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

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

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ISA

67 Alexander Drive
P. O. Box 12277
Research Triangle Park, North Carolina 27709
USA

PREFACE

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INTRODUCTION

This Part 3 standard shows activity models and data flows for manufacturing information that enables enterprise-control system integration. The modelled activities operate between Level 4 logistics and planning functions and Level 2 manual and automated process control functions. The models are consistent with the object models given in ANSI/ISA-95.00.02-2010 (IEC 62264-2 Mod), ANSI/ISA-95.00.04-2012, and the Level 3 (manufacturing operations and control) definitions.

The goal of the standard is to reduce the risks, costs and errors associated with implementing enterprise systems and manufacturing operations systems in such a way that they inter-operate and easily integrate. The standard may also be used to reduce the effort associated with implementing new product offerings.

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

– to emphasize the good practices of manufacturing operations;
– to be used to improve existing manufacturing operations systems; and
– to be applied regardless of the degree of automation.

Some potential benefits produced when applying this standard may include:

– reducing the time to reach full production levels for new products;
– enabling vendors to supply appropriate tools for manufacturing operations;
– enabling more uniform and consistent identification of manufacturing needs;
– reducing the cost of automating manufacturing processes;
– optimizing supply chains; and
– improving efficiency in life-cycle engineering efforts.

It is not the intent of this part of the standard to

– suggest that there is only one way of implementing manufacturing operations;
– force users to abandon their current way of handling manufacturing operations;
– restrict development in the area of manufacturing operations; or
– restrict use only to manufacturing industries.

Changes from ANSI/ISA 95.00.03-2005 to this version are:

1. The document is based on the IEC/ISO 62264-3 version. This is the IEC version of ISA-95 Part 3 and includes additional changes made by the IEC SC65E and ISO TC 184 SC5 Joint Working Group (JWG 5).
2. Clause *4.1 Manufacturing Operations Management* was moved to Part 1 and therefore was removed from Part 3.
3. Clause *4.2 Functional hierarchy* was moved to Part 1 and therefore was removed from Part 3.
4. Clause *4.4 Criterion for defining activities below Level 4* was moved to Part 1 and therefore was removed from Part 3.
5. Clause *4.5 Categories of production information* was moved to Part 1 and therefore was removed from Part 3.

6. Clause *4.6 Manufacturing operations information* was moved to Part 1 and therefore was removed from Part 3.
7. Clause *5.3 Expanded equipment hierarchy model* was moved to Part 1 and therefore was removed from Part 3.
8. Clause *5.4 Expanded decision hierarchy model* was removed from Part 3. The corresponding section was removed from Part 1 and replaced with a reference to ISO-15704 Industrial automation systems.
9. *Annex A (informative) Other enterprise activities affecting manufacturing operations* was moved to Part 1 and therefore was removed from Part 3.
10. *Annex D (informative) Associated standards* was moved to Part 1 and therefore was removed from Part 3.
11. *Annex F (informative) Applying the decision hierarchy model to manufacturing operations management* was removed from Part 3. The corresponding section was removed from Part 1 and replaced with a reference to ISO-15704 Industrial automation systems.
12. *Annex G (informative) Mapping PSLX ontology to manufacturing operations management* was removed from Part 3. The committee felt that this section is more appropriate as a PSLX white paper or TR.
13. The names for data were changed to match the Part 4 standard names. These name changes were made in all figures and in the text. The following data names were changed or added:
    a. *Detailed Production Schedule* changed to *Work Schedule*
    b. *Production Dispatch List* changed to *Job list*
    c. *Production Work Order* changed to *Job Order*
    d. *Work Order* changed to *Job Order*
    e. *Detailed Maintenance Schedule* changed to *Work Schedule*
    f. *Detailed Inventory Schedule* changed to *Work Schedule*
    g. The addition of *Work Masters* as objects that define how work is to be done.

ENTERPRISE-CONTROL SYSTEM INTEGRATION –

Part 3: Activity models of manufacturing operations management

1 Scope

This Part 3 standard in the ISA-95 series defines activity models of manufacturing operations management that enable enterprise system to control system integration. The activities defined in this part of the standard are consistent with the object models definitions given in ANSI/ISA-95.00.02-2010 (IEC 62264-2 Mod) and ANSI/ISA-95.00.04-2012. The modelled activities operate between business planning and logistics functions, defined as the Level 4 functions and the process control functions, defined as the Level 2 functions of ANSI/ISA-95.00.01-2010 (IEC 62264-1 Mod). The scope of this standard is limited to:

– a model of the activities associated with manufacturing operations management, Level 3 functions; and

– an identification of some of the data exchanged between Level 3 activities.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

— ANSI/ISA-95.00.01-2010 (IEC 62264-1 Mod), Enterprise-Control System Integration - Part 1: Models and Terminology
— ANSI/ISA-95.00.02-2010 (IEC 62264-2 Mod), Enterprise-Control System Integration - Part 2: Object Model Attributes
— ANSI/ISA-95.00.04-2012, Enterprise-Control System Integration - Part 4: Objects and Attributes for Manufacturing Operations Management Integration
— ANSI/ISA-88.00.01-2010, Batch Control - Part 1: Models and Terminology
— ISA-88.00.02-2001, Batch Control - Part 2: Data Structures and Guidelines for Languages
— IEC 61512-1:1997, Batch control - Part 1: Models and terminology
— IEC 61512-2:2001, Batch control - Part 2: Data structures and guidelines for languages

3 Terms, definitions and abbreviations

For the purposes of this document, the following terms and definitions apply.

3.1 Terms and definitions

3.1.1
finite capacity scheduling
scheduling methodology where work is scheduled for a set of manufacturing resources, in such a way that no capacity scheduled exceeds the capacity available

3.1.2
inventory operations management
activities within Level 3 of a manufacturing facility which coordinate, direct, manage and track inventory and material movement within manufacturing operations

3.1.3
job list
collection of job orders for one or more work centers and/or resources for a specific time frame

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

NOTE 2 Job lists are applicable to all operations management areas, such as maintenance, quality test and inventory.

3.1.4
job order
unit of scheduled work that may be dispatched to a work center

3.1.5
maintenance operations management
activities within Level 3 of a manufacturing facility which coordinate, direct and track the functions that maintain the equipment, tools and related assets to ensure their availability for manufacturing and ensure scheduling for reactive, periodic, preventive, or proactive maintenance

3.1.6
manufacturing facility
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, physical assets and material in manufacturing

NOTE This 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.

3.1.8
production operations management
activities within Level 3 of a manufacturing facility which coordinate, direct, manage and track the functions that use raw materials, energy, equipment, personnel and information to produce products, with the required costs, qualities, quantities, safety and timeliness

3.1.9
quality operations management
activities within Level 3 of a manufacturing facility which coordinate, direct and track the functions that measure and report on quality

3.1.10
tracing
activity that provides an organized record of resource and product use from any point, forward or backward, using tracking information

3.1.11
tracking
activity of recording attributes of resources and products through all steps of instantiation, use, change and disposition

3.1.12
work center
process cell, production unit, production line, storage zone, or any other equivalent level equipment element defined as an extension to the equipment hierarchy model

NOTE For compatibility with existing schema implementations the defined term “work center” is used in place of the UK English spelling “work centre”.

3.1.13
work schedule
detailed schedule that may define production, maintenance, inventory or quality operations activities, or any combination of the activities

3.2 Abbreviations

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

AGV	Automated guided vehicles
AMS	Asset management system
ASRS	Automated storage and retrieval system
CAPE	Computer-aided process engineering
CAD	Computer-aided design
CAE	Computer-aided engineering
CIM	Computer integrated manufacturing
CNC	Computerized numerical control
DCS	Distributed control system
ERP	Enterprise resource planning
EWI	Electronic work instructions
HR	Human resources
KPI	Key performance indicator
LIMS	Laboratory information management system
MES	Manufacturing execution system
MPS	Master production schedule
MRP	Material resource planning
OEE	Overall equipment effectiveness
PAT	Process analytical technology
PDM	Product data management
PLC	Programmable logic controller
PLM	Product life-cycle management
PRM	Purdue reference model for computer-integrated manufacturing
QA	Quality assurance
R&D	Research and development
RFQ	Request for quote
ROA	Return on assets
SCADA	Supervisory control and data acquisition
SOC	Standard operating conditions
SOP	Standard operating procedure
SQC	Statistical quality control

SPC Statistical process control

WIP Work in process

WMS Warehouse management system

4 Structuring concepts

4.1 Activity models

Figure 1 illustrates the activity models of this standard in relationship to ANSI/ISA-95.00.01-2010 (IEC 62264-1 Mod) and ANSI/ISA-95.00.02-2010 (IEC 62264-2 Mod) – that is, ISA-95 Part 1 and ISA-95 Part 2. The activities in this Part 3 standard exchange information with activities defined as Level 4 and Level 2 activities. The grey circles indicate the activities detailed in this standard. The information flows between the activities of this standard, indicated as heavy dashed lines, are described in general in this standard. In addition, the information flows between the activities of this standard and dependent Level 2 activities are identified.

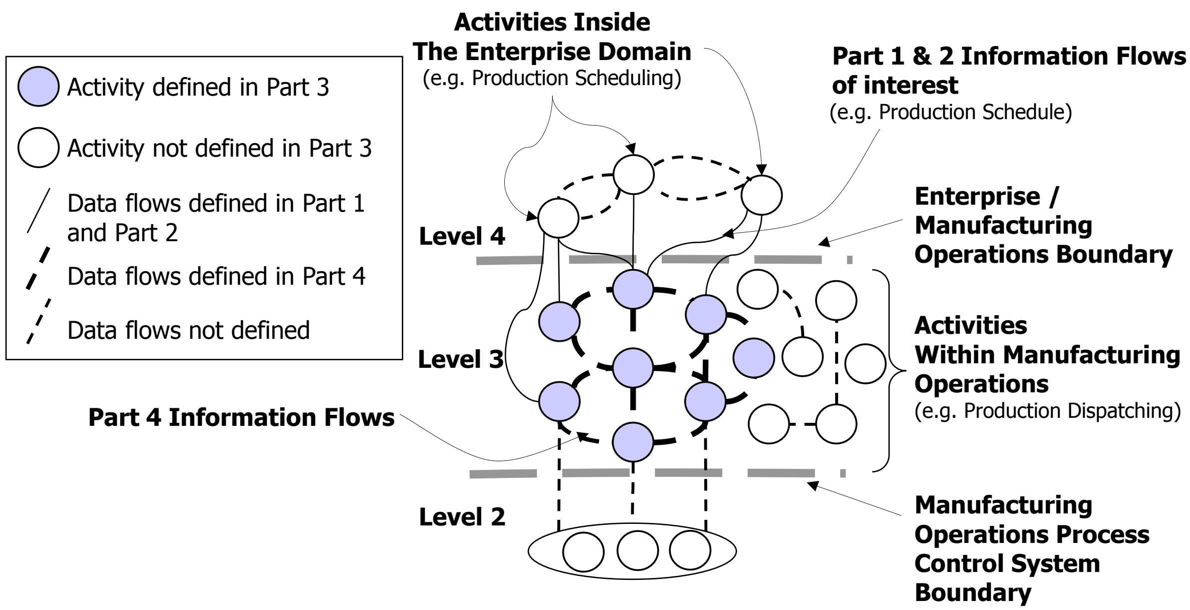

Figure 1 – Activity relationships

4.2 Manufacturing operations management elements

The shaded areas in Figure 1 represent the manufacturing operations management activities modelled in this 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.

This part of the standard defines four formal models: production operations management, maintenance operations management, quality operations management and inventory operations management. These are detailed in Clauses 6, 7, 8 and 9 and are listed below.

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

b) The maintenance operations management model, which shall include the activities of maintenance management (10.0) that operate as Level 3 functions.

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

d) The inventory operations management model, which shall include the activities of management of inventory and material including product inventory control (7.0) and material and energy control activities (4.0) defined as operating as Level 3 functions.

NOTE 1 The numbers in parenthesis "()" refer to the functional model depicted in Part 1.

NOTE 2 Other categories of operation management may exist depending on company policy or organization. They are not formally modelled in this standard but they can make use of the generic standard model.

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 shall be 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 2. This generic model is extended for each specific area in later clauses.

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

5.1.2 Use of the generic model

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

EXAMPLE 1 A company could apply the model to receiving operations management and shipping operations management where these are separately managed.

EXAMPLE 2 A company could apply the model to cleaning and sterilization operations management, where these are separately managed.

EXAMPLE 3 A company could apply the model to independent logistics operations management categories for inbound logistics, outbound logistics, internal transfer and inventory control.

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

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

5.1.3 Generic activity model

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

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

– analysis of the work performed for improvements or corrections;

– management of the resources used in execution of the performed work;

– management of the definitions of the performed work.

The generic activity model and the detailed models are not intended to represent an actual implementation of a manufacturing information system. However, they do provide a consistent framework for such systems. Actual systems may use different structures supporting other task arrangements. The purpose of these models is to identify possible data flows within manufacturing operations. The generic model is illustrated in Figure 2. The ovals in the model indicate collections of tasks, identified as the main activities. Lines with arrowheads indicate some of the information flows between the activities.

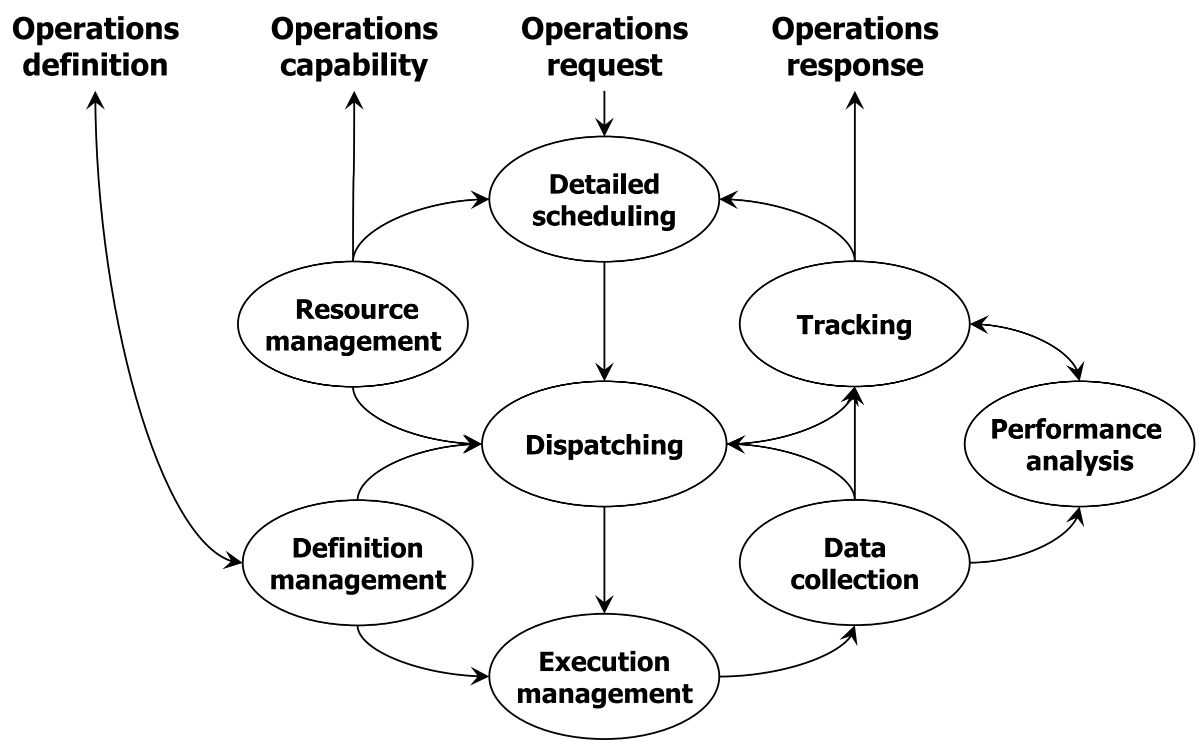

Figure 2 – Generic activity model of manufacturing operations management

NOTE Not all information flows are depicted in Figure 2. In any specific implementation, information from any activity may be required by any other activity. Where the model is expanded for specific activities, the lines indicating information flows are not intended to be exclusive lists of information exchanged.

5.2 Interaction among generic activity models

5.2.1 Information flows between generic activity models

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

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

EXAMPLE 1 In pharmaceutical industries, quality operations may provide the direction for other operations.

EXAMPLE 2 In distribution centres, inventory operations may provide the direction for other operations.

EXAMPLE 3 In consumer packaged goods, production operations may provide the direction for other operations.

EXAMPLE 4 In refining, inventory operations may provide the direction for production operations.

5.2.2 Handling resources within the generic activity models

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

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

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

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

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

5.2.3 Scheduling interactions

An activity in a detailed activity model has interactions with other activities in the same model and interactions with equivalent activities in other activity models. Interactions within each activity model are described in Clauses 6, 7, 8 and 9.

There are many interactions associated with detailed scheduling between activity models because of the need to coordinate between many work tasks assigned to a same resource on a given time interval. Also, the definitions of work tasks in the different types of operations management are closely related.

Clear definition of interactions between detailed production scheduling, detailed inventory scheduling, detailed maintenance scheduling and detailed quality-test scheduling should be specified. For interactions with production the following three interactions shall be defined, as illustrated in Figure 3.

1) Interaction between detailed production scheduling and detailed inventory scheduling. This is defined as coordination of information, at the start or completion of production, of the quantity of materials that is consumed or produced during production and stored or moved by inventory operations.

   NOTE Scheduling of transportation can be defined in either detailed production scheduling or detailed inventory scheduling.

   EXAMPLE 1 Production not scheduled to start before the scheduled issuing of the corresponding inventory of materials.

   EXAMPLE 2 Completion of scheduled production triggers a scheduled inventory operation.

2) Interaction between detailed production scheduling and detailed maintenance scheduling. This is defined as coordination of information about equipment that provides capability and capacity during production and needs to be reserved for maintenance depending on the equipment condition.

   EXAMPLE 3 Not scheduling corrective maintenance and production on equipment simultaneously.

   EXAMPLE 4 Scheduling maintenance based on scheduled use of equipment for production.

3) Interaction between detailed production scheduling and detailed quality-test scheduling. This is defined as coordination of information about the quality of produced and consumed materials, which need to be quality-tested depending on the required level of quality and the latest production performance.

EXAMPLE 5 Detailed inspection schedule embedded in the work schedule.

EXAMPLE 6 Inspection operations requests production operations to schedule rework of the product.

