



GOOD PRACTICE GUIDE:

Equipment Reliability

Equipment Lifecycle

Risk Management

Asset Criticality

Design for Reliability

Reliability Centered Maintenance

Total Productive Maintenance



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GOOD PRACTICE GUIDE:

Equipment Reliability

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ISBN 978-1-946964-37-3

Preface

The current climate within the industry continues to rely upon innovation for success. The appeal for innovation expands beyond new products and is accompanied by increased pressure to provide for affordable healthcare. Whether for new or legacy products, a reliable supply chain and effective cost management are critical for satisfying customer needs.

The application of asset management principles can leverage equipment towards competitive advantage. As innovation extends to and transforms the supply chain, equipment lifecycle costs and availability become ever more relevant to maintaining a competitive advantage. Reliable equipment improves the likelihood of achieving reliable operations and thus improves the supply of critical therapies to patients worldwide.

This *ISPE Good Practice Guide: Equipment Reliability* intends to provide guidance on the application of equipment reliability concepts to systematically and proactively improve equipment reliability at all stages of the equipment lifecycle. This Guide is not intended to provide the basic body of knowledge for equipment reliability or reliability engineering. This Guide offers best practices with respect to equipment reliability, addresses specific opportunities for the pharmaceutical industry beyond the general reliability of equipment, and can serve as the basis for an effective reliability program.

Acknowledgements

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Special Thanks

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The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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1 Introduction

1.1 Background

Equipment reliability is concerned with the risk of failures in equipment and processes, providing focus on equipment availability, fitness for purpose, and cost. The strategy and tactics of reliability contribute to realizing the value of equipment throughout its useful life and mission. Reliability and maintenance strategies are developed to reduce the risk and impacts of equipment failure. From a management perspective, reliability can be viewed as a set of techniques applied through an attitude of anticipating unreliability (instability) and an appreciation for the proactive elimination of issues. The techniques presented in this Good Practice Guide concentrate on equipment reliability, whether directly or indirectly related to product supply.

1.2 Purpose and Value

This Guide aims to provide guidance on the application of equipment reliability concepts in the context of the pharmaceutical, medical device, biologics, blood, and/or advanced therapy industries. These concepts are applicable to facilities, utilities, systems, and equipment assets. The Guide intends to:

- Provide recommendations and best practices for organizations to develop and apply solutions for asset and maintenance strategies to optimize equipment performance and minimize the total cost of ownership
- Allow for flexibility in implementing equipment reliability principles with respect to organizational size, resources, asset age, and maturity
- Apply a lifecycle approach to equipment assets
- Be complementary to other ISPE Guides for related aspects of asset management and maintenance [1, 2]

The value offered by this Guide includes:

- Presenting techniques to systematically and proactively improve equipment reliability at all stages of the equipment lifecycle (design, installation, commissioning/qualification, operations and maintenance, and decommissioning)
- Raising awareness of the contribution of assets (conditions) to the management of business continuity risk
- Influencing the pharmaceutical industry to move toward more reliable assets by focusing on the systematic reduction of equipment performance variation and its operating impact, through improved equipment design and management
- Improving manufacturing processes, support processes, and product quality by ensuring continued fitness for purpose and availability of equipment
- Addressing the events and consequences of equipment failures, by providing guidance on effective tools and strategies to be applied to an organization's systems
- Focusing on equipment reliability as a means of reducing and managing risk with respect to business operations, supply, product quality, compliance, and reputation

1.3 Scope and Audience

This Guide is written for the pharmaceutical and biotechnology industry, including but not limited to pharmaceuticals, medical devices, biologics, blood, and/or advanced therapy medicine industries. In terms of equipment reliability, the application of this Guide may extend to the physical assets, facilities, utilities, and equipment that support:

- Production
- Materials management (e.g., warehousing, transport)
- Packaging and labeling
- Laboratory operations

It is intended that this Guide bridges to existing ISPE guidance documents within and beyond the knowledge base of equipment reliability. The connectivity to other bodies of knowledge is intended to provide deeper and broader understanding of equipment reliability within the context of business, including stability, capacity, risk, and compliance. These supporting ISPE documents include:

- *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [3]
- *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management* [4]
- *ISPE Good Practice Guide: Asset Management* [1]
- *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities* [5]
- *ISPE Good Practice Guide: Good Engineering Practice* [6]
- *ISPE Good Practice Guide: Maintenance* [2]
- *ISPE Good Practice Guide: Operations Management* [7]
- *ISPE Good Practice Guide: Project Management* [8]

This *ISPE Good Practice Guide: Equipment Reliability* is not intended to:

- Be a prescriptive application for equipment reliability, tools, or techniques
- Provide the basic body of knowledge for equipment reliability or reliability engineering
- Define how to fully develop an equipment reliability program
- Address specific asset types
- Apply reliability techniques to specific situations

The strategy and application of equipment reliability to specific equipment is beyond the scope of this Guide. The design and implementation of several equipment types are currently addressed by separate ISPE documents and this Guide may be used to augment its management:

- Biopharmaceutical manufacturing facilities [9]
- Heating, Ventilation, and Air Conditioning (HVAC) [10]

- Process gases [11]
- Quality laboratory facilities [12]
- Sterile product manufacturing facilities [13]
- Water and steam systems [14]

The primary audience is intended to be those in positions responsible for designing, implementing, operating, and maintaining equipment assets, for example:

- Maintenance management
- Operations management
- Quality management
- Reliability and maintenance engineers
- Facilities and utilities engineers
- Project and design engineers
- Craftsperson and operators

Given the intended impact of equipment asset reliability and availability, this Guide also provides strategic insight into additional functions that interface with asset design, operation, maintenance, and decommissioning. These groups may include, for example:

- Process engineering
- Supply chain
- Health, Safety, and Environment (HSE)
- Procurement
- Finance/capital management

1.4 Benefits

This Guide presents guidance to address specific opportunities within the industry beyond the general reliability of equipment. The focus on asset availability, compliance expectations, and strategic management of equipment supports an organization's pursuit of supply chain stability and competitive advantage. Additional benefits of this Guide include:

- Providing a baseline for equipment reliability and asset management best practices that may be implemented to improve the support of aging equipment and facilities
- Providing an approach to new equipment assets and reliability beginning in the design phase, such that equipment lifecycle and total cost of ownership are evaluated as part of the procurement process

- Promoting a broader understanding of equipment assets, emphasizing that asset reliability is influenced (in order of impact) by design, operation, and maintenance
- Providing information advocating that common organizational goals and decision-making account appropriately for risk contributed by equipment assets, including the business, process/product, and compliance risk aspects
- Providing a basis for continual improvement (product quality, risk, operating cost, employee safety, capital management, etc.)

