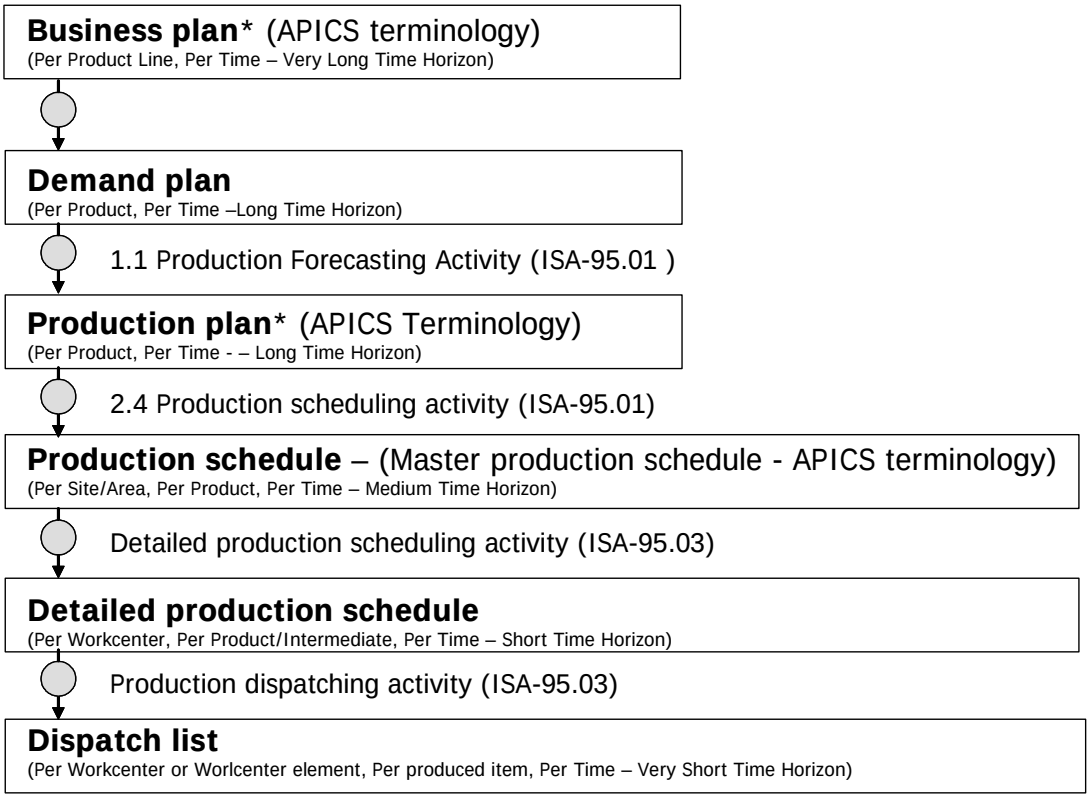
There is a hierarchy of scheduling within many companies. Many companies start with a company-wide plan that balances market demand with company capabilities using constraints such as manufacturing capacity, distribution capacity, and capital capacity.

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 functions activities such as batch management systems

Figure B-1 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 illustrated how the APICS defined elements and the elements in this standard fit together. The hierarchy starts with a business plan and ends with a dispatch list. There may be additional levels of scheduling and planning below the 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 B-1 - 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 Dictionary, Tenth Edition 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 that are 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 dispatch list, which is the immediate list of activities to perform, however there may be ordering and prioritization performed at even lower levels.