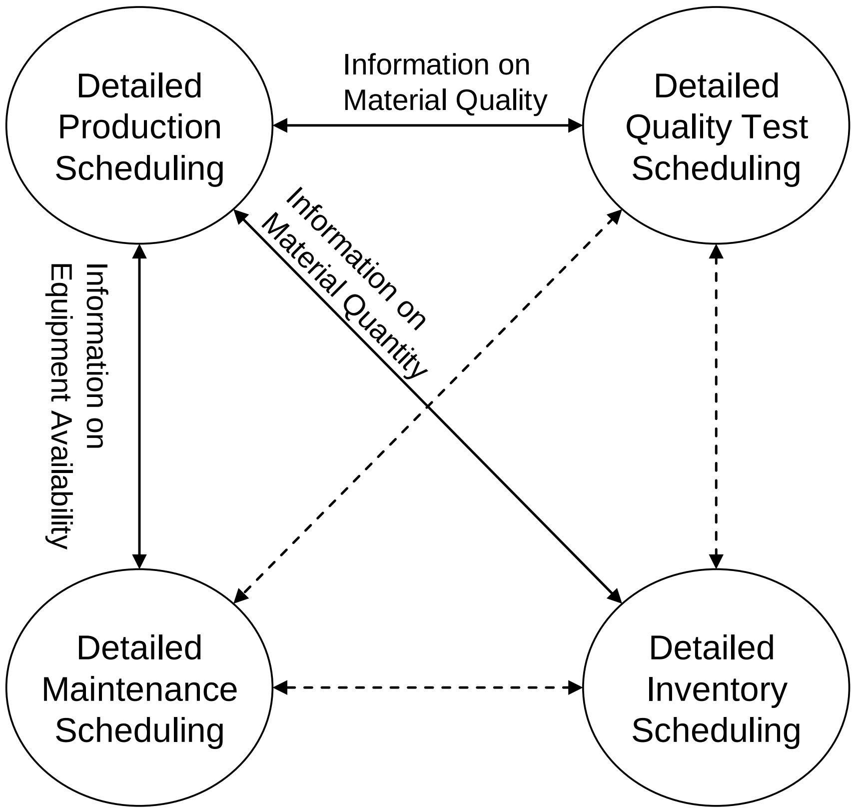

Figure 3 – Detailed scheduling interactions

5.3 Hierarchy of planning and scheduling

In this subclause, planning is defined as an activity for clarifying actions or operations to achieve a given goal and reserving enough amount of resource capacity to hit minimum targets. Scheduling is defined as an activity for allocating actions and operations to particular resources at particular times, taking into account various actual constraints and optimization of several evaluation parameters.

Figure 4 illustrates that in terms of the hierarchy, planning ranks higher than scheduling because a schedule is made using the results of a plan. Planning determines the goals for scheduling. Some constraints and sub-goals for objective functions in scheduling problems are determined in advance by planning activities. The results of scheduling show whether or not the result of planning is feasible and efficient. If it is not feasible, planning usually generates another result for scheduling. Feasibility and efficiency of scheduling are types of constraints of planning.

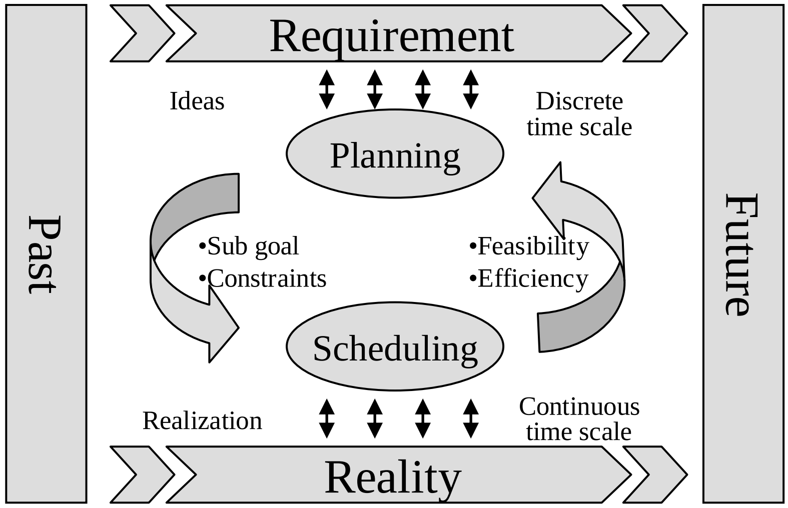

Figure 4 – Schematic relationship of planning and scheduling

The differences between planning and scheduling are the kinds of results which are related to different aspects of time concepts.

In planning, the main results will be target quantities that apply over certain periods of time. The results of planning are represented on a discrete time scale as periodic times.

EXAMPLE 1 Results of planning might be "50,000 widgets this month", "divisional sales of $480,000 next month", "summary of overtime hours for next week", etc.

Results in scheduling represent the specific timing of actions, for example, start time and completion time of operation, inventory issue time, shipping time, etc. The results of sequence information for operations are represented on a continuous time scale as relative or absolute times.

EXAMPLE 2 Results of scheduling might be "9:00 Monday run Work Order 2345 for 6 shifts at 100 % utilization", "9:00 Wednesday perform preventative maintenance on E887e".

5.4 Resource definition for scheduling activities

5.4.1 Consumable resources and non-consumable resources

A resource is defined in ISA-95 Part 1 as personnel, equipment and/or material. In this standard, particularly from the viewpoint of detailed scheduling activities, resources can be divided into two different groups: consumable resources generally corresponding to personnel hours worked, materials (including energy) and non-consumable resources generally corresponding to personnel skills and equipment use. Consumable resources and non-consumable resources are typically handled differently in scheduling activities.

A consumable resource is produced or consumed by production processes. This type of resource usually includes raw materials (including energy), WIP inventories final products, and may also include personnel hours worked or equipment time. The quantity of the resource is measureable and typically changes before or after production. The amount of the utilized resource is a direct expense to the product production processes.

A non-consumable resource is not depleted by production processes but is scheduled on the basis of capability. The quantity of the resource typically does not change before or after production.

5.4.2 Resource capacity and availability

In ISA-95 Part 1 and ISA-95 Part 2, production scheduling depends on the availability of both consumable and non-consumable resources. Available capacity in this standard is a portion of production capacity that can be attained but is not committed to current or future production and may be defined as a rate.

Example 1 For a bicycle factory, the available capacity for production is 10 bicycle seats per hour of operation, during first shift, Monday through Friday.

Example 2 For a bicycle factory, the available capacity for consumption is 30 bicycle seats per hour of operation, during first shift, Monday through Friday.

Example 3 Projected inventories for bicycle seats within a bicycle factory is 380 seats at the start of the first shift on Monday and 360 seats at the end of the first shift. Sixty seats would have been consumed (2 h of consumption) and 40 seats would have been produced (4 h of production).

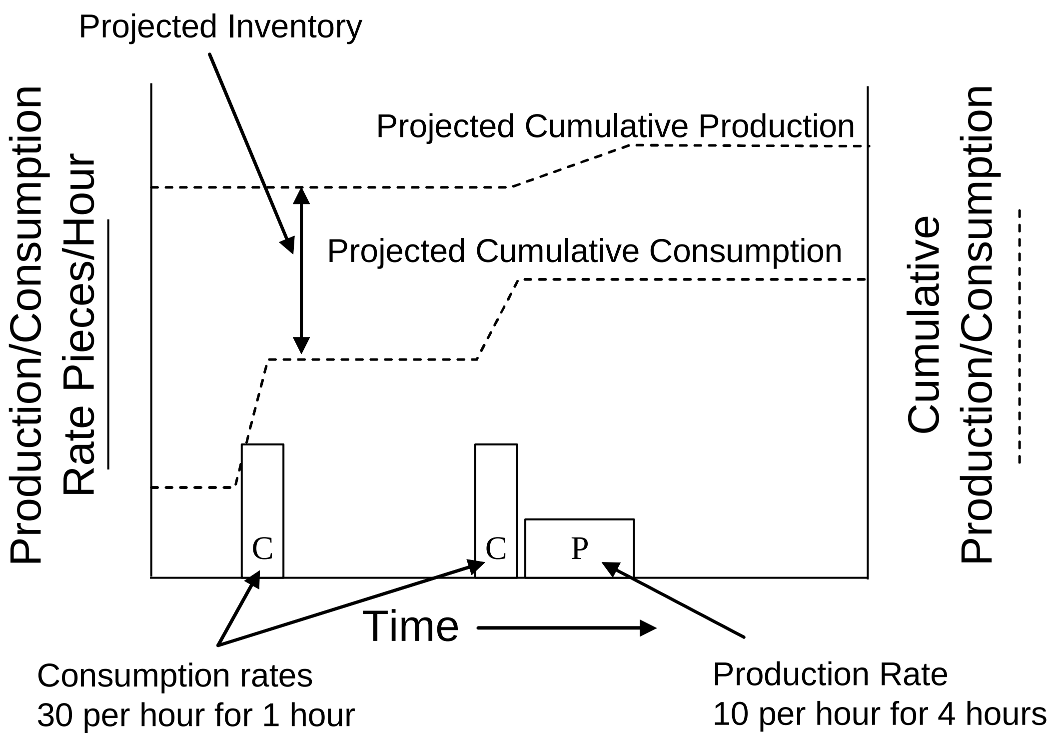

Figure 5 – Projected inventory for a consumable resource

NOTE Consumable resources and non-consumable resources are typically handled differently in scheduling activities. In ISA-95 Part 1 and ISA-95 Part 2, production scheduling depends on the availability of both consumable and non-consumable resources. Production capacity is determined by both the availability of consumable resources (inputs such as raw material, components) and the availability and capacity of non-consumable resources (the physical system such as equipment, facilities and people).

6 Production operations management

6.1 General activities in production operations management

Production operations management shall be defined as the collection of activities that coordinate, direct, manage and track the functions that use raw materials, energy, equipment, personnel and information to produce products, with the required costs, qualities, quantities, safety and timeliness. The general activities in production operations management are listed in ISA-95 Part 1 and include:

a) reporting on production including variable manufacturing costs;

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

c) performing data collection and off-line analysis as required by engineering functions;

NOTE: This may include statistical quality analysis and related control functions.

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

e) establishing the immediate work schedule for its own area accounting for maintenance, transportation and other production-related requests;

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

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

6.2 Production operations management activity model

The production operations management model defined in ISA-95 Part 1 is expanded to a more detailed activity model of production operations shown in Figure 6. The four elements of information (product definition, production capability, production schedule and production performance) correspond to the exchanged information defined in ISA-95 Part 1. The oval-labelled production Level 1-2 functions represent the Level 1 and Level 2 sensing and control functions. The other ovals (with solid outlines) represent the activities of production operations.

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

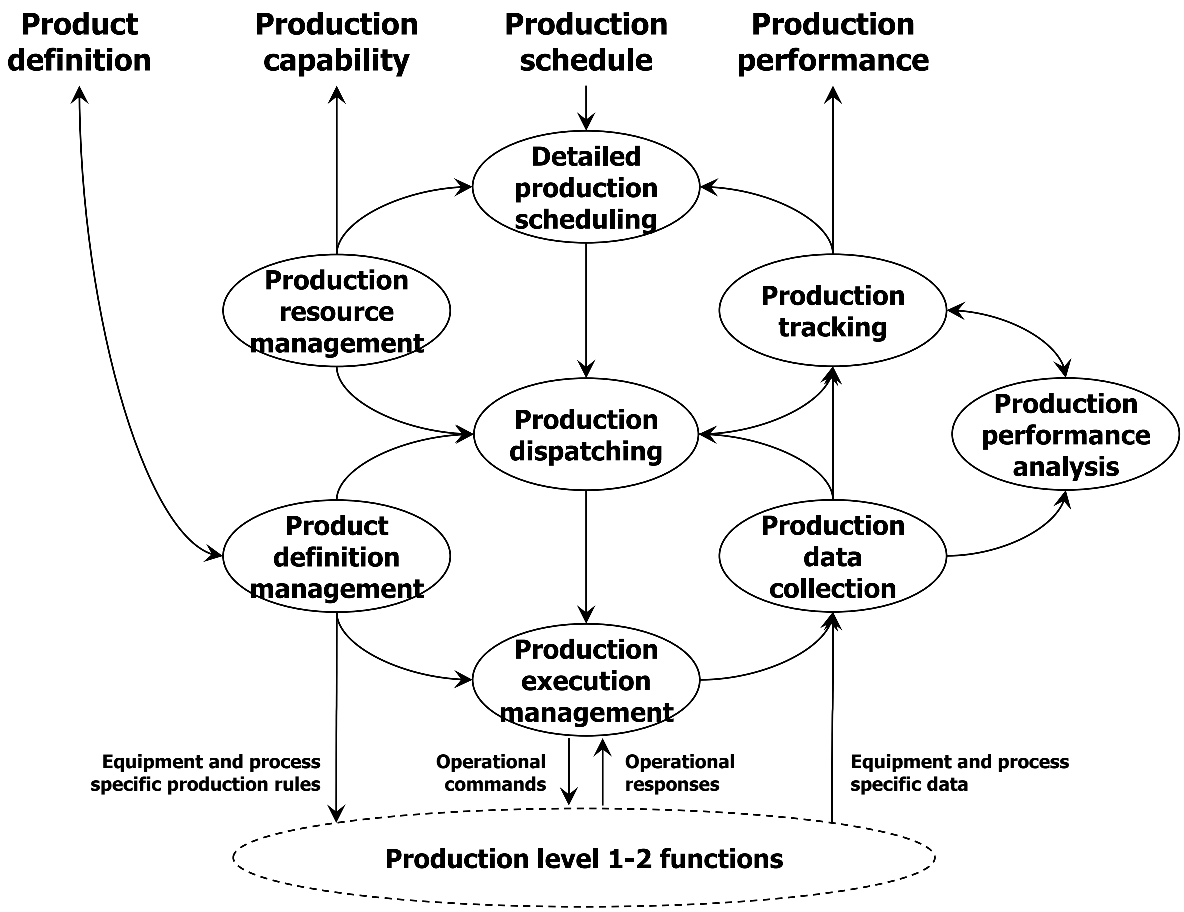

Figure 6 – Activity model of production operations management

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

Not all information flows within production operations management are depicted in Figure 6. In any specific implementation, information from any activity may be required by any other activity. Where activities in the production operations management model are defined in detail in this clause, some additional information flows are identified. Not all data sources and data sinks are identified in the detailed models.

6.3 Information exchange in production operations management

6.3.1 Equipment and process specific production rules

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

EXAMPLE Programmes for CNC machines for a specific product type, PLC programmes that change on the basis of the process under control, or unit recipes where these are executed in Level 2 or Level 1 equipment.

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

6.3.2 Operational commands

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

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

6.3.3 Operational responses

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

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

6.3.4 Equipment and process specific data

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

6.4 Product definition management

6.4.1 Activity definition

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

Product definition information is shared between product production rules, bill of material and bill of resources. The product production rules contain the information used to instruct a manufacturing operation how to produce a product. This may be called a work master (ISA-95 Part 4), general, site, or master recipe (ANSI/ISA-88.00.01 and IEC 61512-1 definitions), standard operating procedure (SOP), standard operating conditions (SOC), routing, or assembly steps based on the production strategy used. The product definition information is made available to other Level 3 functions and to Level 2 functions as required.

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

6.4.2 Activity model

Figure 7 illustrates some of the interfaces to product definition management.

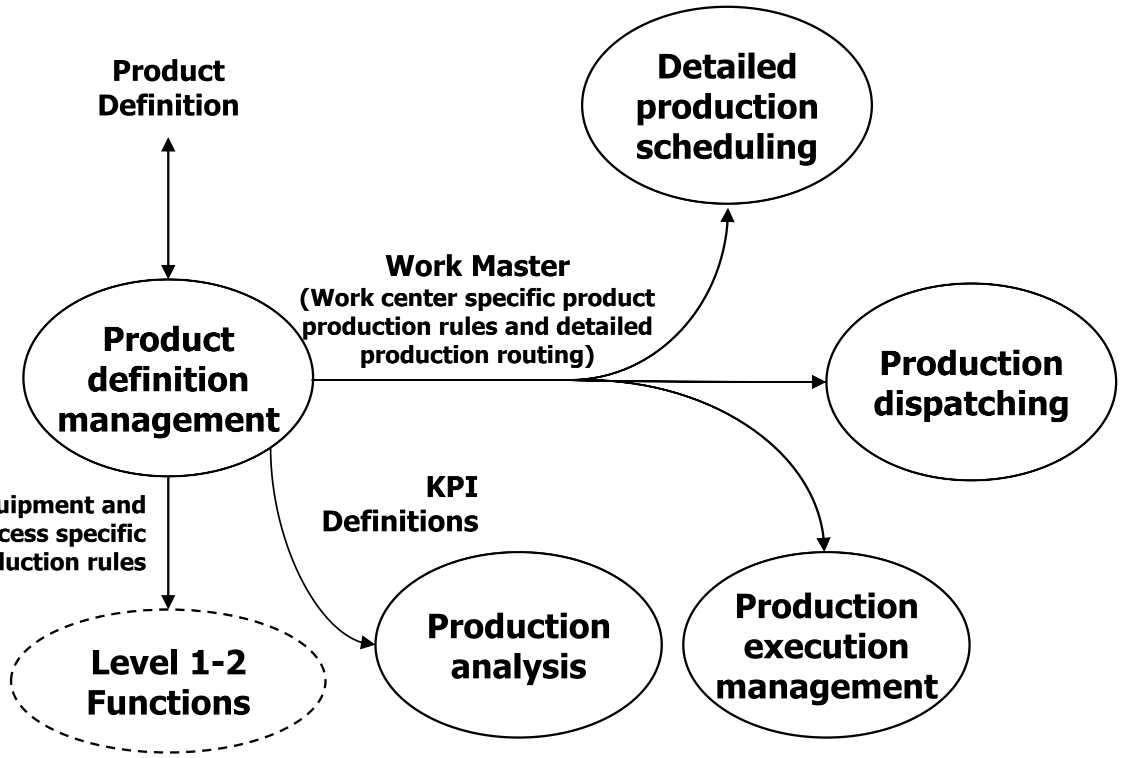

Figure 7 – Product definition management activity model interfaces

6.4.3 Tasks in product definition management

Product definition management tasks may include:

a) managing documents such as work masters, manufacturing instructions, recipes, product structure diagrams, manufacturing bills and product variant definitions;

b) managing new product definitions;

c) managing changes to product definitions;

NOTE 1 This may include the ability to route work masters, designs and manufacturing bill changes through an appropriate approval process, management of versions, tracking of modifications and security control of the information.

d) providing product production rules to personnel or other activities;

EXAMPLE These may take the form of work masters, manufacturing steps, master recipes, machine set-up rules and process flow sheets;

e) maintaining the feasible detailed production routings for products;

f) providing the route to manufacturing operations in the level of detail required by manufacturing operations;

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

h) optimizing product production rules based on process analysis and production performance analysis;

i) generating and maintaining local production rule sets indirectly related to products, such as for cleaning, start-up and shutdown;

j) managing the key performance indicator (KPI) definitions associated with products and production.

NOTE 2 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), recipe management systems, computer-aided process engineering (CAPE) and electronic work instructions (EWIs).

6.4.4 Product definition management information

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

EXAMPLE Translation to work masters, master recipes, machine set-up rules and process flow diagrams.

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

– customer requirements, product design and test specifications;
– process design and simulation;
– technical publications and service materials;
– regulatory filings requirement information.

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

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

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

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

6.5 Production resource management

6.5.1 Activity definition

Production resource management shall be defined as the collection of activities that manage the information about resources required by production operations, and relationships between resources. The resources include machines, tools, labour (with specific skill sets), materials and energy, as defined in the object models given in ISA-95 Part 1. Direct control of these resources in order to meet production requirements is performed in other activities, such as production dispatching and production execution management. Management of information about segments of production is also an activity in resource management.