1.5 How to Use This Guide

This Guide offers best practices with respect to equipment reliability and can serve as the basis for an effective reliability program. For organizations that choose to implement portions rather than the entirety of this Guide, improved performance can be achieved based on specific areas of opportunity, i.e., there is value in employing the concepts described in individual sections even if all aspects of this Guide are not implemented.

Key concepts and terms are covered in Chapter 2.

The following major topics are addressed:

- Equipment lifecycle (Chapter 3)
- Risk management (Chapter 4)
- Supplier activities, including equipment and service providers (Chapter 5)
- Operations and maintenance (Chapter 6)
- Managing reliability in operations (Chapter 7, Appendix 1)
- Managing reliability in new projects (Chapter 8, Appendix 2)
- Special interests, including advanced equipment reliability topics (Chapter 9, Appendix 3)

2 Key Concepts and Terms

2.1 Key Concepts

2.1.1 Equipment Lifecycle

The equipment lifecycle consists of three distinct phases:

- Project phase
- Operation phase
- Decommissioning phase

2.1.1.1 Project Phase

During the project phase, the requirements for the equipment are defined and the equipment is designed, built, installed, commissioned, and turned over.

The project phase is the opportunity to apply Design for Reliability (DfR) principles such that asset philosophy, operating strategy, maintenance strategy, and lifecycle analysis can be incorporated into the equipment design. Analysis and risk assessments performed during the project phase assist with developing the strategies and tactics to mitigate the risk of failures through design, operational, maintenance, and administrative controls. Deploying a method of defect discovery enables prevention or mitigation of equipment issues during design and installation, and it also enables effective maintenance strategies and continual improvement in the Operation phase.

Depending on the project framework employed, elements of the project phase may include:

- Feasibility
- Concept
- Specifications
- Design
- Installation
- Commissioning and Qualification (C&Q)
- Turnover

An additional focus of the project phase is preparing for the operational readiness of the equipment. Operational readiness needs to include the technical, operational, and maintenance aspects of the asset. To achieve right-first-time deployment, the equipment strategies developed during the Project phase need to include capacities, operating envelopes, spare parts availability, maintenance tactics, etc.

For best practices associated with managing projects, refer to *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* [8].

2.1.1.2 Operation Phase

The Operation phase is the longest phase in the equipment lifecycle and encompasses the equipment being actively operated and maintained, providing value to the organization. The maintenance and reliability elements critical in the Operation phase include:

- Change management
- Incident management
- Monitoring and trending
- Continual improvement
- Lifecycle planning

Modifications to either the equipment or its usage may require adapting the maintenance strategy during the Operation phase. The inputs from incidents, performance trends, and improvements can warrant changes to address the effectiveness and efficiency of maintenance strategies. Ongoing capacity planning may necessitate changes to both asset mix and maintenance strategies to effectively manage the impact of demand changes.

2.1.1.3 Decommissioning Phase

The Decommissioning phase applies when the equipment asset is no longer required in service of the organization's objectives. Upon decommissioning, the equipment is no longer utilized for operations. Within regulated environments, equipment or its components may require documentation of End-of-Life (EOL) testing or qualification activities to ensure design performance and fitness for purpose were maintained throughout the asset life. Considerations should be made for equipment components, such as critical safety devices (e.g., pressure relief devices), that need to be maintained even if the equipment is out of service but remains installed. Financial rules may distinguish between an asset that is owned but out of service versus an asset that has been disposed of.

For best practices associated with decommissioning, refer to *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities* [5].

2.1.2 Operational Readiness for Maintenance

The project planning and implementation activities need to ensure that maintenance system deliverables are completed during the project phase and provided to the maintenance organization for deployment in the Operation phase. While final delivery coincides with completion of the project, ideally the project team has collaborated and shared information with the maintenance department beginning with the project's concept development. In order for the maintenance department to be prepared for operational readiness at project turnover, elements of the Maintenance Work Management System should be developed in parallel with project execution, including but not limited to:

- Preventive Maintenance (PM) and Predictive Maintenance (PdM) plans
- Condition-Based Maintenance (CBM)
- Spare parts lists, Bills of Materials (BOMs), and stocking plans
- Standard Operating Procedures (SOPs)
- Specialized tools

- Maintenance consumables
- Equipment asset documentation (e.g., manuals, drawings, warranty, service agreements, etc.)
- Training
- Computerized Maintenance Management System (CMMS)
- Computerized Calibration Management System (CCMS)

2.1.3 Risk-Based Approach

Product, process, compliance, and business understanding should be used as the basis for making risk-based decisions about an asset and its maintenance strategy. Conducting a system-level impact assessment (e.g., direct, indirect, non-GMP) is a best practice that serves from concept through to decommissioning of the equipment lifecycle. Compliance factors may extend beyond GMPs to include HSE and finance characteristics. Understanding and effectively addressing operating requirements and current regulatory expectations contribute to the sustainability of an asset through the Operation phase. Supply chain and cost effects are also key considerations in establishing an asset's criticality and priority.