C - Associated Standards

C.1 Management of Security

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

- ISO/IEC DTR 13335-1 Information technology -- Guidelines for the management of IT security -- Part 1: Concepts and models for IT security
- ISO/IEC DTR 13335-2 Information technology -- Guidelines for the management of IT security -- Part 2: Planning and managing IT security
- ISO/IEC DTR 13335-3 Information technology -- Guidelines for the management of IT security -- Part 3: Techniques for the management of IT security
- ISO/IEC DIS 14980 Information technology -- Code of practice for information security management
- ISO 7498-2:1989 Information processing systems -- Open Systems Interconnection -- Basic Reference Model -- Part 2: Security Architecture
- ISO/IEC 10164-7:1992 Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function
- ISO/IEC 10164-8:1993 Information technology -- Open Systems Interconnection -- Systems Management: Security audit trail function
- ISO/IEC DIS 10164-9 Information technology -- Open Systems Interconnection -- Systems management: Objects and attributes for access control
- ISO/IEC DIS 10181-1 Information technology -- Open Systems Interconnection -- Security Frameworks for Open Systems: Overview
- ISO/IEC DIS 10181-2 Information technology -- Open Systems Interconnection -- Security Frameworks for Open Systems -- Part 2: Authentication Framework
- ISO/IEC DIS 10181-3 Information technology -- Open Systems Interconnection -- Security frameworks in open systems -- Part 3: Access control
- ISO/IEC DIS 10181-4 Information technology -- Open Systems Interconnection -- Security frameworks in Open Systems -- Part 4: Non-repudiation
- ISO/IEC DIS 10181-5 Information technology -- Security frameworks in open systems -- Part 5: Confidentiality
- ISO/IEC DIS 10181-6 Information technology -- Security frameworks in open systems -- Part 6: Integrity
- ISO/IEC DIS 10181-7 Information technology -- Open Systems Interconnection -- Security Frameworks for Open Systems: Security Audit Framework

– ISO/IEC 10745:1995 Information technology -- Open Systems Interconnection -- Upper layers security model

– ISO/IEC DIS 11586-1 Information technology -- Open Systems Interconnection -- Generic Upper Layers Security -- Part 1: Overview, Models and Notation

– ISO/IEC DIS 11586-2 Information technology -- Open Systems Interconnection -- Generic Upper Layers Security -- Part 2: Security Exchange Service Element (SESE) Service Specification

– ISO/IEC DIS 11586-3 Information technology -- Open Systems Interconnection -- Generic Upper Layers Security -- Part 3: Security Exchange Service Element (SESE) Protocol Specification

– ISO/IEC DIS 11586-4 Information technology -- Open Systems Interconnection -- Generic Upper Layers Security -- Part 4: Protecting Transfer Syntax Specification

– ISO/IEC 9798-1:1991 Information technology -- Security techniques -- Entity authentication mechanisms -- Part 1: General model

C.2 Management of configurations

Existing standards and regulations that apply to configuration management, as related to manufacturing operations are:

— ANSI/EIA-649-1998 National Consensus Standard for Configuration Management

— OSHA 1910.119 Process Safety Management

— FDA 21 CFR Part 11 Electronic Records

C.3 Management of documentation

Existing standards related to management of documentation are:

Potentially relevant standards for document management include:

— IEC 61355 – Classification and designation of documents for plants, systems and equipment

— IEC 61506 – Industrial-process measurement and control – Documentation of application software

— IEC 82045-1 – Document management – Part 1: Principles and methods

— IEC 62023 – Structuring of technical information and documentation

— IEC 61346-1 – Industrial systems, installations and equipment and industrial products – Structuring principles and reference designations - Part 1: Basic rules

— IEC 61346-4 – Industrial systems, installations and equipment and industrial products - Structuring principles and reference designation - Part 4 Discussions of concept

— IEC 61175 – Designations for signals and connections

— IEC 61666 – Industrial systems, installations and equipment and industrial products – Identification of terminals within a system

— IEC 60848 – Preparation of function charts for control systems

— IEC 61082-1 – Preparation of documents used in electrotechnology - Part 1: General requirements

— IEC 61082-2 – Preparation of documents used in electrotechnology - Part 2: Function-oriented diagrams

— IEC 61082-3 – Preparation of documents used in electrotechnology - Part 3: Connection diagrams, tables and lists

— IEC 61082-4 – Preparation of documents used in electrotechnology - Part 4: Location and installation documents

— IEC 61082-6 – Preparation of documents used in electrotechnology - Part 6: Index

— IEC 60617-1 – Graphical symbols for diagrams. Part 1: General information, general index. Cross-reference tables