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

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

Information about resources and relationships between 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 ISA-95 Part 1.

6.5.2 Activity model

Figure 8 illustrates some of the interfaces to production resource management.

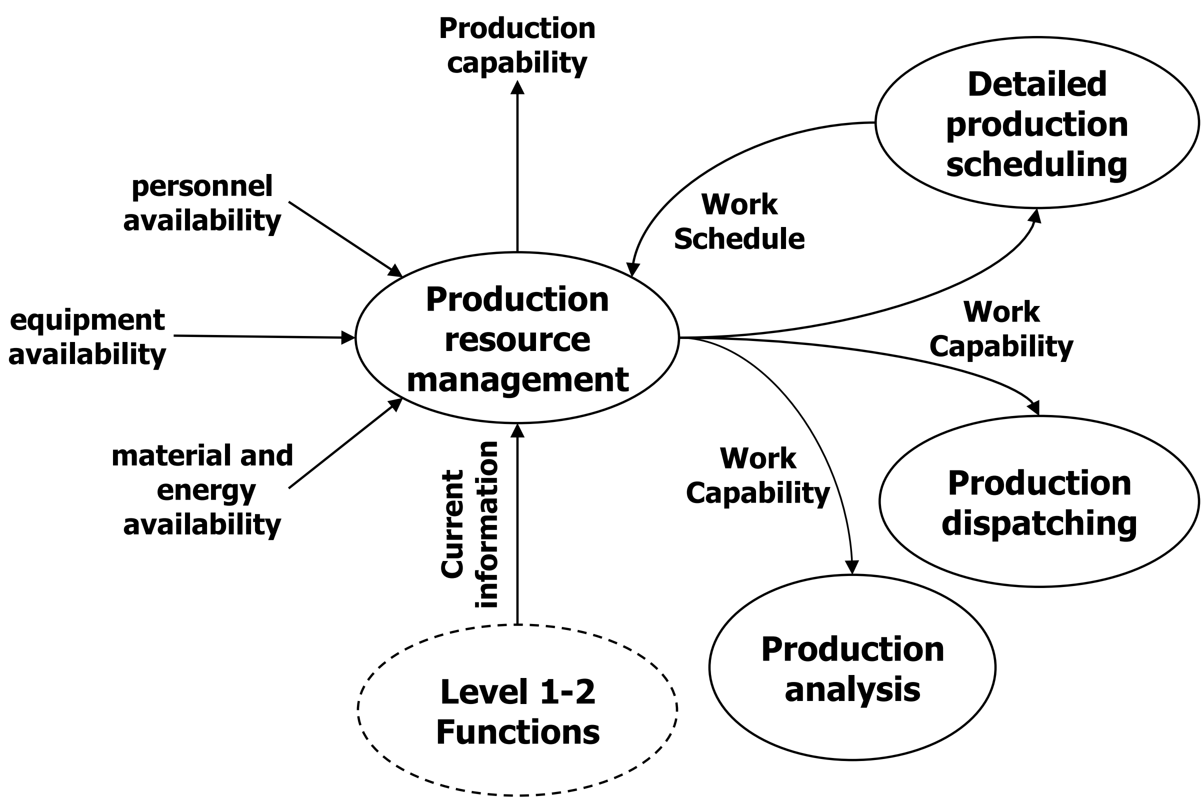

Figure 8 – Production resource management activity model interfaces

6.5.3 Tasks in production resource management

Production resource management tasks may include:

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

b) providing information on resource (material, equipment, or personnel) capability (committed, available, or unattainable). The information is based on the current statuses, future reservations and future needs (as identified in the production plan and work 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 1 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 2 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 on the basis of events, on demand and/or on a defined schedule and may be collected from equipment, people and/or applications;

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

i) maintaining personnel qualification test result information;

j) maintaining equipment capability test result information; and

k) managing reservations for future use of resources.

6.5.4 Resource availability

Resource availability provides time-specific definitions needed for scheduling and reporting on a resource. The resource availability must take into account elements such as working hours, labour 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 a.m. and 2:00 p.m., or a machine may be unavailable for 8 h within a 16-h 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 9 illustrates the types of information about the capacity of a single resource that may be provided by resource management.

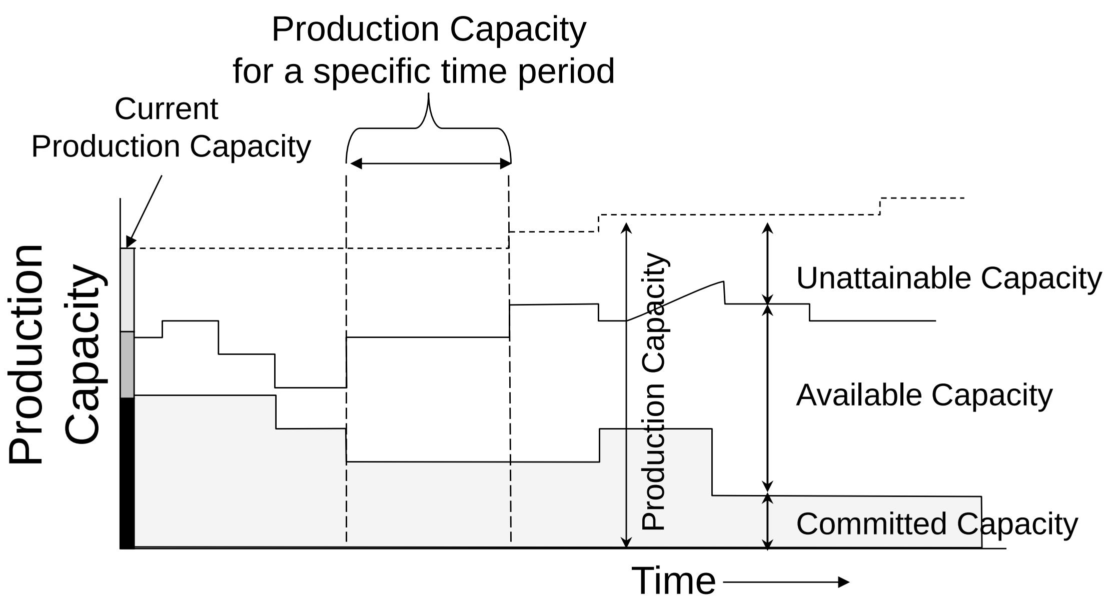

Figure 9 – Resource management capacity reporting

6.5.5 Collecting future committed resource information

Production resource management manages committed resource availability based on the work schedule and product requirements. An assigned resource is identified as committed for the period of time defined by the production plan, or until the completion of the scheduled task.

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

6.5.6 Collecting resource definition changes

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

6.5.7 Personnel resource information management

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

EXAMPLE If an individual has vacation planned or is known to be sick for a certain period of time, then a business-level human resource (HR) function may report this situation to production resource management. This prevents production from assigning the resource within this period of time. As an extension, the whole working schedule of the personnel should 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 systems, but shall 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, labour management can be considered as part of the manufacturing operations activities.

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

6.5.8 Equipment resource information management

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

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

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

Selected equipment may be submitted to an equipment capability test as defined in ISA-95 Part 1 and IEC 62264-1. This test result determines if specific equipment may be assigned for a specific task in a specific process segment.

6.5.9 Material resource information management

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

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

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

6.6 Detailed production scheduling

6.6.1 Activity definition

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

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

6.6.2 Activity model

Figure 10 illustrates some of the interfaces to detailed production scheduling.

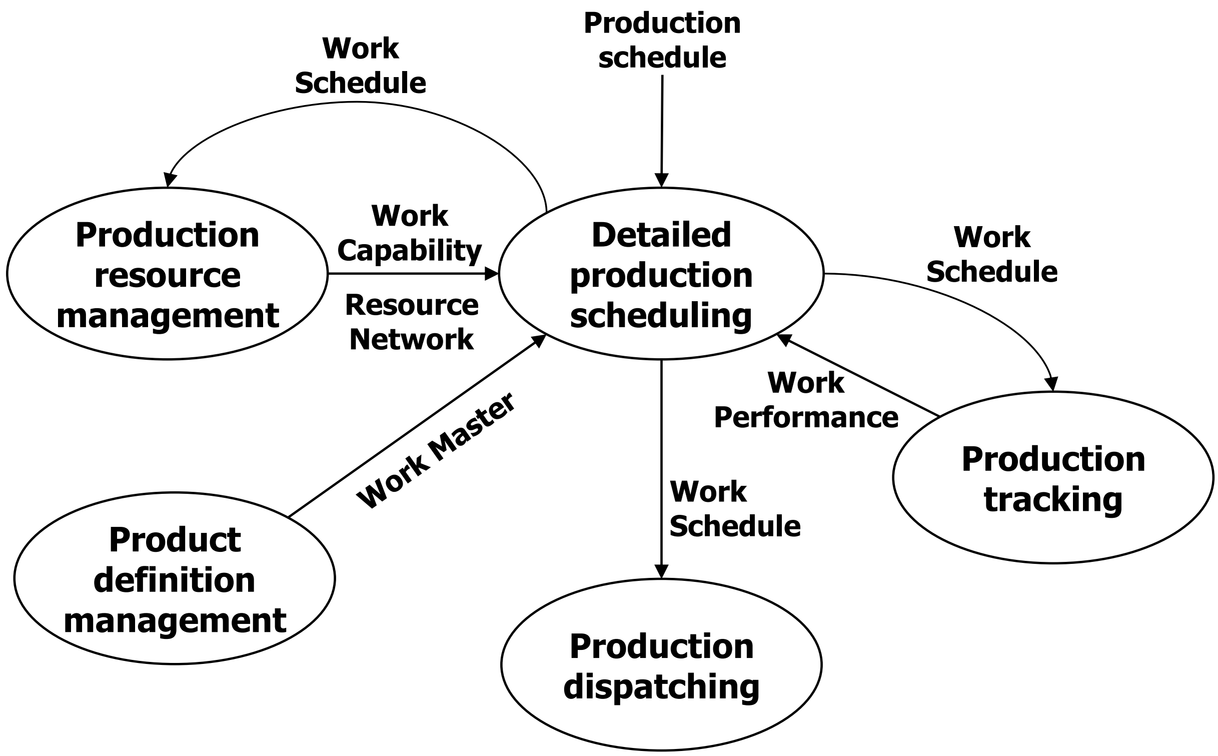

Figure 10 – Detailed production scheduling activity model interfaces

6.6.3 Tasks in detailed production scheduling

Detailed production scheduling tasks may include:

a) creating and maintaining a work schedule;

b) comparing actual production to planned production;

c) determining the committed capacity of each resource for use by the production resource management function;

d) obtaining information from maintenance operations management, quality operations management and inventory operations management; and

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

EXAMPLE 1 Ability to promise inquiry from a Level 4 system.

A work schedule is created from a Level 4 production schedule. A work 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 on the basis of unanticipated events such as equipment outages, manpower changes and/or raw material availability changes. It may be provided to people, to applications, or to other activities.

EXAMPLE 2 Detailed production scheduling may enforce a scheduling strategy such as forward (push) or backward (pull) selection, priority assignment for each job order, application of specific constraints for the plant, time buffer allocation on bottleneck resource and so forth.

6.6.4 Finite capacity scheduling

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

Finite capacity scheduling is typically accomplished locally, at the site or area, because of the amount of detailed local information required to generate a valid work schedule. Information on current and future resource capability and capacity, as defined in ISA-95 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 11 illustrates how production schedules can be split or merged prior to being sent to dispatching. The left side of Figure 11 illustrates how a single schedule is split into multiple work schedules and the right side illustrates how multiple production schedules from multiple sources can be merged into a work schedule.

EXAMPLE 1 Multiple work schedules may be generated from a weekly production schedule, one schedule for each day of production.

EXAMPLE 2 A single work schedule may be created that combines multiple production schedule elements in order to reduce set-up time and optimize production.

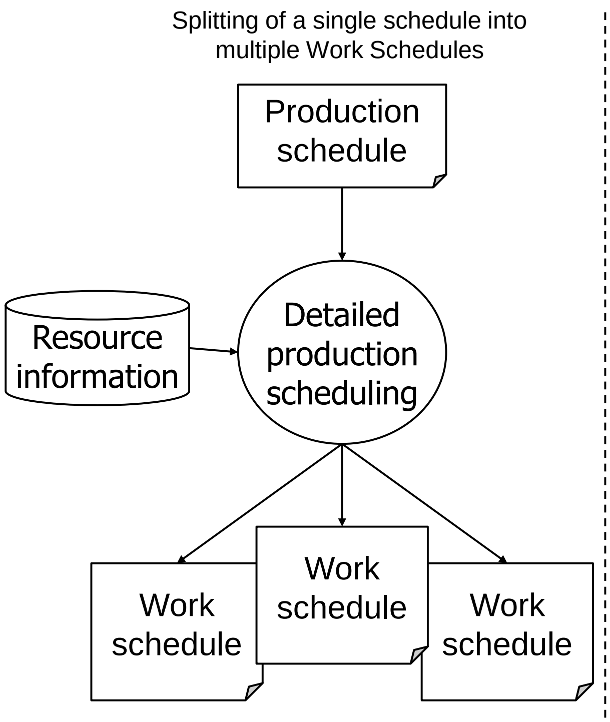

Figure 11 – Splitting and merging production schedules to work schedules

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

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

6.6.6 Work schedule for production

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

A work 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 ISA-95 Part 1, may be realized through the execution of one or more job order elements. For example, the work schedule may define the various sub-levels of “operations-oriented” job order elements that may be required.

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

EXAMPLE Work schedule for production, Figure 12 illustrates an example work schedule for equipment represented in a Gantt chart format. The hashed rectangles in the figure represent job orders and each different hash pattern represents a different work request.

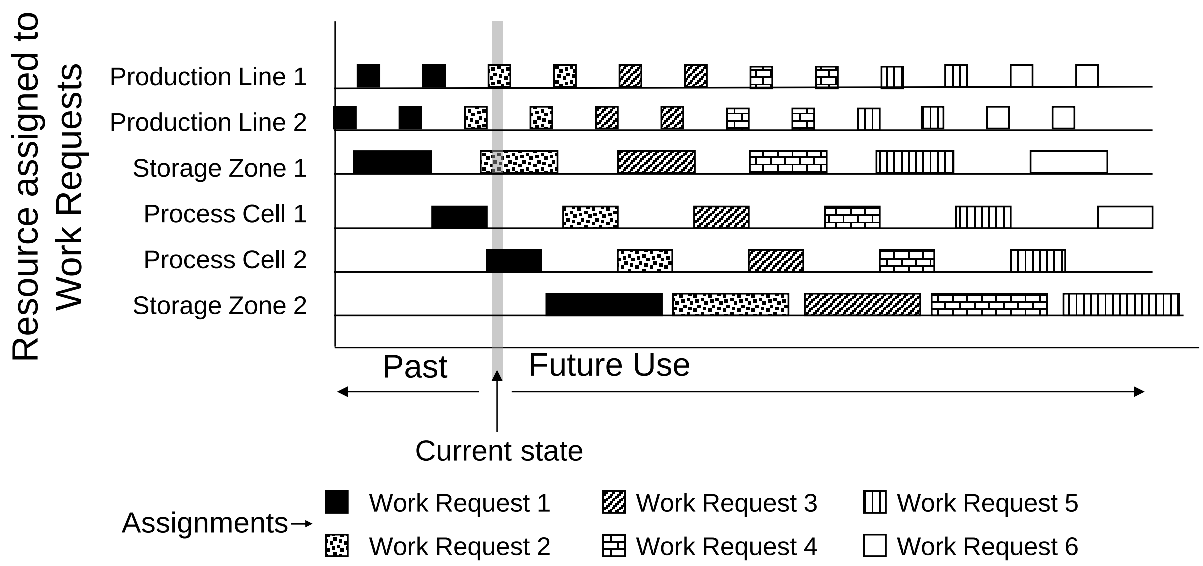

Figure 12 – Work schedule

6.7 Production dispatching

6.7.1 Activity definition

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

a) scheduling batches to start in a batch control system;

b) scheduling production runs to start in production lines;

c) specifying standard operating condition targets in production units;

d) sending job orders to work centers;

e) issuing job orders for manual operations.

EXAMPLE Dispatched job orders may be machine set-up, grade change switchovers, equipment cleaning, run rate set-up, or production flow set-up.

6.7.2 Activity model

Figure 13 illustrates some of the interfaces to production dispatching.

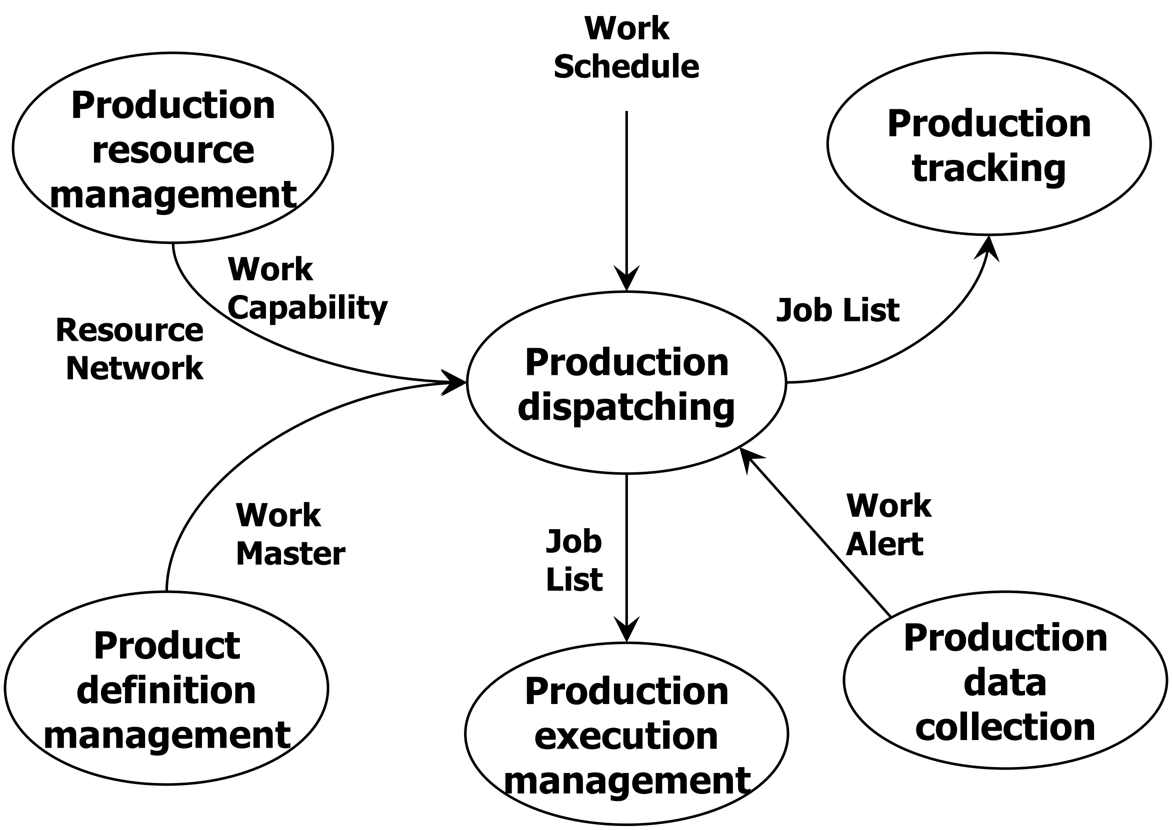

Figure 13 – Production dispatching activity model interfaces

6.7.3 Tasks in production dispatching

Production dispatching tasks may include:

a) issuing job orders as identified by the schedule;

b) assigning local resources to production, where these are not identified as part of the work schedule;

c) releasing local resources to start job orders;

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

e) maintaining status of job orders;

EXAMPLE Approved, fixed, in process, or cancelled.