A deeper understanding of risk may be developed with the evaluation of equipment functions and features, the components involved in those functions and features, likelihood of failure, and severity of failure impact. Failure Modes and Effects Analysis (FMEA) and/or Failure Modes, Effects, and Criticality Analysis (FMECA) may be used to assess potential equipment failures and identify mitigations to address risks presented within the context of a maintenance strategy.

2.1.4 Efficiency and Effectiveness

Maintenance strategies need to provide for both effective and efficient equipment maintenance. During the operating life of an equipment asset, the applied maintenance strategy may become sub-optimized for various reasons. Factors including operating changes, improved equipment understanding, component wear, and predictive tools can impact an asset's performance and its maintenance strategy. Preventive Maintenance Optimization (PMO) may be intentionally exercised to improve sub-optimized performance with focus on one or more contributing factors, including but not limited to:

- Improper initial maintenance strategy
- Incorrect Root Cause Analysis (RCA) findings and/or corrective actions
- Changes in an asset's operation
- Newly available and/or improved technologies and tools
- Changes with respect to reevaluated Asset Criticality and risk
- Changes with respect to FMEA/FMECA identified risks and mitigations
- Cumulative effects of changes and incidents

Decisions on design and strategy made during the project, properly founded in reliability engineering, will influence both the effectiveness and efficiency of equipment maintenance tactics in the Operation phase. The following actions and considerations should be considered:

- Vendor availability and technical support

- Spare parts criticality, availability, storage, and consignment
- Technology platform, complexity, and level of automation
- Improvement tools (RCA, FMEA/FMECA, etc.)
- Asset Criticality
- Deployment of predictive tools and technologies
- CMMS, CCMS, and data analysis
- Equipment education (e.g., technical, operation, maintenance)

For best practices associated with the execution of equipment maintenance, refer to *ISPE Good Practice Guide: Maintenance* [2] and *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management* [4].

2.1.5 Operability

Beyond equipment design, operations is the second leading factor that contributes to the overall reliability of an asset. The operator-equipment interface and error proofing are worthwhile considerations during and after equipment selection, whether accomplished through design, engineering controls, or procedural controls.

Critical to reliability and the success of the maintenance strategy is ensuring that the operation honors the equipment design envelope, whether with respect to constraints, intended functions, or capacities. Intentionally operating outside of the equipment's design envelope both increases the potential for premature or unexpected component failures as well as places the failure modes, effects, likelihood, and risks beyond the perspective of the evaluation supporting the current maintenance strategy.

Dependent upon the operating strategy and the organization's culture, a productive opportunity exists to bridge equipment operation with maintenance. Operator care recognizes that an operator has greater exposure and sensitivity to the performance of operating equipment. Maintenance approaches, such as Total Productive Maintenance (TPM), leverage an operator's observations and access to the equipment to perform shop floor adjustments and routine maintenance. With properly trained operators, there is more opportunity to provide more efficient maintenance with at-hand resources. In addition, maintenance resources may be utilized for higher priority and/or more technical tasks.

For best practices associated with manufacturing operations, refer to *ISPE Good Practice Guide: Operations Management* [7].

2.1.6 Asset Management

Asset management comprises developing a holistic view of assets and its lifecycles. Beginning with a case for new equipment, asset management presents the framework for applying lifecycle strategies and tactics that bridge the Project, Operation, and Decommissioning phases. Asset management reflects and interacts with the operations and maintenance strategies, including rebuild, replacement, and acquisition activities.

With key understanding of equipment reliability and the business case for asset availability, an Asset Management Plan applies a long-range approach to an organization's equipment assets. A sound plan provides the mechanisms to address changes to assets, whether planned (e.g., end of operation, useful life), obsoleted, altered, functionally failed, or decommissioned. As applied through equipment reliability, asset management offers perspective on the full equipment lifecycle and the total cost of ownership.

For best practices associated with an asset management strategy, refer to *ISPE Good Practice Guide: Asset Management* [1].

2.2 Key Terms and Acronyms

This section introduces key terms as they are used in the context of this Guide. Refer to Chapter 11 (Appendix 5) for an expanded listing of definitions.

Asset

As defined in ISO 55000 [15]:

“An item, thing, or entity that has potential or actual value to an organization.”

Asset Criticality

Asset Criticality is both an attribute of an asset and a process by which the importance of the equipment is determined to sustain production in a compliant manner. Asset Criticality is used to prioritize those assets in the management system(s) that provide the most value toward operating throughput and are most important to quality, health, safety, and environment.

Asset Management

A coordinated set of activities that will help the organization achieve the optimal amount of value from the assets.

Asset Management System

A management system that supports the asset management policy and the strategic asset management plans.

Availability

When a tangible asset is ready for its intended use. Availability is one of three factors that determine the Overall Equipment Effectiveness (OEE).

Bad Actor

Equipment that performs the worst in terms of effectiveness to sustain production in a safe and compliant manner.

Design for Reliability (DfR)

The process of incorporating equipment reliability and availability into equipment design.

Downtime

The time during which an asset is not available for its intended use. Downtime may be composed of both planned and unplanned events.

Equipment

The items, articles, and implements utilized for a specific purpose in an operation or activity. The fixed assets of an organization, other than land and buildings.

Facility

An area or building that is built, installed, or established to serve a particular purpose.

Lifecycle

The stages that an equipment asset progresses through, from initial development through to disposal.

MTBF

Mean Time between Failure

MTBM

Mean Time between Maintenance

MTTF

Mean Time to Fail

MTTR

Mean Time to Repair

MWT

Mean Waiting Time

Overall Equipment Effectiveness (OEE)

A calculated measurement that indicates how effectively a manufacturing operation performs with respect to its design capacity, when scheduled to run. The factors in determining OEE are Availability (% Scheduled Time), Performance (% Design Performance), and Quality (% Good Units). OEE is expressed as a percentage.

Preventive Maintenance Optimization (PMO)

An intentional and structured process that targets the effectiveness and efficiency of an equipment's PM program. The focus is upon preserving and restoring the equipment's condition, with value-added tasks, materials, and downtime.