— IEC 60617-2 – Graphical symbols for diagrams – Part 2: Symbol elements, qualifying symbols and other symbols having general application

— IEC 60617-3 – Graphical symbols for diagrams – Part 3: Conductors and connecting devices

— IEC 60617-4 – Graphical symbols for diagrams – Part 4: Passive components

— IEC 60617-5 – Graphical symbols for diagrams – Part 5: Semiconductors and electron tubes

— IEC 60617-6 – Graphical symbols for diagrams - Part 6: Production and conversion of electrical energy

— IEC 60617-7 – Graphical symbols for diagrams –Part 7: Switchgear, controlgear and protective devices

— IEC 60617-8 – Graphical symbols for diagrams – Part 8: Measuring instruments, lamps and signaling devices

— IEC 60617-9 – Graphical symbols for diagrams – Part 9: Telecommunications: Switching and peripheral equipment

— IEC 60617-10 – Graphical symbols for diagrams – Part 10: Telecommunications: Transmission

— IEC 60617-11 – Graphical symbols for diagrams – Part 11: Architectural and topographical installation plans and diagrams

— IEC 60617-12 – Graphical symbols for diagrams – Part 12: Binary logic elements

— IEC 60617-13 – Graphical symbols for diagrams – Part 13: Analogue elements

— IEC 61734 – Application of IEC60617-12 and IEC 60617-13 standards

— ISO 11714-1 – Design of graphical symbols for use in the technical documentation of products. Part 1: Basic rules.

— IEC 81714-2 – 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.

— IEC 81714-3 (1998) Design of graphical symbols for use in the technical documentation of products. Part 3: Classification of connect nodes, networks and their encoding.

— IEC 61286 (1995) Information technology – Coded graphic character set for use in the preparation of documents used in electrotechnology and for information interchange

— IEC 60417 – Graphical symbols for use on equipment. Index, survey and compilation of the single sheets

— IEC 60416 – General principles for the formulation of graphical symbols

— IEC 61360-1 – Standard data element types with associated classification scheme for electric components - Part 1: Definitions - Principles and methods

— IEC 61360-2 – Standard data element types with associated classification scheme for electric components - Part 2: Express dictionary schema.

— IEC 61360-3 – Standard data element types with associated classification scheme for electric components - Part 3: Maintenance and validation procedures

— IEC 61360-4 – Standard data element types with associated classification scheme for electric components - Part 4: IEC reference collection of standard data element types, component classes and terms

C.4 Management of regulatory compliance

Potentially relevant standards related to regulatory compliance include:

— ISO 14001:1996 Environmental management systems – Specification with guidance for use

— ISO 14004:1996 Environmental management systems – General guidelines on principles, systems and supporting techniques

— ISO 14015:2001 Environmental management – Environmental assessment of sites and organizations (EASO)

— ISO 14020:2000 Environmental labels and declarations – General principles

— ISO 14021:1999 Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling)

— ISO 14024:1999 Environmental labels and declarations – Type I environmental labeling - Principles and procedures

— ISO/TR 14025:2000 Environmental labels and declarations – Type III environmental declarations

— ISO 14031:1999 Environmental management – Environmental performance evaluation – Guidelines

— ISO/TR 14032:1999 Environmental management – Examples of environmental performance evaluation (EPE)

— ISO 14040:1997 Environmental management – Life cycle assessment – Principles and framework

— ISO 14041:1998 Environmental management – Life cycle assessment – Goal and scope definition and inventory analysis

— ISO 14042:2000 Environmental management – Life cycle assessment – Life cycle impact assessment

— ISO 14043:2000 Environmental management – Life cycle assessment – Life cycle interpretation

— ISO/TR 14047 Environmental management – Life cycle assessment – Examples of application of ISO 14042

— ISO/TS 14048:2002 Environmental management – Life cycle assessment – Data documentation format

— ISO/TR 14049:2000 Environmental management – Life cycle assessment – Examples of application of ISO 14041 to goal and scope definition and inventory analysis

— ISO 14050:2002 Environmental management – Vocabulary

— ISO/TR 14061:1998 Information to assist forestry organizations in the use of the Environmental Management System standards ISO 14001 and ISO 14004

— ISO/TR 14062:2002 Environmental management – Integrating environmental aspects into product design and development

— ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing.