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

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

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

i) receiving information from production resource management about unanticipated future resource availability that may relate to scheduled events; and

j) sending, or making available, the job list specifying the production activities to be performed.

6.7.4 Job list for production

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

A production job list may take multiple forms, including batch lists (see IEC 61512-1, Clause 2), operating directives, line schedules, set-up times, or process flow specifications. The production job list correlates equipment to detailed production elements and makes this information available to production data collection and production tracking activities.

6.7.5 Sample production job list and jobs

Figure 14 illustrates an example of a production work schedule and production job list represented in a Gantt chart format. Each of the hatched rectangles in the figure represents a job and each different hash pattern represents a different work request. A job list is represented as a set of job orders for a specific period of time. A job order may be defined by lower-level elements. The collection of job orders for a specific resource is represented as a detailed resource schedule.

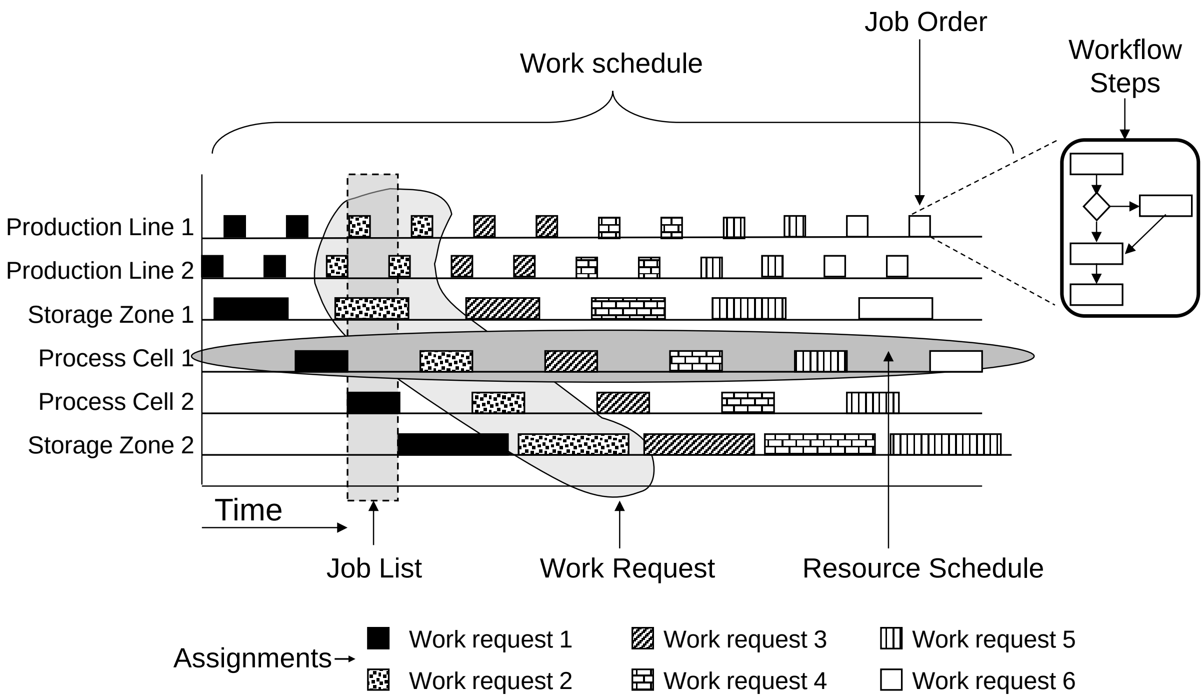

Figure 14 – Sample job list

6.7.6 Assigning work

Production dispatching may include:

a) assigning material to be used in a job order;

b) assigning equipment to be used in a job order;

c) assigning personnel to execute a job order;

d) assigning storage and other resources to be used in a job order.

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

Figure 15 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, job lists would specify set-up for a continuous premix operation, including any initial charging. The job list would then define the sequence of batches for primary production and would also define the set-up of the back-end discrete packaging system.

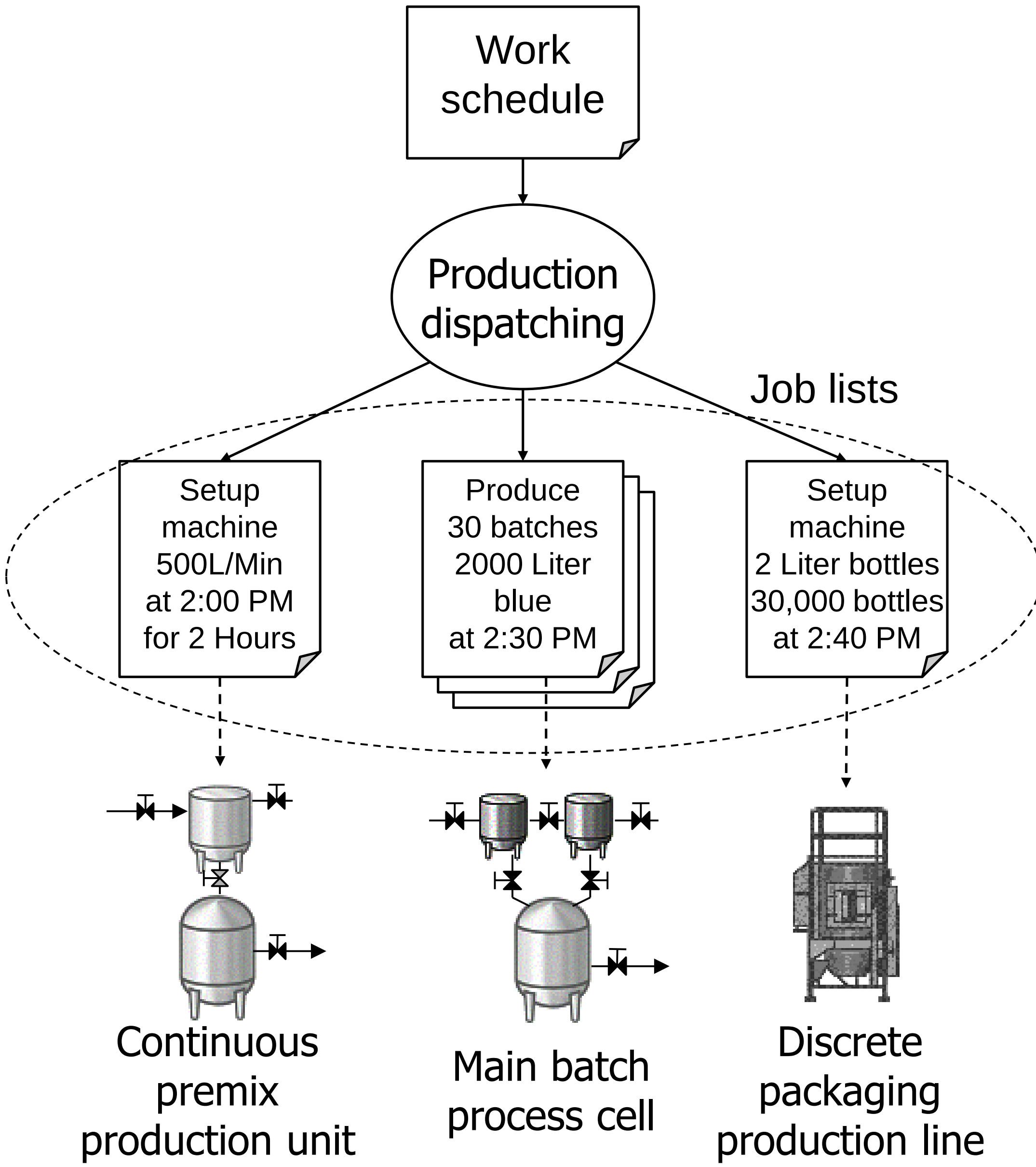

Figure 15 – Work dispatching for mixed process facility

6.8 Production execution management

6.8.1 Activity definition

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

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

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

6.8.2 Activity model

Figure 16 illustrates some of the interfaces to production execution management.

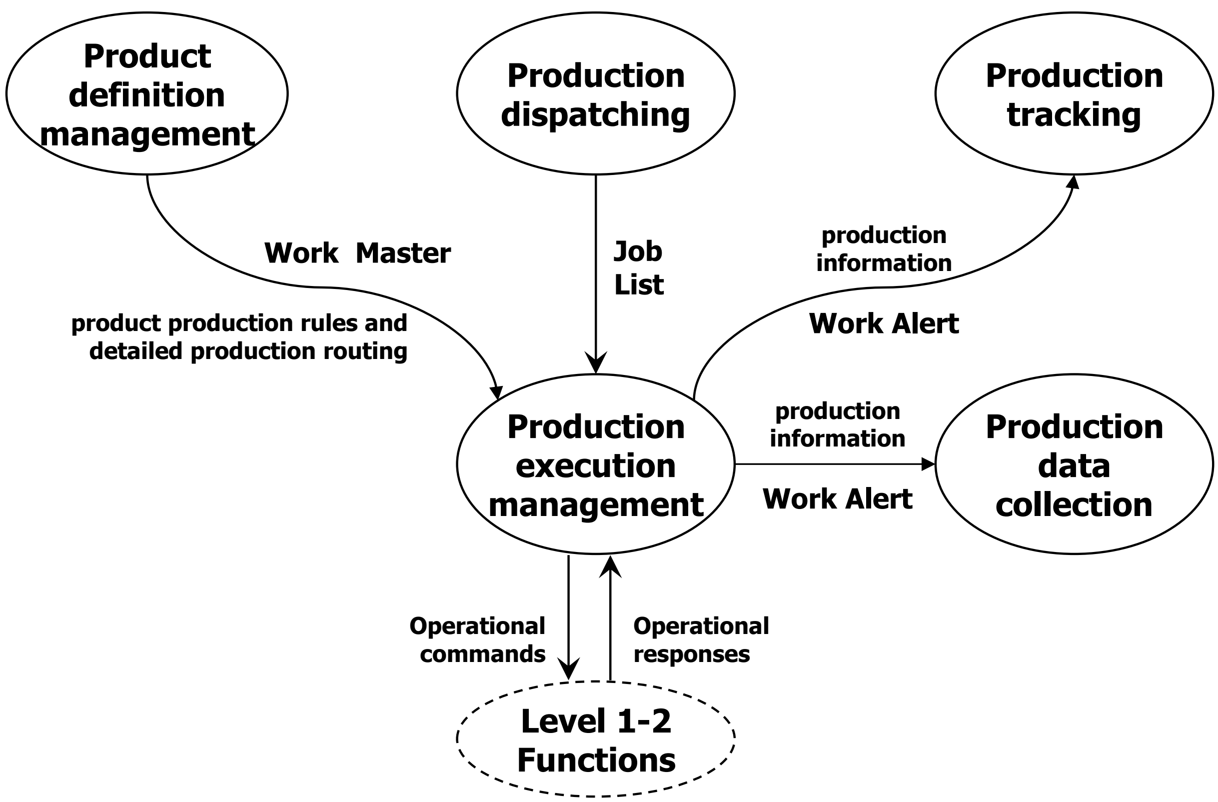

Figure 16 – Production execution management activity model interfaces

6.8.3 Tasks in production execution management

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

Production execution management tasks may include:

a) directing the performance of work and initiating Level 2 activities; this task includes
   - creating work directives from work masters for each job order
   - orchestrating the execution by means of the workflow process associated to a job order's work directive

   NOTE: The term work directive is defined in Part 4.

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

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

d) ensuring that resources are valid for the assigned tasks;

   EXAMPLE 1 This may be ensuring that equipment sterilization status is correct for the assigned operation (for example, a vessel is "clean" before use in production).

   EXAMPLE 2 Equipment certifications are current, personnel qualifications are up to date and materials are released for use.

e) assigning resources under local run time control;

   EXAMPLE 3 The assignment of units to a batch, if the work 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; and

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

6.9 Production data collection

6.9.1 Activity definition

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

6.9.2 Activity model

Figure 17 illustrates some of the interfaces to production data collection.

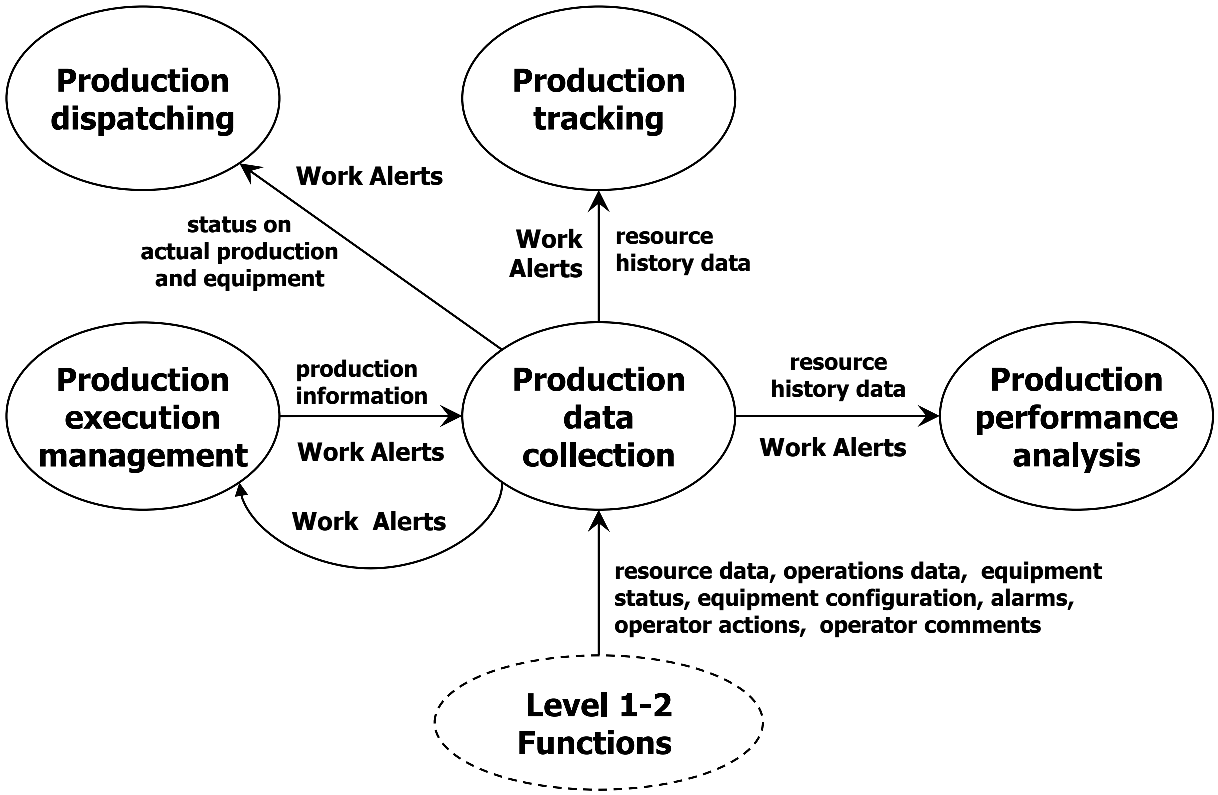

Figure 17 – Production data collection activity model interfaces

6.9.3 Tasks in production data collection

Production data collection tasks may include:

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

EXAMPLE: This could include the following:

– process data;

– equipment status data;

– lot and sublot location and amount data collection;

– operations logs (plant entries and comments).

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

c) providing reports on production data;

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

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

f) providing compliance monitoring and alarm management functionality (event logging and sequence of events); and

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

6.10 Production tracking

6.10.1 Activity definition

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

6.10.2 Activity model

Figure 18 illustrates some of the interfaces to production tracking.

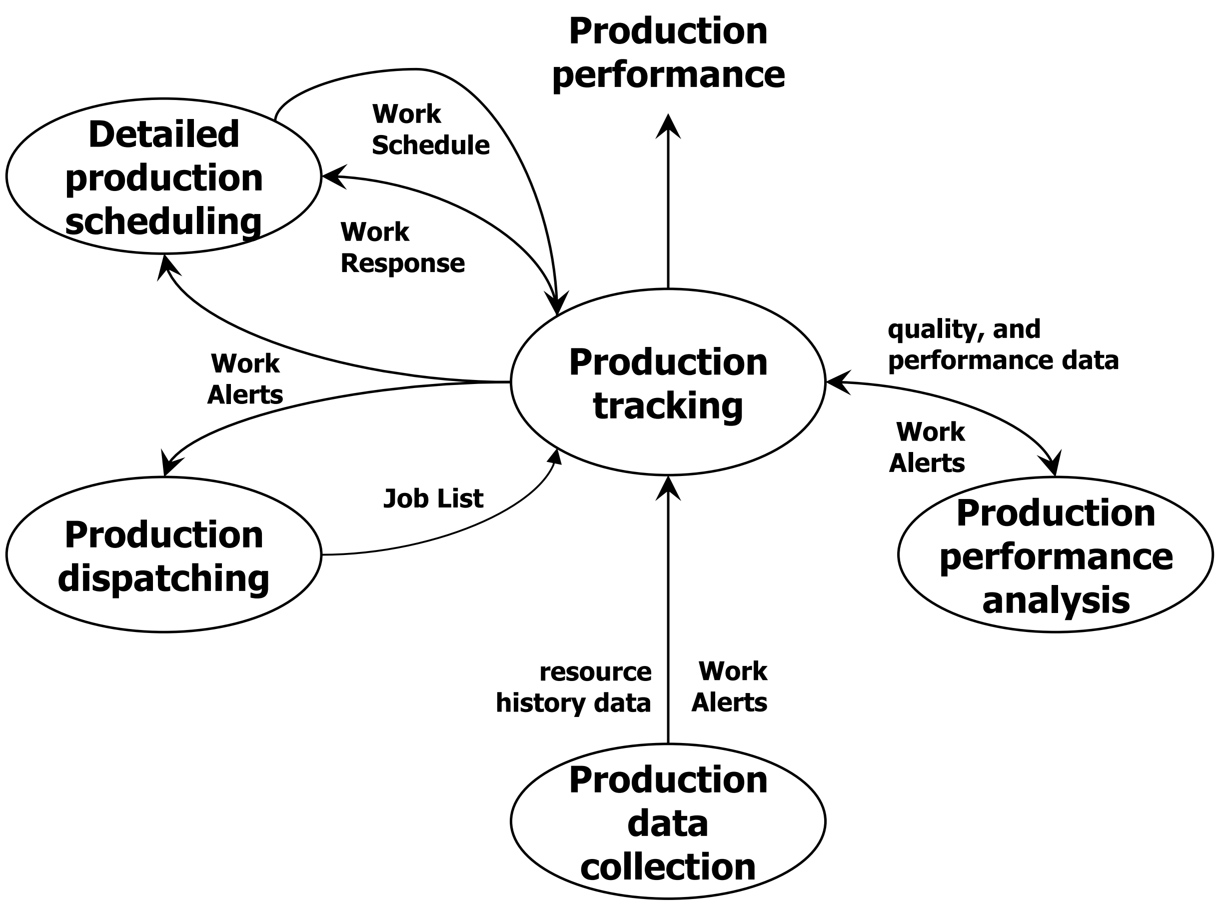

Figure 18 – Production tracking activity model interfaces

6.10.3 Tasks in production tracking

Production tracking tasks may include:

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

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

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

d) translating process events, including production and movement events, into product information;

e) providing information for tracking (recording) and tracing (analysis);

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

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

6.10.4 Merging and splitting production information

Production tracking may involve compiling production data into business information on actual production including in-work inventory, raw material usage, and energy usage. Production tracking may require combining resource history data from multiple batches or runs into a single production performance report. Alternatively, it may require splitting information about a single batch or run into multiple production performance reports. These are illustrated in Figure 19.