Reliability

The probability that the equipment will perform satisfactorily for a given period of time under stated conditions.

Reliability Centered Maintenance (RCM)

A systematic and structured process used to develop an efficient and effective maintenance plan for an asset to minimize the probability of failure.

Reliability Growth

The positive improvement in a reliability parameter over a period of time due to the implementation of corrective actions to system design, operation, maintenance procedures, or the associated manufacturing process.

Reliability Integration

The process of seamlessly and cohesively integrating reliability tools to maximize equipment reliability at the lowest possible cost.

Root Cause Analysis (RCA)/Root Cause Failure Analysis (RCFA)

A method used to determine the underlying cause(s) of a failure. The focus is upon identifying the causes to be eliminated that prevent additional failures versus treating failure symptoms.

Total Effective Equipment Performance (TEEP)

A calculated measurement that indicates how effectively a manufacturing operation performs with respect to its design capacity, based upon total calendar time. The factors in determining TEEP are Utilization (% Utilized Time), Performance (% Design Performance), and Quality (% Good Units). TEEP is expressed as a percentage.

Total Productive Maintenance (TPM)

An operational philosophy where the total workforce of an organization plays a role in ensuring the performance of equipment is maintained and improved. TPM is similar to Total Quality Management but with the difference that the focus is on assets and not products.

Utility

An equipment asset that generates and/or distributes an essential supply service (e.g., electricity, water, steam, etc.) to support a facility's operation.

3 Equipment Lifecycle

3.1 Approach

An asset is defined as follows in ISO 55000 [15]:

“An asset is an item, thing or entity that has potential or actual value to an organization. The value will vary between different organizations and their stakeholders, and can be tangible or intangible, financial or non-financial.

The period from the creation of an asset to the end of its life is the asset life. An asset’s life does not necessarily coincide with the period over which any one organization holds responsibility for it; instead, an asset can provide potential or actual value to one or more organizations over its asset life, and the value of the asset to an organization can change over its asset life.”

For the purpose of this Guide, the term equipment used to describe the subset of an organization’s assets that includes facilities, utilities, systems, and equipment and that has a useful life of more than one year. The financial world refers to these assets as Property, Plant, and Equipment which are tangible, long-term, fixed assets. Fixed assets should have a useful life assigned to them, which means they have a set period of time that the equipment will produce value for an organization.

The equipment lifecycle management process consists of three distinct phases:

1. Project phase
2. Operation phase
3. Decommissioning phase

An organization should have a capital asset replacement planning program that incorporates the equipment lifecycle management process. Figure 3.1 is an example swimlane diagram showing typical policies, plans, and processes included in a capital asset replacement planning program.

Figure 3.1: Example of Capital Asset Replacement Planning Program (Swimlane Diagram)

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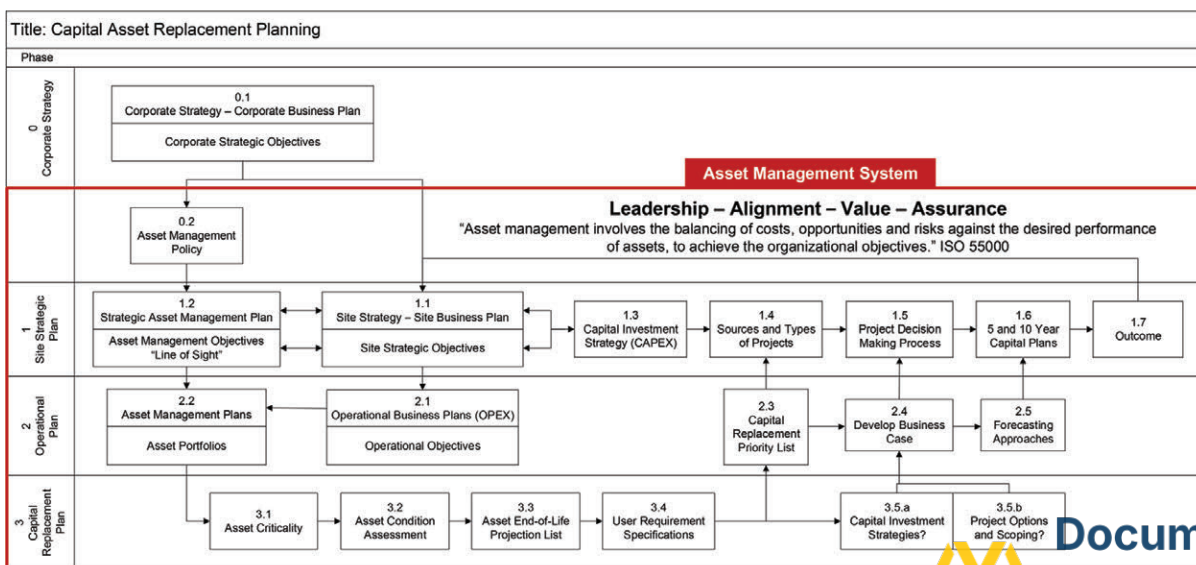
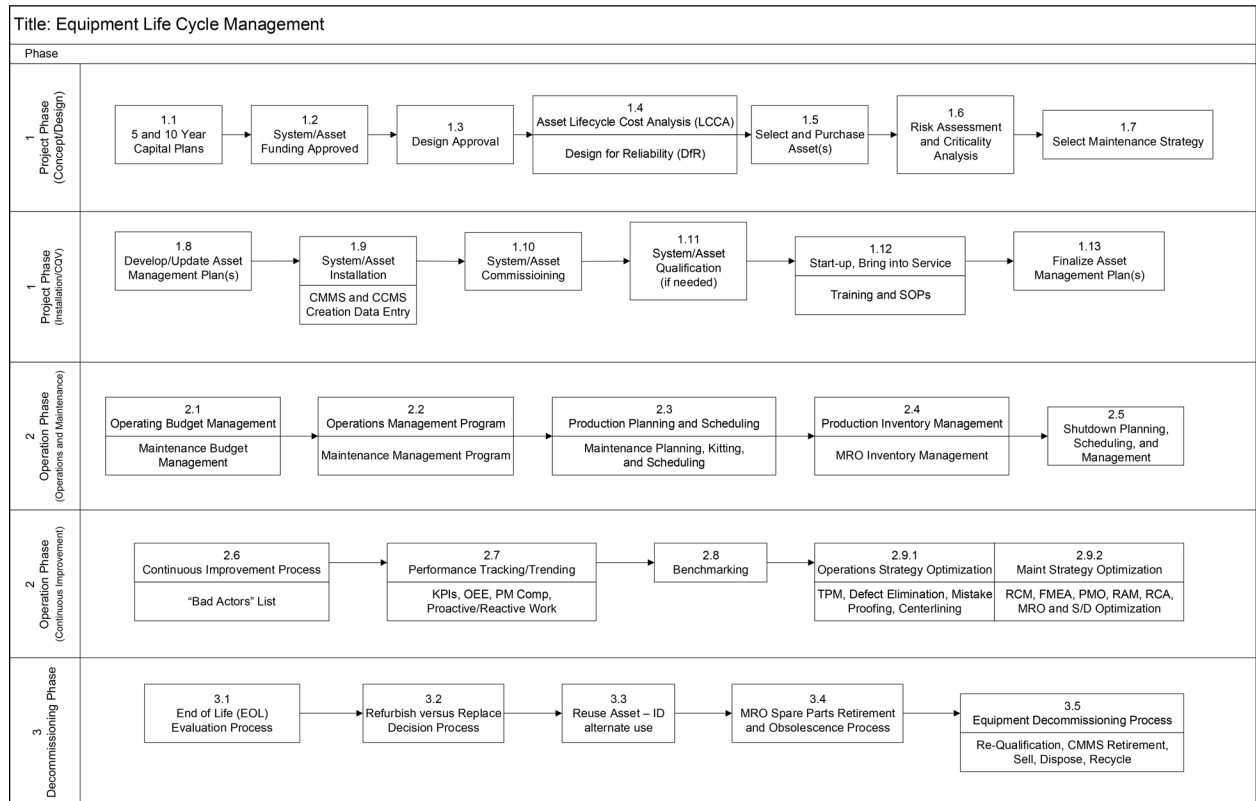