— 29 CFR 1910 Occupational Health and Safety Standard.

D – Frequently asked questions

D.1 What are some of the main expected uses of this standard?

A main use of this part of the standard is in the development of requirements for manufacturing operations management and related systems. The terminology and models defined in this part of the standard have been used as the structure for requirement specifications in RFQ (Request For Quotes).

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.2 How does this standard relate to Enterprise and Control System Integration?

Control systems are Level 2 systems and enterprise business systems are Level 4 systems. The scope of this part of the 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.

D.3 How does this facilitate connection to ERP systems?

Part 1 and 2 specify the interfaces between enterprise and the control domain. Part 3 of the standard does more than facilitate the connection to ERP systems. It provides a common way to specify the interfaces that are independent of the specific ERP / manufacturing management systems deployed. It also identifies the components (activities) and interfaces of the manufacturing management systems.

D.4 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.5 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.6 What industry does the standard apply to?

This part of the 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 7 What is the relation between this standard and MES

This standard uses the basic MESA definitions of MES and expands them by adding activity detail, tasks, and extends them into additional operational areas.

D.8 How does this part of the standard relate to Level 2 of PRM

The levels shown in Figure 29 are defined by the Purdue Reference Model for CIM (Computer Integrated Manufacturing). The focus of the ISA-95 parts are also labeled in the figure. ISA-95 part 1 and 2 focus on the interfaces between Level 4 enterprise and Level 3 manufacturing control systems. ISA-95 Part 3 focuses on the activities within manufacturing.

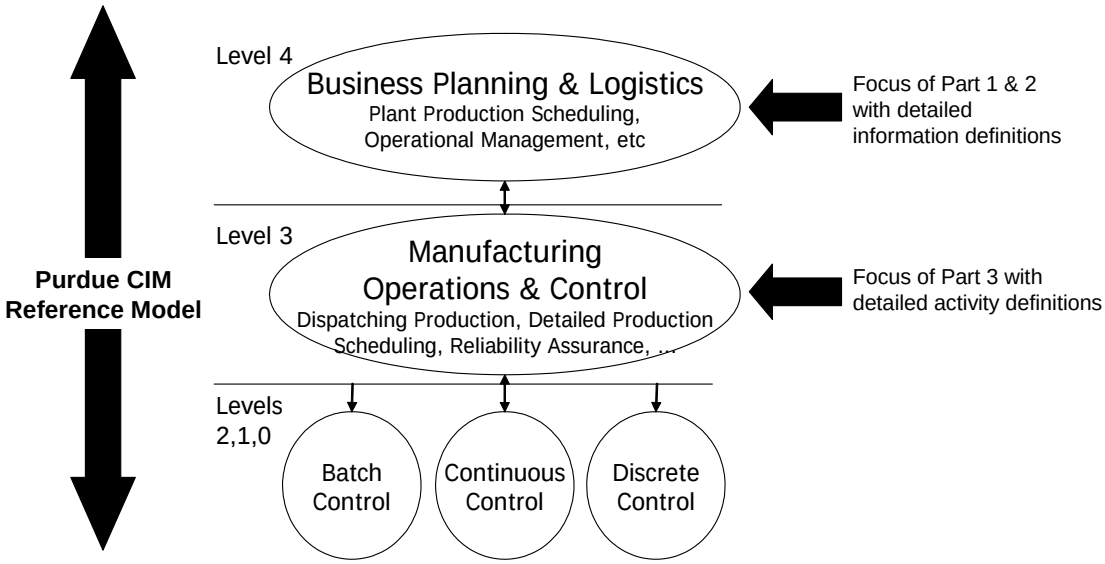


Figure 29 - CIM and Standard Levels

D.9 How do the ANSI/ISA-88 and ANSI/ISA-95 standards relate?

This will be addressed in a separate technical report.