EXAMPLE 1 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 2 Information from a single production run may be split into multiple production performance reports, one report for each shift used in the production.

EXAMPLE 3 A portion of a product run may be sent to an outside entity to perform a portion of the life cycle of completing the product. In this case, the product would share history until it leaves the internal manufacturing processes and upon return to the normal internal manufacturing processes, the same product would have a slightly different history than its peer product.

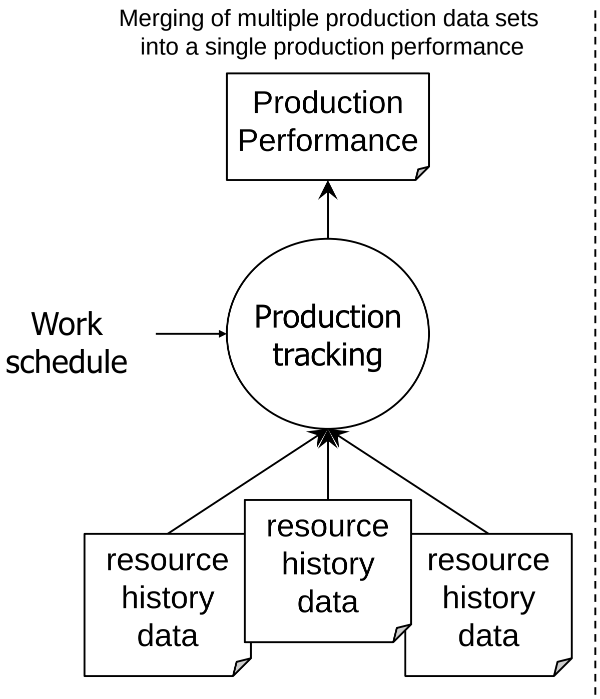

Figure 19 – Merging and splitting production tracking information

6.11 Production performance analysis

6.11.1 Activity definition

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

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

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

6.11.2 Activity model

Figure 20 illustrates some of the interfaces to production performance analysis.

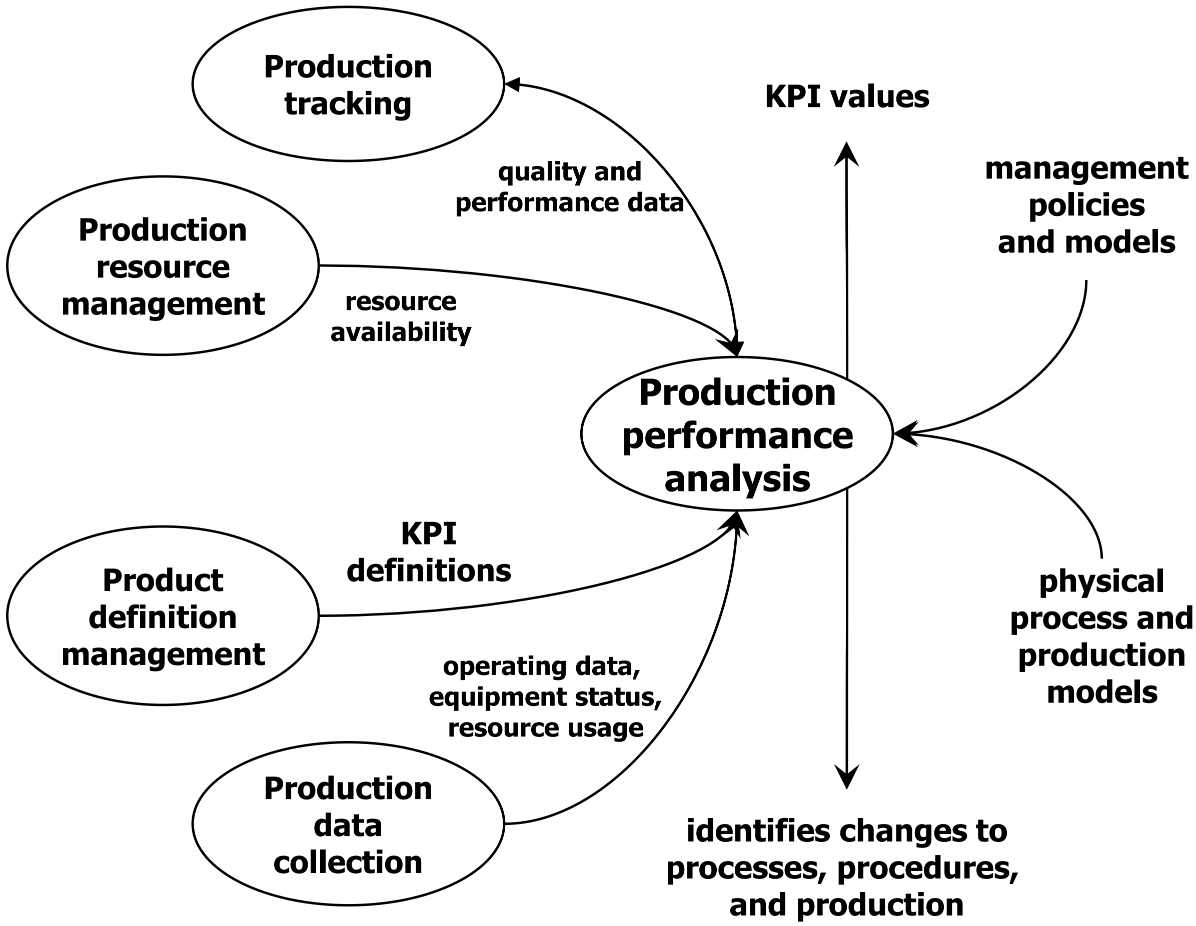

Figure 20 – Production performance analysis activity model interfaces

6.11.3 Tasks in production performance analysis

Production performance analysis tasks may include:

a) producing reports of performance and cost;

b) evaluating constraints to capacity and quality,

c) performing performance tests where necessary to determine capacity;

d) comparing different production lines and creating average or target runs;

e) comparing and contrasting one run against another;

f) comparing production runs to identify "golden" runs;

NOTE 1 "Golden" runs are runs that are the best run ever produced, where best may be the highest quality, or lowest cost, or any other criteria.

g) determining why the "golden" runs are exceptional;

h) comparing runs against defined "golden" runs;

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

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

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

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

NOTE 2 In addition to this main question, questions related to resource tracking, such as "what was where, when and why?" for material tracking may be answered. This ability to track down product and minimize the impact from contamination can be the critical analysis tool needed to ensure future orders from customers.

6.11.4 Resource traceability analysis

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

Resource traceability analysis may include analysis on

– materials produced, consumed, stored and moved;
– equipment used in production, testing and storage;
– personnel involved in the production and storage of material and operation of equipment.

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

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

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

Resource traceability has two components, tracking and tracing.

a) Tracking is the process of following and recording the movements and change of resources and recording all inputs to the resource through all steps and agents.
b) Tracing is the process that determines a resource’s history of use from any point, forward or backward, using tracking information.

NOTE 4 For example, material tracing may be characterized as

a) backward material tracing – which shows the upstream history of the material as inputs to manufacturing processes and the equipment used to transfer the material;

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

6.11.5 Product analysis

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

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

6.11.6 Process analysis

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

6.11.7 Production performance simulation

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

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

– adding additional capacity without significant addition of new equipment, machinery, or labour;
– increasing the efficiency and effectiveness of an existing system;
– eliminating bottlenecks, using existing assets better;
– evaluating possibilities for quality and throughput improvements or cost reductions;
– improving the ability to meet deadlines, customer commitment and changing customer requirements;
– educating operators without putting personnel, the environment, physical systems, or production at risk.

6.11.8 KPIs

In addition to the formally defined performance data model defined in ISA-95.02, there is additional information about operations that provides summaries of past performance, indications of future performance, or indicators of potential future problems. Collectively, this information is defined as KPIs (Key Performance Indicators). One of the activities within production performance analysis is the generation of KPIs. 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.

Manufacturing oriented KPIs are defined in ISO 22400-2, Automation systems and integration — Key performance indicators for manufacturing operations management — Part 2: Definitions and descriptions.

6.11.9 Performance management

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

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

– monitoring to enable visibility of KPIs;
– ability to utilize KPI information in a model;
– root cause analysis;
– prediction of future KPI values;
– capability to enact control based on KPI values.

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

EXAMPLE 1 This could be the ability to analyze all inventory by product families down to the individual product stock-keeping unit.

EXAMPLE 2 A simple model could be a summation of all subsidiary node values of an indicator.

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

EXAMPLE 3 An example of a visibility metaphor is the use of a traffic light indicating the status of an indicator. The green light indicates that the indicator is within specification. Yellow and red lights indicate an indicator has exceeded acceptable ranges. No light represents a lack of data or that the data is of poor quality. A single report may be made up of tens or hundreds of indicators allowing a quick survey if large amounts of information.

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

EXAMPLE 4 Performance management activities may be cross-functional and may look at the raw information used in the analysis. For example, this may include visibility into a lab system to see detailed results for recent lots. Another example could be visibility into production to see the current active constraints in the process control.

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

EXAMPLE 5 An example might be to take the historical mean time between failure values and develop a trend to predict the next failure for a piece of equipment.

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

EXAMPLE 6 A change of a control set point could be based on an online SPC high alarm for a key process or derived parameter.

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

7 Maintenance operations management

7.1 General activities in maintenance operations management

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

a) Providing maintenance responses to equipment problems

NOTE 1 In some industries this is known as corrective maintenance or reactive maintenance response.

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

NOTE 2 In some industries this is known as preventive maintenance.

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

NOTE 3 In some industries this is known as condition-based maintenance.

NOTE 4 This includes predictive maintenance based on a prognosis of expected future failure.

d) Optimizing resource operating performance and efficiencies

NOTE 5 In some industries this could also be considered as part of production and process analysis.

NOTE 6 This includes minor changes in production or support equipment. These minor changes may often consume a significant fraction of maintenance resources.

Maintenance operations management may include:

a) providing corrective, preventive and condition-based maintenance;
b) providing equipment monitoring activities to anticipate failure, including equipment self-check and diagnostic activities;
c) developing maintenance cost and performance reports;
d) coordinating and monitoring contracted work;
e) supervising requested maintenance;
f) reporting on performed maintenance, including spare parts used, maintenance labour and maintenance costs;
g) coordinating planned work with operators and plant supervision;
h) making performance verifications of production equipment;
i) assisting with product changeover needs that involve equipment changes;
j) monitoring and updating maintenance history files.

7.2 Maintenance operations management activity model

The maintenance operations management model defined in ISA-95 Part 1 is expanded to a more detailed activity model of maintenance operations, shown in Figure 21, using the generic activity model shown in Figure 2. This maintenance activity model identifies the main maintenance tasks and some of the information exchanged between these activities, but not how the activities are to be performed in a specific organizational structure. Companies differ in the organization of maintenance activity roles and the assignment of these roles to personnel or system resources.

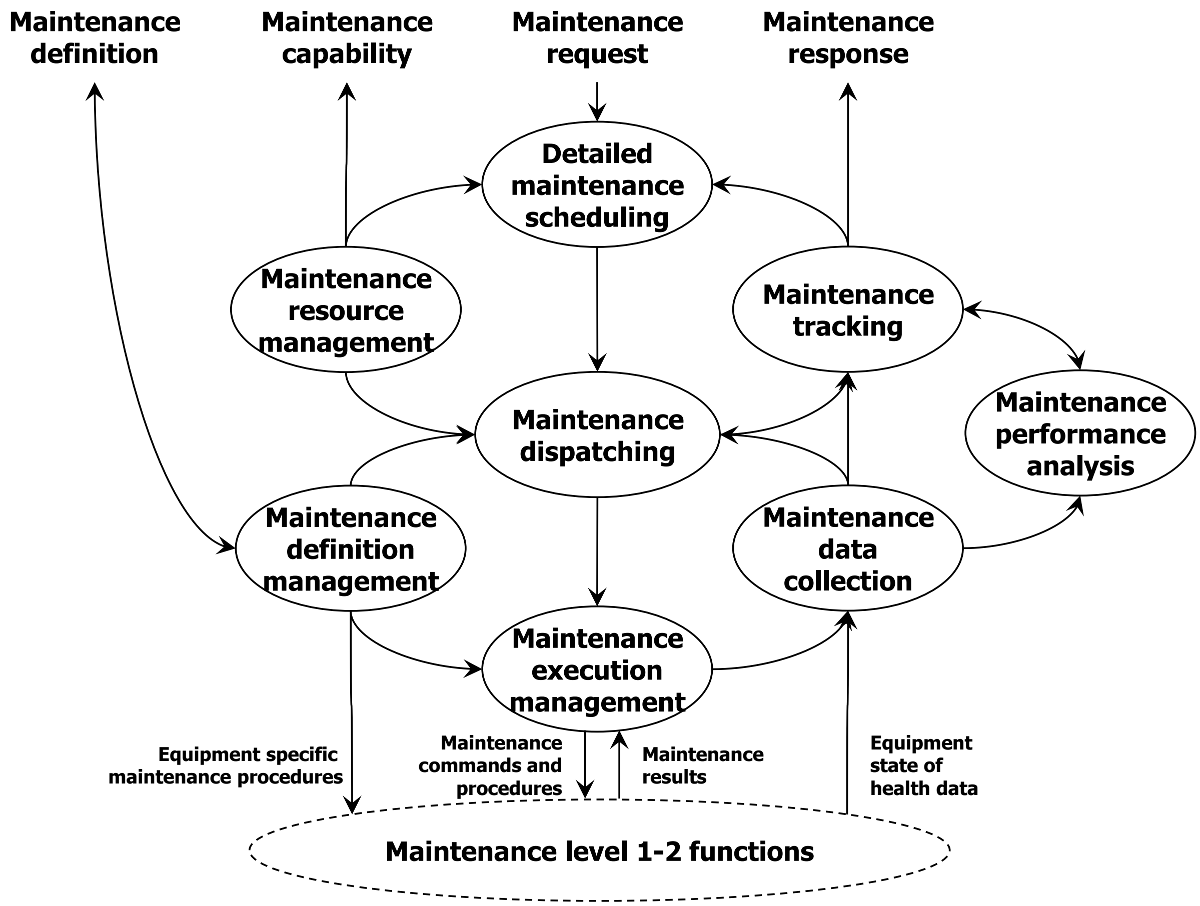

Figure 21 – Activity model of maintenance operations management

The ovals in the maintenance operations model indicate collections of activities, identified as the main activities. Lines with arrowheads indicate an 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 21 only illustrates some major information flows between activities.

7.3 Information exchanged in maintenance operations management

7.3.1 Maintenance information

Maintenance requests, maintenance work orders and maintenance responses, as defined in ISA-95 Part 1 and ISA-95 Part 2, do not always cross the boundary between Level 3 and Level 4 systems. Maintenance requests, maintenance work orders and maintenance responses are often generated internally within manufacturing operations. Maintenance requests and maintenance responses may be exchanged individually or as sets.

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

7.3.2 Maintenance definitions

Maintenance definitions shall be defined as the documentation sets for the manufacturing assets under maintenance. These include work masters, equipment and system drawings (with revisions), engineering documentation, specifications, vendors' manuals, standard operating procedures for repair and servicing, maintenance instructions and equipment diagnostic and prognostic procedures.

Maintenance definitions include the information, as work masters, used to instruct maintenance personnel on which activities are required to perform the specified maintenance activity, how to perform those activities, how long they typically take and the resources required for each 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 shall be defined as the collection of the expected future available, committed and unattainable capability of resources used in maintenance activities. The maintenance capability includes the capacity of the resources. Maintenance capability is based on the capability in:

– personnel – typically based on qualification, training, experience and discipline (such as system, mechanical and facility). May also be based on device or equipment-specific proficiencies;
– equipment – such as calibration equipment, transport equipment and special tools;
– material – such as maintenance-consumable materials and spare parts; and
– physical assets – such as spare parts

7.3.4 Maintenance request

Maintenance requests shall be defined as requests for maintenance services. Maintenance requests may be for corrective, preventive, proactive and condition-based maintenance. Maintenance requests may be generated from Level 3, Level 4, or lower-level activities, based on the business and operations processes in place. Intelligent instruments and controllers at Level 1 and control systems at Level 2 may automatically generate condition-based requests for maintenance services. See ISA-95 Part 1 and ISA-95 Part 2 for definitions of maintenance requests and attributes.

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

7.3.5 Maintenance response

Maintenance responses shall be defined as the documented information on the corrective or improving action taken as specified in the maintenance request. See ISA-95 Part 1 and ISA-95 Part 2 for definitions of maintenance responses and attributes.

7.3.6 Equipment-specific maintenance procedures

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

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

7.3.7 Maintenance commands and procedures

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

7.3.8 Maintenance results

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

EXAMPLE A result may contain information such as, “pressure plate #43 was removed and replaced, set to 0,25 inches clearance gap and put back into service”.

7.3.9 Equipment state of health data

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

EXAMPLE 1 This could include bearing temperature, vibration and self-test status.

EXAMPLE 2 This could be an indication of a valve’s full stroke travel time exceeding a specified limit.

NOTE 1 See ISO 13374-1:2003 for examples of this type of data.

NOTE 2 This may include equipment self-check and diagnostic activities.

7.4 Maintenance definition management

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

Maintenance definition management may include:

a) managing documents such as maintenance instructions in work masters, vendor documentation, CAD drawings, database records and analysis tools;

b) deriving and managing a set of maintenance definitions;

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

d) providing maintenance definitions to other applications, equipment, personnel, or activities;

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

f) optimizing maintenance definitions based on process and maintenance performance analysis;

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

h) managing the KPI definitions associated with maintenance;

i) managing maintenance definitions related to safety and environmental procedures;

j) maintenance definition management includes management of the distribution of maintenance definitions. Some maintenance definitions may exist for Level 2 and Level 1 equipment. When that is the case, downloads of this information shall be coordinated with other manufacturing operations management functions to reduce the impact on production. This information may be included as part of maintenance commands and procedures when the download is initiated as part of a maintenance execution management activity.