Figure 3.2 is an example swimlane diagram showing typical steps that comprise an equipment lifecycle management process.

Figure 3.2: Example of Equipment Lifecycle Management Process (Swimlane Diagram)

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Each step in the equipment lifecycle management process flow is not intended to be applied to all assets. The steps represent best practices to be considered during the lifecycle of an asset. Depending on the complexity, criticality, or size of the asset, some steps will require more or less effort, or may not be required. A step does not need to be completed before the next step is started. There is typically overlap between the activities in the various steps. Often, multiple steps will have tasks being conducted at the same time and in conjunction with other steps.

The equipment lifecycle management process starts when a need has been identified for a new or replacement asset(s) and the priority has risen to the top of the 5 and 10-year capital plans based on lifecycle planning and decision-making methods. These methods include:

- Risk management
- Operational planning
- Capital investment planning
- Financial planning

The output from the project decision-making process should include:

- Schedule of projects, including their costs (capital expenditures (CAPEX), operating expenses (OPEX), and valuation impacts)

- Timings required to deliver the service levels
- Benefits of the preferred options

This information will then be used to help build the 10-year capital plan. The forecasting approaches used will have a major influence on the capital project priorities and timing. With a 10-year capital plan, the forecasts need to be robust over the same period. All asset lives and replacement dates need to have a reasonable level of robustness for asset valuation and depreciation purposes.

A conservative approach for developing the 10-year capital plan is to assume the eventual replacement of all existing assets. This plan is based on an estimated replacement date that is adjusted based on periodic condition assessments to produce a more accurate replacement date. For assets which have exceeded their projected life expectancy but are still performing at an acceptable level, the asset life should be extended accordingly.

3.2 Project Phase

This section focuses on the following elements of the Project phase:

- Concept and design
- Installation, C&Q, and validation

3.2.1 Concept and Design

In the concept and design portion of the Project phase, the requirements for the equipment are defined and the equipment is designed and built. During this phase, the organization should perform a DfR analysis that includes establishing the asset philosophy, operating strategy, maintenance strategy, and conducting a Lifecycle Cost Analysis (LCCA). The results from the DfR analysis can then be incorporated into the equipment design and can assist with the development or revision of the Strategic Asset Management Plan (SAMP). The DfR analysis should also include risk assessments, including Reliability Centered Maintenance (RCM) or FMEA and Asset Criticality analysis to assist with developing the strategies and tactics to mitigate the risk of failures through technical design, operations, and maintenance controls.

The initial User Requirement Specification (URS) that was included in the business case will be reviewed and updated, as required. The user requirements are used as the basis for developing project specifications and drawings.

The functional and detailed design should take into consideration the defined user requirements, layouts, constructability, relevant codes, regulations, technical norms, and standards. Included as part of the functional and detailed design review process, an asset LCCA and DfR review should be conducted.

The LCCA is used to estimate the total cost of ownership of an asset over the entire asset lifecycle. Often investment decisions are based on the initial capital cost to acquire the asset, unduly focusing on the low bid. Basing the asset purchase decision solely on the lowest initial cost ignores the considerations that most capital assets incur the bulk of their lifecycle costs during the operational phase and that the ratio of operating costs to capital costs can vary significantly between otherwise equivalent assets.