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

7.5 Maintenance resource management

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

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

Maintenance resource management may include:

a) maintaining information about maintenance personnel, including qualification information, such as qualification status and qualification test results, as defined in the ISA-95 Part 1 and ISA-95 Part 2 personnel model;
b) maintaining information about equipment used in maintenance and equipment capability tests, as defined in the ISA-95 Part 1 equipment model;
c) maintaining information about maintenance supplies, defined as consumable materials, as described in the ISA-95 Part 1 material model;
d) maintaining information about the health and state, assignment and availability status of resources to be used and being used in all Level 3 maintenance activities;
e) coordinating and monitoring contracted work;
f) supervising requested maintenance.

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

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

7.6 Detailed maintenance scheduling

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

a) reviewing maintenance requests;
b) confirming or denying the maintenance request;
c) determining the priority of the request and the level of effort and availability of all resources;
d) scheduling the maintenance request to be performed within a work schedule as one or more job orders;
e) coordinating planned work with operators and plant supervision;
f) a work schedule may be generated for each site or area, based on the required job orders and available resources (personnel, equipment, physical assets, and materials). Detailed

maintenance scheduling maintains the requirements and develops the necessary organization of job 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 work schedule for maintenance is often generated for communication to the business planning and logistics system (Level 4).

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

7.7 Maintenance dispatching

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

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

7.8 Maintenance execution management

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

a) ensuring that maintenance procedures and regulations are followed during maintenance activities;

b) documenting the status and results of the work performed;

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

d) confirming that the work was performed according to the accepted quality standards;

NOTE This may involve receiving information from quality operations that indicated an unanticipated condition.

e) ensuring that the correct resources are used in maintenance;

f) verifying that equipment and personnel certifications are valid for the assigned tasks; and

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

7.9 Maintenance data collection

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

7.10 Maintenance tracking

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

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

EXAMPLE 1 An equipment condition may be dirty, cleaned, or sterile.

EXAMPLE 2 An equipment usability may be "qualified for use" or "unqualified for use".

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

EXAMPLE 3 Equipment used to perform maintenance could be handheld sensor calibration tools, voltmeters and oscilloscopes.

7.11 Maintenance performance analysis

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

Maintenance performance analysis functions may include identifying conditions such as:

– what equipment may fail if it does not receive maintenance intervention?

– what intervention should be taken and how soon?

– where routine preventive maintenance activities can be reduced?

– where efforts can be focused to improve return on assets (ROA) by eliminating costly or repetitive failures?

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

– should any adjustments be made to the process to prolong the life of critical plant assets?

– at what level can production continue without incurring an unacceptably high risk of process slowdown, downtime, quality problems, or safety shutdowns?

– what is the probability of successfully producing a specified amount of product in a period of time?

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

– which materials were used in maintenance activities?

– which tools were used in maintenance activities and which equipment was maintained?

– which personnel were involved in maintenance activities?

– developing maintenance cost and performance reports;

– reporting on performed maintenance, including spare parts used, maintenance labour and maintenance costs.

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

NOTE Maintenance indicators may be combined at Level 4 with financial information or at Level 3 using Level 4 financial information to provide cost-based indicators. Often maintenance operations management recognizes two categories for accounting purposes: expense and capital. These are segregated for purposes of reporting, accounting and asset management.

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

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

Data collected and analysed aligns with the maintenance philosophy of the respective portion of the enterprise. Each portion of the enterprise may have a different maintenance philosophy with some portions analysed for maximum reliability and other portions analysed for potential failure.

EXAMPLE Examples of maintenance indicators are defined in ISO 22400-2.

8 Quality operations management

8.1 General activities in quality operations management

8.1.1 Quality operations management activities

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

Quality operations management may include:

a) testing and verifying the quality of materials (raw, final and intermediate);
b) measuring and reporting the capability of the equipment to meet quality goals;
c) certifying product quality;
d) setting standards for quality;
e) setting standards for quality personnel certification and training;
f) setting standards for control of quality;
g) potentially relevant standards for quality operations management are defined in Annex C.

8.1.2 Quality operations scope

The following parts of this clause focus only on quality test operations management activities.

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

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

a) conducting periodic quality evaluations;
b) setting non-empirical standards for material quality;
c) setting non-empirical standards for product specifications;
d) setting non-empirical standards for production specifications;
e) setting non-empirical standards for personnel qualifications;
f) setting non-empirical classifications and certification processes for materials; and
g) creating and reviewing non-empirical procedures and processes to ensure that quality is defined and maintained.

8.1.3 Quality test operations management

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

Quality operations management activities addressed in this clause include:

a) raw materials evaluation:
   - testing of incoming raw materials and approval for use if in accordance with set standards;
   - collecting and maintaining quality control file for data for quality control analysis; and
   - testing of non-consumed materials used in the process, such as catalysts;
b) evaluation of product:
   - testing of intermediate and final product and report results to classification;
   - collecting and maintaining quality control file for data for quality control analysis;
   - checking of product data versus customer's requirements to assure adequate quality before shipment; and
   - using at-line process analytics to drive real-time release or disposition of products based on process data;
c) testing of classification and certification:
   - classifying quality and properties of end product in accordance with set standards;
   - reporting on test results and classification to finished product inventory control;
   - certifying that product was produced according to standard process conditions;
   - reporting process data and certification to finished product inventory control; and
   - using at-line or in-line process analytics for checking consistency of processes;
d) measurement validation:
   - checking of reference sample results against standards;
   - ongoing analysis of testing methods using statistical quality control methods; and
   - maintaining quality statistics on each item checked for continuing quality control studies;
e) laboratory and automatic analysis:
   - conducting metric, chemical and physical tests on sample product items to obtain data for on-going quality control tests;
   - transmitting test data to analysis facilities and quality control systems to assure future quality of product; and
   - inferring material attributes based on on-line models.

8.1.4 Types of testing

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

a) tests of material, suppliers, equipment, or other resources – tests to determine that resources to be used meet defined quality requirements;
b) environmental tests – environmental tests are performed to check the environment and the impact of production on the environment, for example, contamination of equipment or consumables such as water or solvents, the air in the production facility and/or the discharges;

c) reference analyses tests – reference analysis consists of sending known samples to various laboratories in order to check the performance of a specific laboratory; and

EXAMPLE 1 Performing a test to see if a laboratory is able to produce correct results.

d) asset reliability tests – preventative maintenance tests conducted to provide consistency of product and process.

EXAMPLE 2 Examples include vibration profiles to product and equipment set-ups, oil/fluid testing for physical properties, contaminates and metal contents and ultrasonic profiling.

8.1.5 When testing occurs

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

a) in-line testing – in-line testing is part of the production execution management, where the test equipment is part of the process;

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

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

8.1.6 Quality systems

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

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

8.2 Quality test operations activity model

The quality operations management model defined in ISA-95 Part 1 is expanded to a more detailed activity model of quality test operations, as shown in Figure 22, using the generic activity model shown in Figure 2. The model shown in Figure 22 defines the activities as they relate to inspections or test operations. The model defines what quality test activities should be carried out 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.

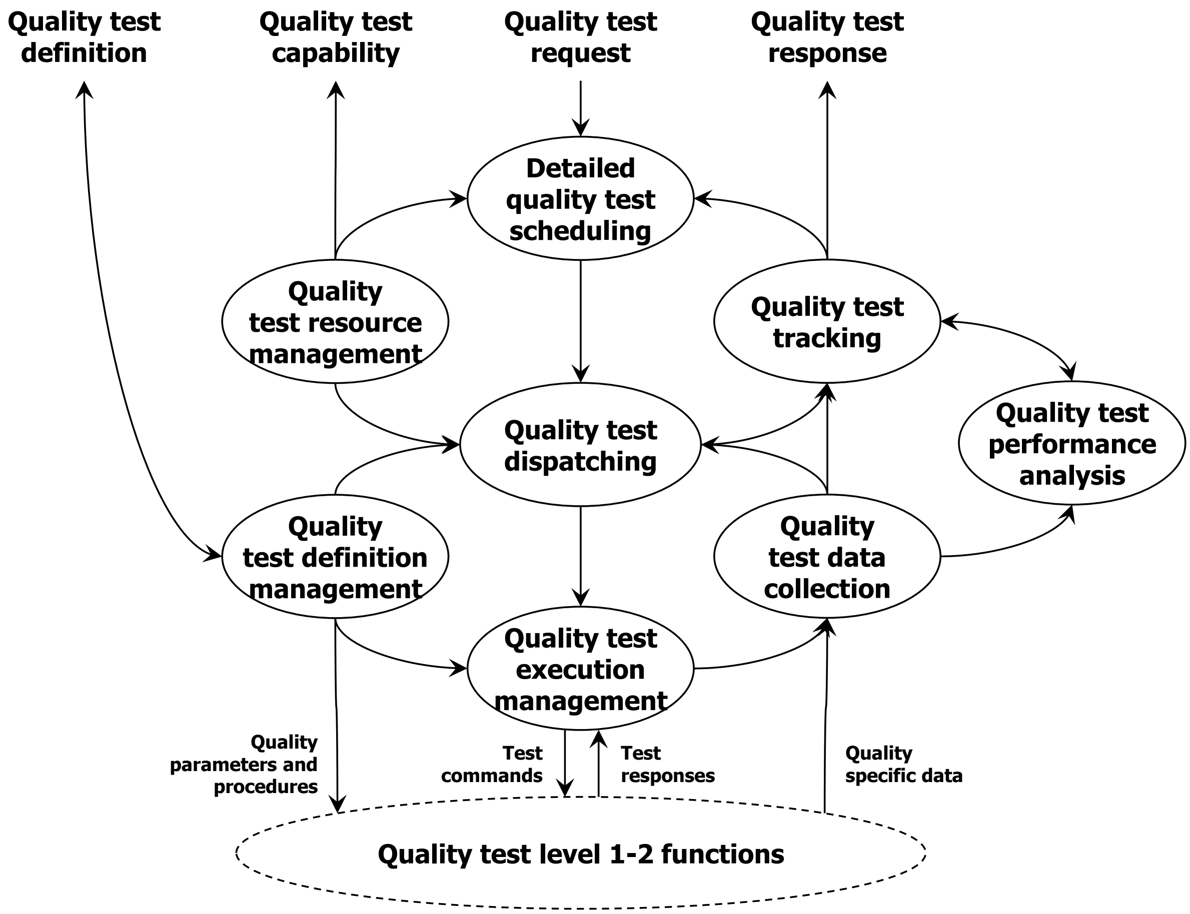

Figure 22 – Activity model of quality test operations management

The ovals in the quality test operations activity model indicate the activities, identified as the main functions. Lines with arrowheads indicate an 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 22 only illustrates some major information flows between activities.

8.3 Information exchanged in quality test operations management

8.3.1 Quality test definitions

Quality test definitions shall be defined as test specifications for testing of materials, environment and equipment. Quality test definitions may be sent to Level 3 from a Level 4 system, such as from an enterprise resource planning system (ERP), a product life-cycle 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 in work masters.

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

8.3.2 Quality test capability

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

– personnel – typically based on qualification, training, experience and discipline. May also be based on device or equipment specific proficiencies;
– equipment – such as test equipment; and
– material – such as test consumable materials.

8.3.3 Quality test request

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

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

8.3.4 Quality test response

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

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

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

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

– continuing production with corrective adjustments;
– reworking the material following specific work instructions;
– scrapping or discarding the WIP material and rescheduling the job order(s);
– placing quarantine or hold on job order(s) to conduct further analysis;
– discarding the test sample and acquiring a new sample;
– recalibrating the testing equipment.

8.3.5 Quality parameters and procedures

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

8.3.6 Test commands

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

8.3.7 Test responses

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

8.3.8 Quality-specific data

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

EXAMPLE 1 Appropriate context may be process data, material, timeframe and location.

EXAMPLE 2 Aggregated data may be the number of measurements, minimum, maximum, average and standard deviation.

8.4 Quality test definition management

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

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

EXAMPLE 1 Always test non-certified suppliers and test certified suppliers only every tenth delivery except when the last delivery was non-compliant.

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

EXAMPLE 2 Release status could be “in development,” “ready for use,” or “obsolete.”

Quality test definition management tasks may include:

a) managing new quality test definitions;
b) managing changes to quality test definitions. This may include the ability to route changes through an appropriate approval process, management of definition versions, tracking of modifications and security control of the definitions;
c) providing quality test definitions to other applications, personnel, or activities;
d) managing the exchange of quality test definition information with Level 4 functions, at the level of detail required by the business operations;
e) optimizing quality test definitions based on quality test analysis;
f) generating and maintaining quality test definitions not related to product, such as for test equipment validation and standard sample validation; and
g) managing the key performance indicator (KPI) definitions associated with quality tests.

8.5 Quality test resource management

Quality test resource management shall be defined as the collection of activities that manage the resources and relationships between resources needed to perform quality tests.

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

Quality test resource management tasks may include:

a) providing quality personnel, material, equipment, and physical asset resource definitions. The information may be provided on demand or on a defined schedule and may be provided to people, to applications, or to other activities. These resources include
   - test material – includes material that is consumed during the execution of a test;
   - test equipment – includes equipment used for on-line, off-line and at-line testing;
   - personnel – includes management of such attributes as skill sets, certifications, authorizations and security clearances;

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

   EXAMPLE 1 A qualified scanning electron microscope may be unattainable for third shift in January due to planned maintenance on the equipment.

c) ensuring that requests for acquisition of resources to meet future test capabilities are initiated;

d) ensuring that equipment is available for the assigned tasks and that job titles are correct and training is current for personnel assigned to tasks;

e) providing information on the location of resources and assignment of resources to areas;

   EXAMPLE 2 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, physical asset, 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; and

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

8.6 Detailed quality test scheduling

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

Detailed quality test scheduling tasks include:

a) creating and maintaining a detailed quality test schedule.

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

   EXAMPLE 1 A regularly scheduled test may be a raw material test run every month.

   EXAMPLE 2 An event-initiated test may occur when a material arrives and a sample is pulled and sent to the lab.

EXAMPLE 3 A Level 4 activity-initiated test may occur when there is a new delivery from a non-certified supplier and samples need to be tested.

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

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

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

b) comparing actual test execution to planned test execution; and

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

8.7 Quality test dispatching

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

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

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

8.8 Quality test execution management

8.8.1 Introduction

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

8.8.2 Testing

8.8.2.1 In-line testing

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

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

8.8.2.2 At-line testing

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

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 laboratory analyst. The results of an off-line test might take longer to generate (minutes, hours, days) than at-line tests.

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

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

8.8.2.4 Pass/fail testing

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

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

8.8.2.5 Measurement testing

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

8.8.2.6 Retesting

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

8.8.2.7 Blind sample testing

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

8.9 Quality test data collection

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

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

8.10 Quality test tracking

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

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

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

8.11 Quality test performance analysis

8.11.1 Introduction

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

EXAMPLE 1 Quality variability may be reported on non-compliance reports, KPI reports and quality indicator reports.

Quality test performance analysis activities may include:

a) analysing production data for trends of critical quality indicators;

   EXAMPLE 2 Critical quality indicators may be SPC and SQC analysis over time or across lots.

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

c) determining the cause of quality analysis problems;

d) recommending actions to correct identified problems, including correlating the symptoms, actions and results;

e) providing information for use in supplier evaluations.

8.11.2 Quality resource traceability analysis

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

a) which materials were used in quality activities;

b) which equipment was used in quality activities;

c) which personnel were involved in quality activities.

8.11.3 Quality indicators

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

EXAMPLE: Examples of quality indicators are defined in ISO 22400-2

8.12 Supported activities

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

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

b) Product definition management – Quality assurance of master data including items utilized in production operations, including the BOM. Management of quality attributes for master data including approval, modification and substitution of appropriate materials. Approval and modification of work instructions and master recipes.

c) Production execution management – This is a destination of information about quality approval and sign-off for critical quality checkpoints. Quality actions for out-of-spec conditions and re-work. In-line testing.

d) Production data collection – Statistical quality control (i.e., process analysis technology). Data analysis for quality investigations (i.e., system of record).

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

The following production operations activities directly benefit from quality operations:

– production tracking – tracking WIP and associated quality status;

– production dispatching – quality attributes and status;

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

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

EXAMPLE 1 LIFO (last in, first out) checking at a pack-out operation.

EXAMPLE 2 pH check at batch reactor.

9 Inventory operations management

9.1 General activities in inventory operations management

The general activities in inventory operations management include

a) managing and tracking the inventory of product and/or material;

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

b) performing periodic and/or on-demand inventory cycle counts;

c) managing the transfer of material between work centers;

d) measuring and reporting on inventory and material transfer capabilities;

e) coordinating and controlling the personnel and equipment used in material transfer;

f) directing and monitoring the transfer of material to and from production, quality, or maintenance;

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

h) routing raw material to and from storage;

i) identifying pack-out schedules; and

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

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

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

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

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

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

9.2 Inventory operations management activity model

The model shown in Figure 23 defines the activities of inventory operations management as they relate to the transfer of materials between and within work centers. The model defines what transfer activities may be done and the relative sequencing of the activities, but not how they should be performed in a specific organizational structure. Different companies may have different organization of roles and assignments of roles to personnel or systems.

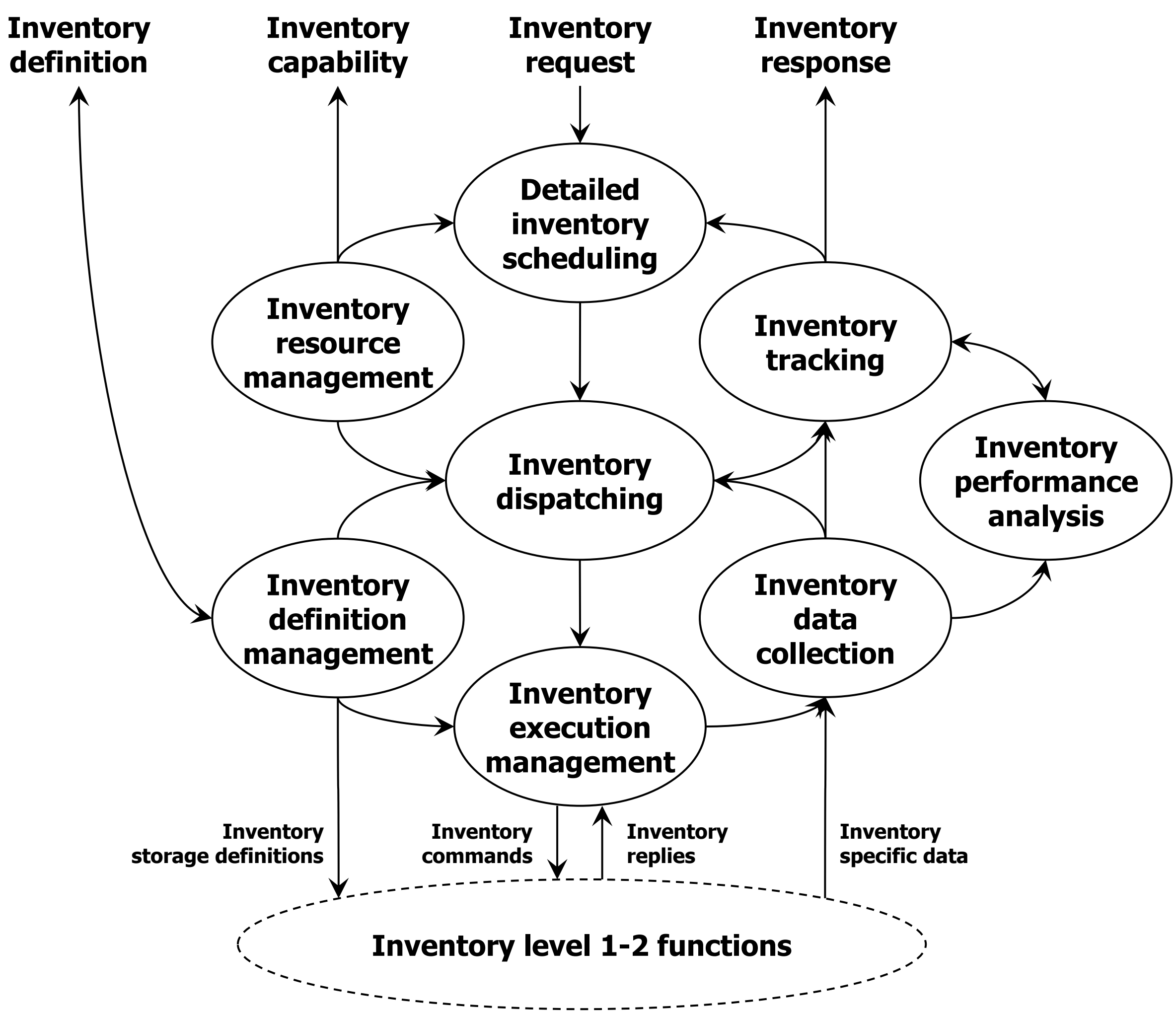

Figure 23 – Activity model of inventory operations management

The ovals in the inventory operations management model indicate collections of activities, identified as the main functions. Lines with arrowheads indicate an 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 23 only illustrates some major information flows between activities.