The information gathered and analyzed from a LCCA is used to compare the relative merits of different asset alternatives considered during the evaluation and procurement stages in order to make the selection that offers the lowest total cost of ownership. The LCCA should satisfy four characteristics established by industry best practices: credible, well documented, accurate, and comprehensive. [43]

The LCCA provides for a more informed equipment selection by allowing decision makers to:

- Compare the total cost of ownership for equivalent assets from different manufacturers
- Estimate the timing of expected cash flow requirements at all stages of the asset lifecycle
- Assess the feasibility of investing in a specific asset (“go” or “no go”)
- Evaluate the costs of alternative design options to minimize lifecycle costs
- Decide between sources of supply (manufacturers or vendors)
- Select the asset maintenance strategies to maximize asset life
- Assess asset expected EOL, replacement, and disposal requirements

DfR is applied with the purpose of designing out failure modes and defects. The DfR process analyzes the various “abilities”, e.g., reliability, maintainability, operability, accessibility, cleanability, repairability, serviceability, etc. A cross-functional team performs the DfR process to evaluate the performance requirements of an asset such as:

- Safety requirements (e.g., HSE, process, etc.)
- Operating context (operational, maintenance, and reliability functional attributes)
- Environmental conditions (e.g., level of vibration, sound, temperature, etc.)
- Precision requirements (e.g., balancing, alignment, torque, tolerances, etc.)
- Metrics (e.g., Mean Time between Failure (MTBF), Mean Time to Repair (MTTR), Overall Equipment Effectiveness (OEE), etc.)
- Redundancy
- Technology (new or existing)
- Maintenance service and support (e.g., parts standardization and availability, annual service contracts, etc.)
- Failure modes (eliminate or reduce need for mitigation)
- Maintenance and Reconditioning (M&R) standards (e.g., lubrication, materials of construction, foundations, fasteners, etc.)
- Capacity of equipment cleaning
- Materials of construction compatibility
- Level of automation complexity
- Predictive technologies
- Condition-based monitoring and instrumentation

Studies have documented that up to 85% of an asset’s lifecycle cost is committed during the design phases of the asset’s life, yet up to 85% of the actual costs are incurred after it is put into operation. [41]

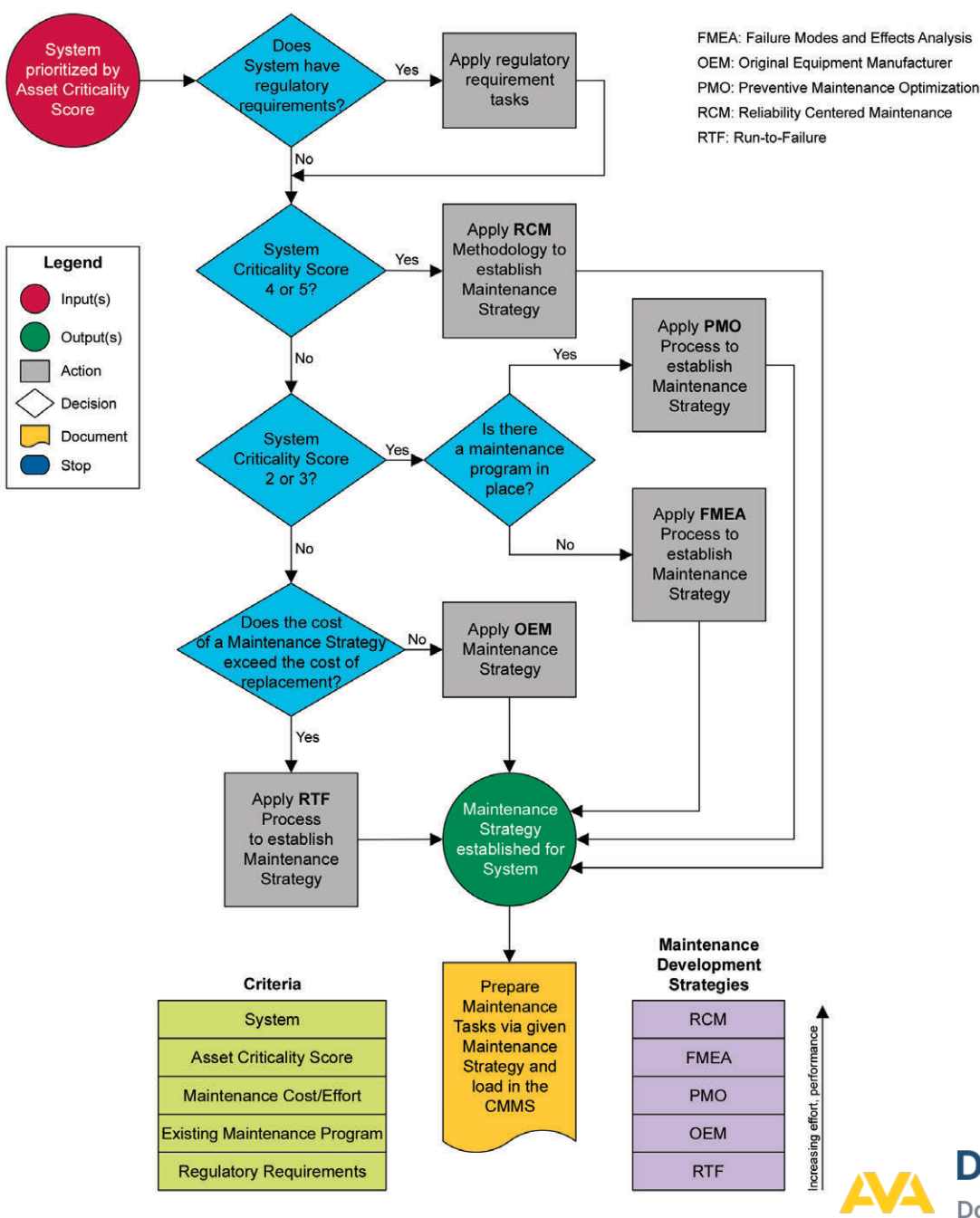
An Asset Criticality analysis identifies significant unrecognized risks and costs associated with the risk potential. The analysis ensures that overall success is balanced against the reality of limited capital and maintenance budgets. This prime constraint is most commonly known as the level of service versus cost to maintain factor.