9.3 Information exchanged in inventory operations management

9.3.1 Inventory definitions

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

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

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

9.3.2 Inventory capability

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

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

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

– personnel – typically based on qualification, training, experience and discipline. May also be based on device or equipment-specific proficiencies;
– equipment – such as movement equipment, trucks and carts; and
– material – such as packing materials consumed in material movement or storage.

9.3.3 Inventory requests

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

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

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

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

9.3.4 Inventory response

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

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

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

9.3.5 Inventory storage definitions

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

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

9.3.6 Inventory commands

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

9.3.7 Inventory replies

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

9.3.8 Inventory-specific data

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

9.4 Inventory definition management

Inventory definition management tasks shall include:

a) managing information about transfer criteria for materials;

EXAMPLE 1 This could be work masters containing handling instructions and warehouse storage restrictions. For example, there may be specific handling instructions on how to handle specific toxic materials during material transfers, how to handle traceability, or specific handling restrictions for controlled or regulated substances.

b) managing new inventory definitions and work masters;

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

d) providing inventory definitions to other applications, personnel, or activities;

EXAMPLE 2 Managing information about locations where materials may be stored, appropriate range of volume of the storage material and other material inventory operations constraints that are sent to dispatching or detailed scheduling activities.

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

f) optimizing inventory definitions based on quality test analysis;

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

9.5 Inventory resource management

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

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

- transfer equipment – this includes equipment such as conveyors, fork lifts, trucks, railcars, valve arrays, pipes, automated storage and retrieval systems (ASRS), containers and automated guided vehicles (AGV). Transfer equipment also includes storage location control equipment, such as heating or cooling control, positive or negative pressure control, ventilation (flow rate, humidity and particulate level) control and electrostatic grounding;
- storage equipment – this includes tanks, silos, containers, pallets, stock area of stocker machines, shelves and so forth. Some equipment has specific ranges of capacity in terms of physical constraint and/or operational efficiency;
- personnel – this includes management of such attributes as skill sets, certifications, authorizations and security clearances;
- material and energy used in the movement, such as disposable consumables like gloves, gowns, masks and ink;

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

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

d) ensuring that requests for acquisition of resources to meet future capabilities are initiated;

e) ensuring that equipment is available for the assigned tasks and that job titles are correct and training is current for personnel assigned to tasks;

f) providing information on the location of resources and assignment of resources to areas;

EXAMPLE Providing a location for a fork lift truck and its assignment to a movement job 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 on the basis of 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;

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

9.6 Detailed inventory scheduling

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

a) creating and maintaining an work schedule for inventory.

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

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

b) comparing actual movements to planned movements;

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

d) creating inventory job orders in accordance with inventory requests from Level 4 functions;

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

f) determining start time and completion time of inventory job orders with respect to future capacity of storage resource, future availability of transfer resources and future amount of available inventory material;

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

9.7 Inventory dispatching

Inventory dispatching shall be defined as the collection of activities that assign and send inventory job 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 pick-up commands to an AGV.

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

9.8 Inventory execution management

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

Inventory execution management may include:

a) directing the performance of work, including executing the job and initiating Level 2 activities;

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

b) ensuring that the correct resources (equipment, physical asset, material and personnel) are used in inventory operations;

c) ensuring that job procedures and regulations are followed during the transfer operations;

d) documenting the status and results of the work performed;

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

f) confirming that the work was accomplished according to the accepted quality standards;

g) verifying that equipment and personnel certifications are valid for the assigned tasks;

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

9.9 Inventory data collection

Inventory data collection shall be defined as the collection of activities that gather and report data on inventory operations and materials manipulated.

Figure 24 illustrates some of the interfaces to inventory data collection.

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

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

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

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

EXAMPLE: Examples of collection information follow.

– Silo or tank inventory and movement data collection.

– Lot and sub-lot location and amount data collection.

– Material balances and reconciled data.

– Location of WIP.

– Records of positive pressure in a storage building.

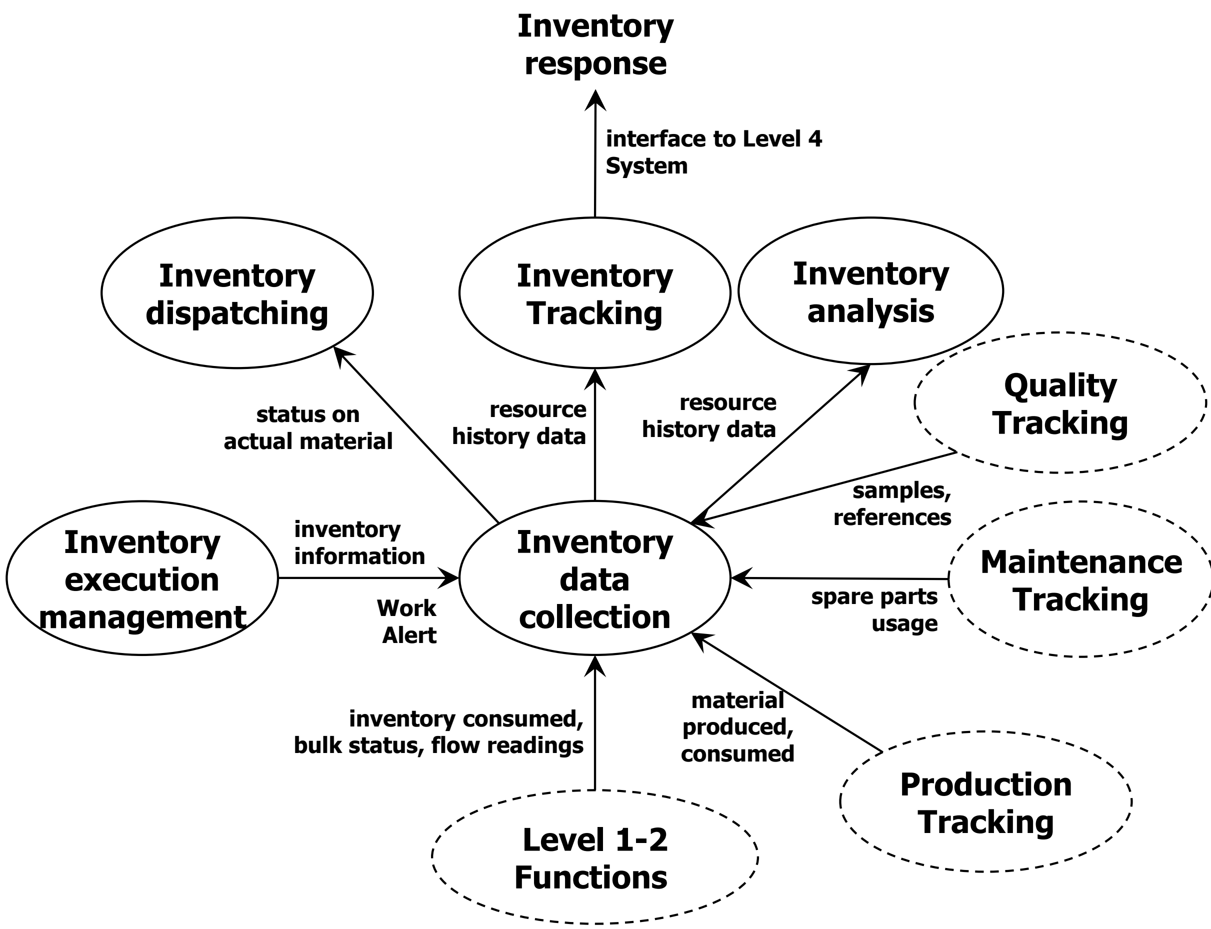

Figure 24 – Inventory data collection activity model

9.10 Inventory tracking

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

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

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

9.11 Inventory performance analysis

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

EXAMPLE 1 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 performance 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 performance analysis is the generation of inventory indicators. This information may be used internally within manufacturing operations for improvements and optimization, or if there is a receiving business process that requires the information, it may be sent to higher-level business processes for further analysis and decisions. Inventory indicators may be combined at Level 4 with financial information, or at Level 3 using Level 4 financial information to provide cost-based indicators.

EXAMPLE 2 Examples of inventory indicators are defined in ISO 22400-2.

10 Completeness, compliance and conformance

10.1 Completeness

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

10.2 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.

10.3 Conformance

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

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

Annex A
(informative)

Technical and responsibility boundaries

A.1 Introduction

The models shown in Figure 6 – Activity model of production operations management, Figure 21, Figure 22 and Figure 23 define a large collection of activities, only some of which have been traditionally identified with operations management. One reason for this is because the boundary between what is done by Level 3 operations (production, maintenance, quality and inventory) personnel and by Level 4 personnel is not invariant. There may be three different boundaries, one that defines the scope of required responsibilities, one that defines the scope of actual organizational responsibilities and one related to areas of technical integration.

A.2 Scope of responsibility

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

a) Is the function or activity critical to product quality? If yes, then it should be part of manufacturing operations.

b) Is the function or activity critical to maintaining regulatory compliance, such as FDA, EPA, USDA, OSHA, TÜV, EC, EU, EMEA and other agency regulations? If yes, then it should be part of manufacturing operations.

c) Is the function or activity critical to plant safety? If yes, then it should be part of manufacturing operations.

d) Is the function or activity critical to plant reliability? If yes, then it should be part of manufacturing operations.

e) 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 A.1. 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 standard.

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

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

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

– the work schedule defines 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 A.1. In this situation the manufacturing operations management layer would be significant and cover all of the defined aspects of production.

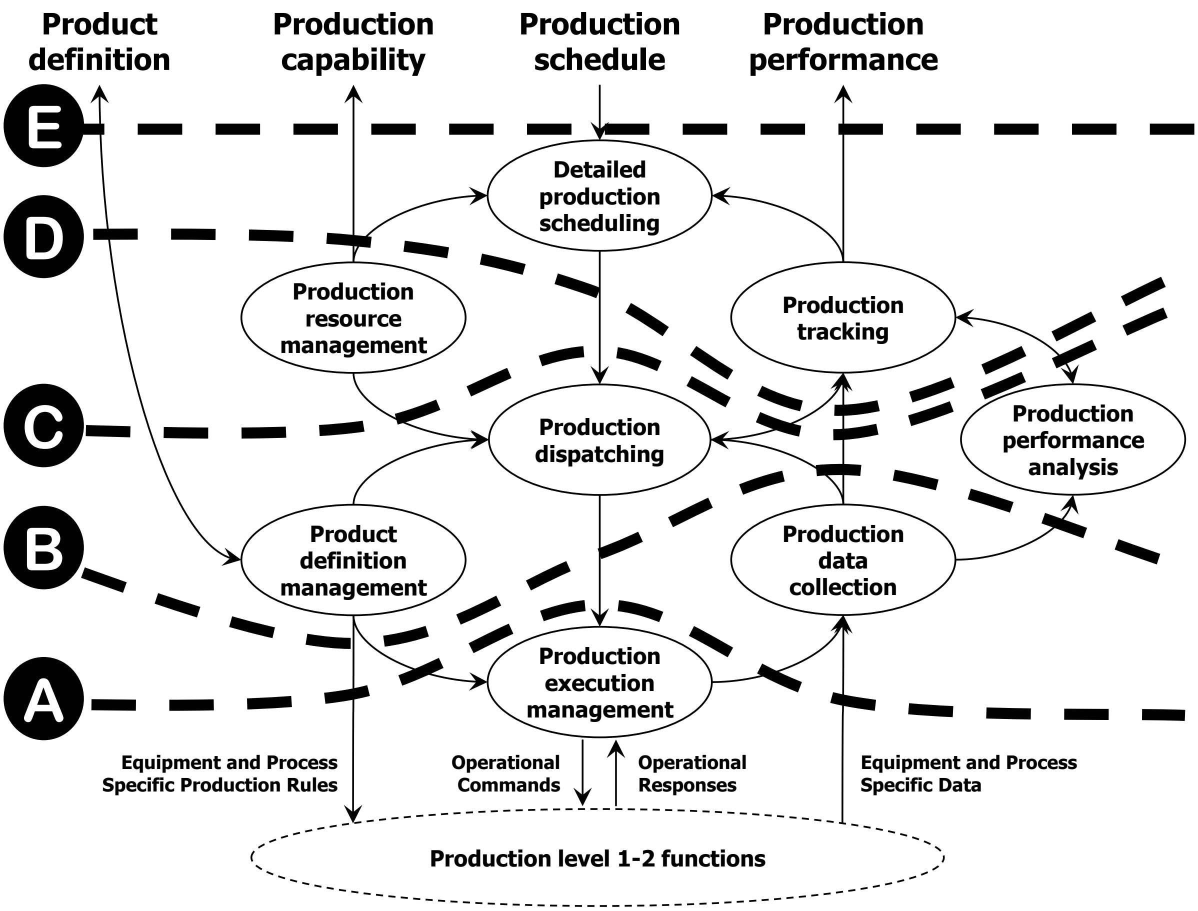

Figure A.1 – Different boundaries of responsibility

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

– quality is only determined by production execution management. The production paths are fixed and production scheduling does not affect quality, safety, or compliance;
– production safety is managed at the Level 2 function through safety interlocks, PC and PLC programmes;

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

In this situation perhaps only production execution management is within the scope of control of production operations management. This is shown in Line A in Figure A.1.

A.3 Actual responsibility

The five questions in the ISA-95 Part 1 definition of levels define the required boundary of responsibility, but there may be an actual boundary of responsibility different from the required responsibility. Usually this occurs due to business reasons, such as local site management of activities and local accountability. In these cases the line of actual responsibility should be the same as, 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 6, Figure 21, Figure 22 and Figure 23 may be implemented in Level 3 or Level 4 systems.

EXAMPLE The functions may be implemented by systems such as enterprise resource planning (ERP) systems, manufacturing execution systems (MES), laboratory information management systems (LIMS), asset management systems (AMS), warehouse management systems (WMS), or distributed control systems (DCS).

The lines of technical integration might not be determined by the same rules as the lines of responsibility. The lines of technical integration are based on technical decisions, including the availability of installed systems, the cost of new systems and integration of existing systems. The line of technical integration may include several systems in the maintenance, quality, production and inventory area, as well as several systems in the business logistics area. Figure A.2 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.

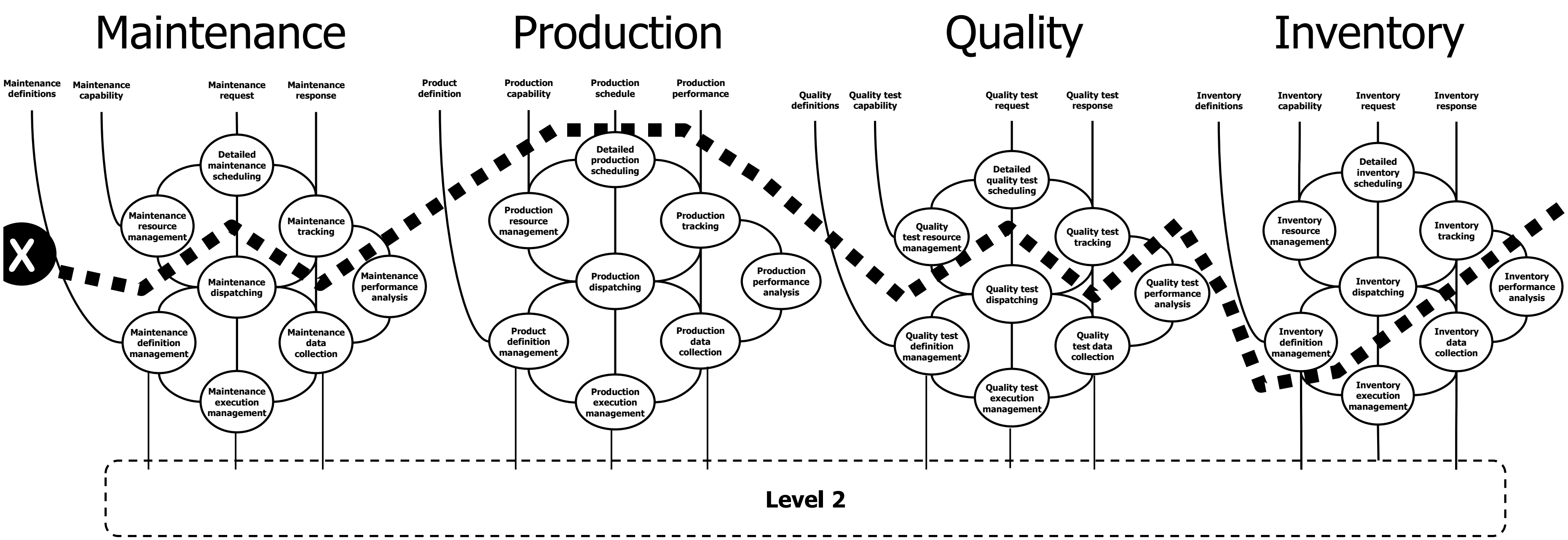

Figure A.2 – Lines of technical integration

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 as follows.

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

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

– There are four criteria for determining if an activity should be under the scope of control of manufacturing operations (see Part 1).