An Asset Criticality analysis provides the basis to quantifiably rank systems for analysis via reliability priority and to define the most cost-effective manner for developing the right maintenance strategy for each category of system criticality.

Figure 3.3 below is an example of a maintenance strategy decision flowchart used to select the right maintenance strategy for developing asset maintenance programs based on system criticality.

Figure 3.3: Maintenance Strategy Decision Flowchart

Used with permission from CAI, www.cagents.com.



Refer to the *ISPE Good Practice Guide: Asset Management* [1] for best practices associated with developing the Strategic Asset Management Plan and to the *ISPE Good Practice Guide: Good Engineering Practice* [6] for information about the design process.

3.2.2 Installation, C&Q, and Validation

In the installation, C&Q, and validation portion of the Project phase, the equipment is installed, commissioned, qualified, validated and turned over to the operating department. During this phase, the operating department is responsible for ensuring development of the Asset Management Plan (AMP) which defines the activities undertaken on the equipment, including specific and measurable objectives. These objectives need to align with operating plans, site organizational plans, and operating unit business plans.

The AMP is developed for groupings of assets, e.g., assets managed by a business unit, assets at a site/facility, or a complex asset system. It is common practice for the AMP to contain the rationale for the proposed asset management activities and the objectives they are intended to achieve, operational and maintenance plans, capital investment plans (overhaul, renewal, replacement, enhancement, and disposal), and financial and resource plans.

After the system/asset is purchased, and during installation, the asset registry information is verified and entered into the CMMS system. This information includes, for example:

- Asset hierarchy development and asset attributes
- Criticality and system impact
- Projected useful life
- P&ID information

When a project is approved to install a system/asset, documents are assembled into an Engineering Turnover Package (ETOP or TOP). The ETOP documentation typically includes the design basis, fabrication, assembly, installation and testing of equipment and facilities which provides the basis for qualification, and operations and maintenance information. As the ETOP documentation is made available, PM/PdM tasks and calibrations, spare parts, vendor records, service contracts, warranty period, and Maintenance, Repair, and Operations (MRO) BOM are developed and entered into the CMMS.

The system/asset goes through a C&Q process before turnover to the end-user or to the validation team. The *ISPE Baseline® Guide: Commissioning and Qualification (Second Edition)* [3] describes a Quality Risk Management approach (based on ICH Q9 [16] and ICH Q8 [17]) for the classification of systems and equipment based on its potential impact to product quality.¹ System classification is performed to establish whether a system is commissioned and qualified (direct impact) or only commissioned (not direct impact). A system risk assessment is performed with direct impact systems to identify the product quality risk controls.

Prior to accepting the system/asset, training and SOPs need to be developed and personnel need to read the applicable SOPs and complete required training prior to bringing the system/asset(s) into service. Examples of these SOPs include:

- Operational
- Cleaning

¹ The system risk assessment approach, as described in the C&Q Baseline® Guide [3], refers to Critical Design Elements as the engineering and automation design elements used to implement the design controls (Critical Aspects) and to ensure documented Critical Process Parameter operation. Examples of engineering design features include components, instruments, and materials of construction. Critical Design Elements are identified and documented based on technical understanding of the product Critical Quality Attributes, process Critical Process Parameters, and equipment design/automation.

- Testing
- Maintenance
- Calibration

Refer to the ISPE Good Practice Guides for additional best practices related to the Project phase:

- Project management [8]
- AMP development [1]
- C&Q [3]
- Process validation [18]

3.3 Operation Phase

The Operation phase comprises operations and maintenance and is the longest phase in the equipment lifecycle. During this phase, the manner in which the equipment is operated and maintained determines the amount of value created for the organization. The critical elements in the Operation phase include:

- Ongoing risk management
- Change management
- Continual improvement (performance monitoring and trending)

The outputs of these critical elements will require changes to the operations, equipment, maintenance, and reliability strategies.

3.3.1 Operations

The first question to answer is: "Who owns the equipment?" Ownership of assets depends on its main function and purpose. In the pharmaceutical industry, assets are typically broken down into four main categories:

- Process
- Facility
- Utility
- Laboratory

Ownership of some equipment is obvious, such as process or laboratory equipment. Shared asset ownership is not as obvious. With shared assets, it will be important to determine who has overall responsibility for the assets and how these assets will be managed. The engineering, maintenance, and reliability departments provide support functions for the operational departments. The operational and support departments need to work closely together to provide reliable operations that maximize the value created by the equipment for the organization.

The remainder of this section includes select examples to be considered when involving operations in an operations-driven equipment reliability program.

3.3.1.1 Operator Training and Qualification

Operator training and qualification are critical to the safe and reliable operation of equipment and systems. Typical items that are included in an operator training and qualification program include:

- Complete overview of the piece of equipment
- Technical discussion on the operation of the unit
- Technical discussion specific to the start-up and shutdown of the unit
- Emergency procedures
- Safety precautions
- Manual and automatic mode operation
- Methods for setting machine operating parameters (i.e., feed rate) and centerlining
- Appropriate machine sanitation measures
- Theory of operation
- Sequence of operation
- Autonomous maintenance activities
- Supporting One-Point Lessons (OPLs)

3.3.1.2 Total Productive Maintenance (TPM)

“Total Productive Maintenance (TPM) is a holistic approach to equipment maintenance [and reliability] that strives to achieve perfect production:

- *No breakdowns*
- *No small stops or slow running*
- *No defects . . .*
- *No accidents*

TPM emphasizes proactive and preventative maintenance to maximize the operational efficiency of equipment. It blurs the distinction between the roles of production and maintenance by placing a strong emphasis on empowering operators to help maintain their equipment.