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

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Annex B
(informative)

Scheduling hierarchy

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

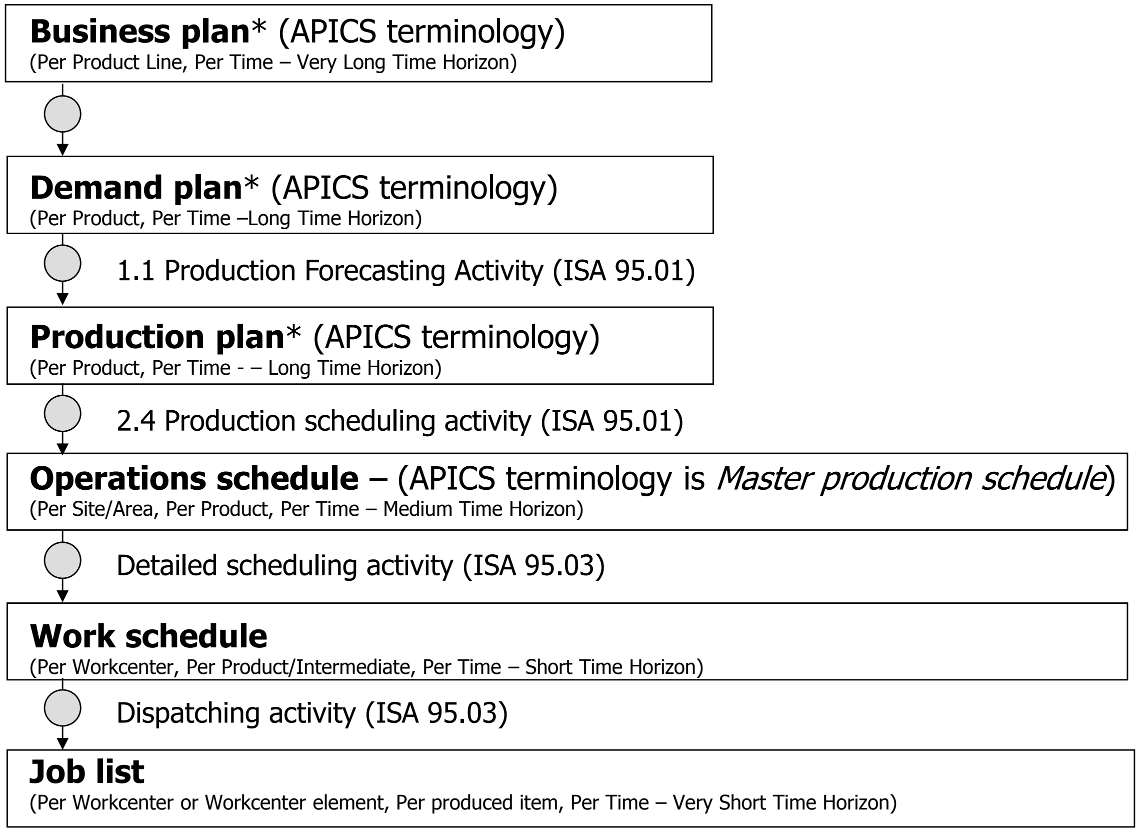
In a multi-site company this plan is often divided among the facilities and results in a master production schedule (MPS) for each facility. Depending on how the organization defines demand, the MPS may be used to create the production schedules through a material resource planning (MRP) activity or enterprise resources planning (ERP) activity. Alternatively, a company may use the MPS to reconcile customer orders and forecast to drive the ERP/MRP planning function to create the production schedules.

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

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

Figure B.1 illustrates a hierarchy of scheduling, combining the terminology of APICS [4][1] and this standard. This hierarchy is only an example of a possible scheduling and planning hierarchy within a company. It illustrates how the APICS-defined elements and the elements in this standard fit together. The hierarchy starts with a business plan and ends with a job list. There may be additional levels of scheduling and planning below the job 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.

[1] Figures in square brackets refer to the Bibliography.



* 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 Association for Operations Management (APICS) Dictionary, 11th ed. [4], is a statement of long-range strategy and revenue, cost and profit objectives. A business plan is usually stated in terms of money and grouped by product family. A business activity, not defined in this standard, uses information in the business plan plus other information to generate a demand plan.

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

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

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

Annex C
(informative)

Frequently asked questions

C.1 Does this apply to more than just manufacturing applications?

As stated in the Introduction, it is not the intent of this standard to restrict its use only to manufacturing applications. The models defined have been applied in other industries, such as power distribution, oil and gas production, pipelines, warehouse/shipping management and other industries not identified as manufacturing.

C.2 Why are the models more detailed for production operations management than for the other categories?

The primary focus of the standard is on manufacturing enterprises, where production operations management is usually the main focus of the business and the other activities support production. The other operations management category details can be derived from the examples shown for production operations management.

C.3 What are some of the main expected uses of this standard?

The main use of this standard is in the development of requirements for manufacturing operations management and related systems. The terminology and models defined in this standard have been used as the structure for requirement specifications.

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.

C.4 How does this standard relate to enterprise–control system integration?

Control systems are Level 2 systems and enterprise business systems are Level 4 systems. The scope of this 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 ISA-95 Part 1. It defines the functions within Level 3 that convert business requirements into actual Level 2 control requirements and that convert Level 2 information back into business information. This standard also describes some of the information that flows between the Level 3 activities and activity categories.

C.5 How does this facilitate connection to ERP systems?

ISA-95 Part 1 and ISA-95 Part 2 specify the interfaces between enterprise (Level 4) and the control domain (everything below Level 4). This standard does more than facilitate the connection to ERP systems. It provides a common way to specify the interfaces independent of the specific ERP/manufacturing management systems deployed. It also identifies the components (activities) and interfaces of the manufacturing management systems.

C.6 Why is genealogy not discussed?

The terms tracking and tracing are used as the formal definitions of the functions required for genealogy (traceability). These terms can be applied to materials, personnel and equipment, in production, maintenance, quality testing and inventory operations. The methods for doing genealogy (traceability) may also be industry-specific, while the concepts of tracking and tracing appear to be consistent across industries.

C.7 Why are only some information flows shown?

Any activity may provide information to any other activity, based on the business and production processes. The committee decided to illustrate information flows that they felt were the most common. The information flows are intended to represent the usual flow of information in a large number of cases. In any specific circumstance, other information flows may be more relevant.

C.8 What industry does the standard apply to?

This 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.

C.9 What is the relation between this standard and MES?

This standard uses the basic MESA definitions of manufacturing execution systems (MES) and expands them by adding activity detail and tasks and extends them into additional operational areas including maintenance, quality and inventory.

C.10 How does this standard relate to Level 2 of PRM?

This standard defines activities that coordinate and direct PRM Level 2 activities. The levels shown in Figure C.1 are defined by the Purdue reference model for CIM and are defined in Part 1. The focus of this standard is illustrated in Figure C.1. ISA-95 Part 1 and ISA-95 Part 2 focus on the interfaces between Level 4 enterprise and Level 3 manufacturing control systems. This standard focuses on the activities within manufacturing.

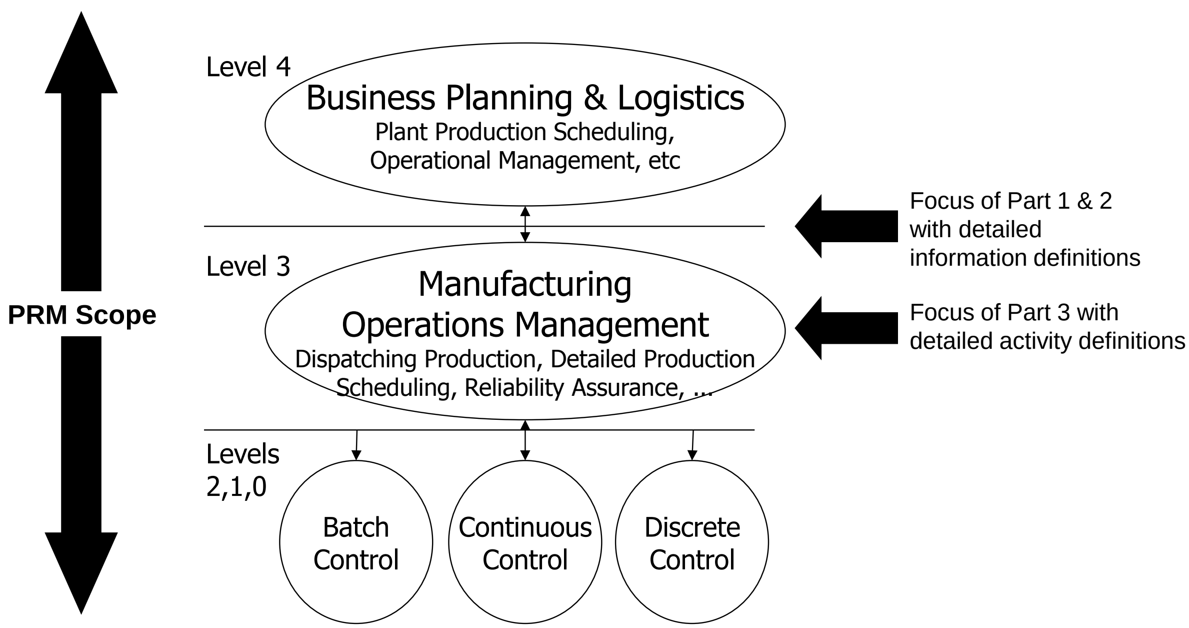


Figure C.1 – PRM scope and standard focus

C.11 How does the QA (quality assurance) element in ISA-95 Part 1 relate to this standard?

The term “quality assurance,” or QA for short, was used in ISA-95 Part 1 and in the referenced documents. QA has been variously defined as

a) the planned and systematic activities implemented within the quality system and demonstrated as needed to provide adequate confidence that an entity will fulfil requirements for quality (source: ANSI/ISO/ASQ A8402-1994, Quality Management and Quality Assurance – Vocabulary);

b) a program that is intended by its actions to guarantee a standard level of quality;

c) planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality;

d) planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality;

e) a result of quality control processes to provide security to the end-user that the product is wholesome, meets high quality standards and is safe;

f) a system of inspections and/or tests instituted at various stages in a manufacturing or printing process to ensure that the end product will meet predetermined standards.

The terminology "quality operations management" has been defined in this standard as the activities that include all of the above definitions. In addition to the activities, the term QA has often been used to indicate either a quality programme or a quality department and has led to confusion in its use in ISA-95 Part 1. This standard uses the term "quality operations management" for Level 3 functions instead of QA or quality assurance to make it consistent with the names of other operations management categories.

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Annex D
(informative)

Advanced planning and scheduling concepts for manufacturing operations management

D.1 Introduction

Advanced planning and scheduling (APS) is defined as a system and methodology in which decision-making, such as planning and scheduling for industries, is federated and synchronized between different divisions, within or between enterprises, to achieve total and autonomous optimization. The original concept of APS was launched in the U.S. in the late 1990s, introducing advanced techniques of production planning or supply chain planning with detailed scheduling and optimization algorithms. The techniques developed since then have been partially employed as the engine of planning systems in some ERP and supply chain planning (SCP) software packages.

This annex explains the latest concept of APS, which is closely related to manufacturing operations management to make effective collaboration within Level 3 activities, as well as collaboration between Level 3 and Level 4. For example, the concept and framework of APS proposed by the PSLX consortium has features that improve on the conventional concept to meet the concerns of advanced manufacturing enterprises. These new concepts of APS are not a part of the planning system in ERP, but rather the fundamentals of decision-making for all the planning and scheduling systems in the manufacturing management.

D.2 Fundamental technologies of APS

Some manufacturers have implemented APS and its related technologies. This clause introduces some of these technologies in APS implementations.

a) Operation-centric bill of materials (BOM)

   The conventional BOM represents relations between a product or component and materials, directly connecting a parent to a child. This is useful for calculating the quantity of each material needed to produce the required quantity of final product. On the other hand, routing information or recipe for producing the product is managed using independently represented data, which is necessary for calculating the load of each resource. APS integrates the conventional BOM and routing data via a new data structure referred to as an operation-centric BOM, focusing on operations that can connect both items in the old BOM and resources in the routing table.

b) Detailed modelling of constraints on actual plants

   Detailed schedules for a job list requires high levels of accuracy. In order to achieve this, the scheduler has to be aware of the many different constraints existing on the actual plant and has to apply them to the schedule. Conventional schedulers can deal with very simplified constraints, such as resource capacity constraints and precedence constraints. In addition to this, schedulers in APS can represent more detailed constraints, such as material constraints, changeover (cleaning) and routing (pipe connectivity) constraints, sub-resource (labour and tools) allocation constraints, storage space (tank capacity) constraints and so forth.

c) Finite capacity and inventory scheduling (FCIS) algorithms

   Finite capacity scheduling (FCS) deals with resource capacity constraints and calculates a schedule that does not exceed the maximum capacity. One of the best advantages of scheduling logics in APS is the finite capacity and inventory scheduling (FCIS) capability, in which an operation is never scheduled on a Gantt chart if the materials necessary to produce a product do not exist. FCIS explicitly deals with inventory in a storage zone or tank, which tries to be balanced between consumption of the downstream processes and production of the upstream processes or procurement.

d) Bottleneck optimization and synchronized scheduling

If the performance of a bottleneck process significantly affects the performance of the entire system, APS can provide a schedule for the process and let the other processes synchronize to the bottleneck. For example, APS first takes care of optimizing the bottleneck process, then, backward and forward scheduling algorithms are applied to the upstream and downstream processes, respectively. According to the theory of constraints (TOC), time buffers in the schedule protect against any disturbances to the bottleneck.

e) “What-if?” simulation of the master production schedule (MPS)

The master production schedule (MPS) contains important information for collaboration between the sales and manufacturing divisions. In APS, the date on which each product is shipped to customers is always elaborated upon, taking into account detailed production information from the actual plant. Feasibility of the schedule is evaluated by detailed scheduling, which functions as a “what-if ?” simulator. Simulation results may be approved in conjunction with the MPS.

f) Dynamic full-pegging technique for dispatch orders and manufacturing lots

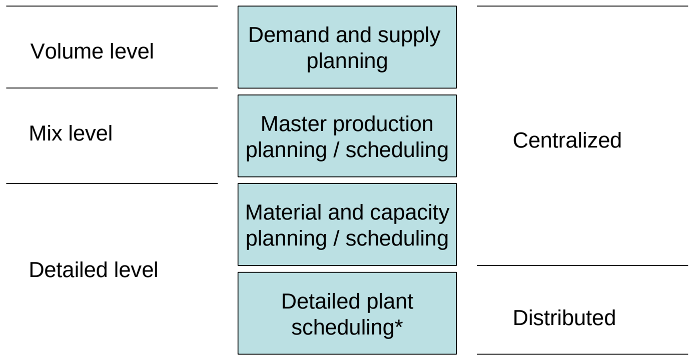
The MRP system generally cannot detect a direct effect on final customer orders when delays or problems occur for a particular dispatching order or manufacturing lot. This is due to single-level pegging capability. On the other hand, production on a static full-pegging system allows plant operators to determine the final customers for each operation. This is flexible and allows customer requests to be easily changed, but it is inefficient because of uneconomical lot size. Dynamic full-pegging in APS is a technique that shows the relationship between final customer orders and actual job orders or lots in the plant, even for an economical lot production. At the same time, the relationship can be revised when urgent, high priority orders come in.

g) Optimization methods using meta-heuristic algorithms

In order to create an optimum planning solution for manufacturers, APS has several optimization algorithms, such as Genetic Algorithm (GA) and Tabu-search techniques. Planning and scheduling problems have many different constraints and many decision variables, which can result in an explosion of combinations. However, these optimization algorithms, called meta-heuristics, allow planners or schedulers to find sub-optimum feasible solutions within a practical computation time.

D.3 Decision-making functions of APS

The area covered by APS in the decision-making functions can be classified by two consideration aspects. The three levels shown on the left in Figure D.1 represent different granularity of the target of decision-making parameters. The top level deals with decision-making for total volume of production, where information on different product items is summarized in the same group or category. Considering a product mix on the second level, each product item is distinguished and parameters associated with the products are decided. The third, or detailed level, is where not only information about final products but also information on their components, such as sub-assemblies, parts and materials, is discussed.



* Scope of Part 3 of this standard

Figure D.1 – Levels of decision-making for production

The right-hand categories in Figure D.1 indicate whether decision-making is centralized or distributed. In general, most decision-makers in manufacturing business divisions prefer the centralized approach. On the other hand, decisions for detailed manufacturing management are better made by the distributed method. As shown in Figure D.1, the border between the two is at the detailed level in the left, because all items from product to materials need to be considered enterprise-wide at least once in order to achieve synchronization across all processes.

According to the two aspects described above, decision-making in APS can have four detailed levels, each of which corresponds to a functional module of decision-making. In the hierarchy, activities in one level on a single site of the enterprise should be managed with one consistent decision-making module. Furthermore, different decision-making modules in some adjacent levels or distributed sites need to be integrated or federated by advanced software support. The four decision-making modules shown in Figure D.1 are explained as follows. This standard focuses especially on the last.

a) Demand and supply planning

In demand and supply planning, production is considered at an aggregate level, such as “product family”. In terms of resources, demand and supply planning deals with capacity aggregated either at a plant level or at particular area level within the plant. This decision-making cycle has a relatively long- or medium-term planning horizon. The maximum capacity of resources for production can be changed with additional investments. Financial division is involved in this decision-making so that enterprise-wide benefits can be optimized. Demand and supply planning can be referred to as sales and operations planning (S&OP).

b) Master production planning and scheduling

Master production planning and scheduling decides production volumes and timing for particular final products, according to customer demand. This is a short- to medium-term decision-making horizon. The quantity of each product is determined relative to a combination of received customer orders and projected orders calculated by demand forecasting. Target resources in this level are similar to those for demand and supply planning; however, the capacity limitation for a whole factory or particular area is based on constraint parameters rather than decision parameters. A schedule generated at this level is used to forge a kind of “contract” between the sales and manufacturing divisions. At the same time, all business activities are synchronized to this by confirming feasibility of the schedule according to their capability information. MPS is a general term for this function.

c) Material and capacity planning and scheduling

In material and capacity planning and scheduling, the quantity and finishing date of final products in the master production schedule provided by the upper level are extended to manufacturing operations necessary for producing the products. Then, those operations are allocated to particular resources at certain times on the planning horizon. This decision-making process deals primarily with operations; subsequently, resource capacities and inventory of intermediate materials are discussed in relation to the associated operation. The concepts of MRP and CRP are included in this level.

d) Detailed plant scheduling

Finally, detailed plant scheduling is addressed for actual manufacturing operations management. As with material and capacity planning and scheduling, this also focuses on operations. A feature of detailed plant scheduling is dealing with detailed constraints and requirements on each distributed area. Furthermore, the granularity of scheduling outputs by this decision-making process is more precise than that of material and capacity planning and scheduling. Generally, the granularity of the elements of detailed plant scheduling corresponds to an appropriate unit of activities ordered by area managers as part of daily procedures. As defined in this standard, output of the detailed plant scheduling is used as a source for dispatching information when the time for an activity in a schedule is approaching and entering the action period. Job orders in the dispatching list are forwarded to the corresponding plant operators.

From the viewpoint of system implementation, detailed scheduling deals with more than one activity model. Since a scheduler can manage job orders for inventory and quality-test as a sort of job orders for detailed scheduling, a production sequence can have storage operations, maintenance operations and quality-test operations and it generates an integrated detailed schedule.

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[1] ISO 15704:2000, *Industrial automation systems – Requirements for enterprise-reference architectures and methodologies*

[2] APICS Dictionary Edition 11, Association for Operations Management Dictionary ISBN 1558221956

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