The implementation of a TPM program creates a shared responsibility for equipment that encourages greater involvement by plant floor workers. In the right environment this can be very effective in improving productivity (increasing up time, reducing cycle times, and eliminating defects).” [19]

3.3.1.3 Centerlining

Centerlining is a continual improvement program that enables an organization to reduce variation in their processes. To centerline a process, these four steps should be performed:

- “1. Identify the important process factors, Critical Process Parameters (CPP), or variables*
- 2. Determine the [optimal] settings and ranges for all of the important variables – by grade or product if multiple products are being produced*
- 3. Determine how these variables affect the process and the product*
- 4. Ensure that the centerlined settings are always used during production*

Centerlining is a never-ending process, and continuous work on all of these steps is needed in order to reap the most benefits. Benefits can include one or more of the following: improved product quality, increased production, reduced downtime, reduced off-quality product, reduced waste, reduced costs, and/or increased profits. Centerlining can also help in the detection of process upsets, which allows corrective or preventative actions to be taken.” [20]

Centerlining requires input from multiple data sources and can also provide data to support production and process improvement initiatives such as Lean/Six Sigma.

“It must be stressed that centerlining alone cannot achieve all of the potential benefits. The best results can only be achieved if the equipment is properly maintained and upstream processes are also centerlined. Additionally, easy access to process data and trends from past runs can enhance centerlining efforts by making it easy to determine where the process is, where it’s supposed to be, and where it has been historically.” [20]

3.3.1.4 Implementation of Lean Management and Six Sigma Techniques

The goal of Lean management techniques is to maximize value by eliminating waste in operations. The goal of Six Sigma techniques is to reduce variation in the operation.

Lean management and Six Sigma technique examples include [19]:

- Kaizen: A continual improvement process that involves employees at all levels of an organization to work together to proactively accomplish ongoing, incremental operational improvements
- 5S Program: Visual workplace
 - Sort (clearing)
 - Set in Order (configure)
 - Shine (clean and check)
 - Standardize (conformity)
 - Sustain (consensus)
- Mistake Proofing: Developing a process for equipment operators to avoid mistakes
- Gemba Walks: “Go to where the work is done” (plant floor)
- Standard Work: Creating, clarifying, and sharing information about the important tasks that are performed routinely in an operation
- Kanban (Pull System): Automated replenishment of production supplies through signal cards or lights that indicate when more supplies are needed

- Key Performance Indicators (KPIs): Tracking and encouraging progress toward meeting key production goals and driving desired behaviors in support of achieving these goals
- Overall Equipment Effectiveness (OEE) and 6 Big Losses: Measuring productivity loss for a given production process by tracking Availability, Throughput, and Quality
 - OEE is a key measurement to help with the elimination of waste in a production process
 - 6 Big Losses are used to track the most common causes of waste in a production process:
 - > Breakdowns
 - > Setup/Adjustments
 - > Small Stops
 - > Reduced Speed
 - > Start-up Rejects
 - > Production Rejects
- Value Stream Mapping: Visually mapping the flow of a production process in order to highlight opportunities to improve the process flow and eliminate waste
- Statistical Process Control (SPC): Using statistical methods to monitor and control a process
- Root Cause Analysis (RCA): Problem solving method
- Suppliers, Inputs, Process Outputs, and Customers (SIPOC) Process: Defining a business process from beginning to end before work begins by summarizing the inputs and outputs
- Responsible, Accountable, Consulted and Informed (RACI) Matrix: Using a responsibility assignment matrix to map out tasks, milestones or key decisions involved in completing a project or operational process

3.3.2 Maintenance

Key aspects of equipment reliability are improved when a well-designed and managed maintenance program is implemented.

"Maintenance is a combination of all technical and administrative actions, including supervision actions, intended to retain an item in, restore it to, or replace it so that it can perform a required function." [21]

Maintenance management and work execution consists of the processes and controls used in the delivery of maintenance services. A maintenance-driven equipment reliability program employs techniques like RCM, Condition-Based Maintenance (CBM), and precision maintenance techniques. A maintenance organization that is focused on equipment reliability strives to optimize maintenance activities.

A maintenance-driven equipment reliability program should include the following aspects:

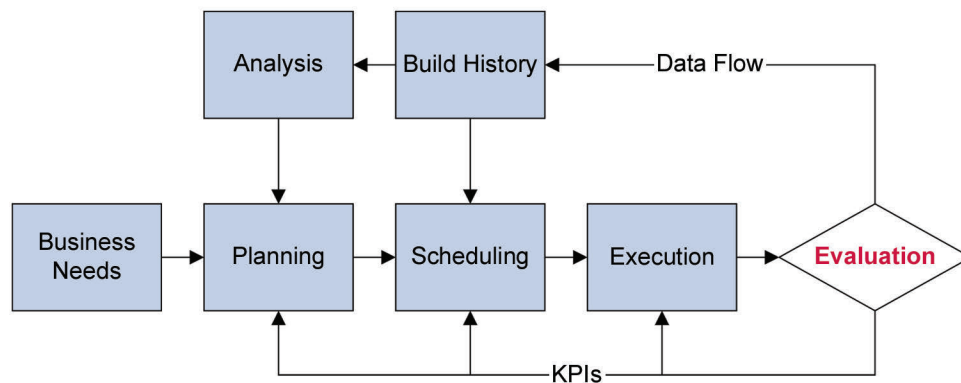
- **Maintenance Training and Qualifications** are critical to the safe and reliable maintenance of equipment and systems. Typical items that are included in a maintenance training and qualification program include:
 - Training of maintenance technicians in the complete operation of the equipment and understanding the theory of operation, sequence of operation, and operating limits

- Vendor-provided training, operations and maintenance manuals
 - Emergency procedures
 - Safety precautions
 - PM activities
 - Conditioned-based maintenance activities
 - Precision maintenance activities
 - Lubrication procedures
 - Common troubleshooting
 - Corrective Maintenance (CM) work plan content
- **Maintenance Management** processes and controls normally involve the following systems: [2]
 - Records for equipment, facilities, and systems
 - Labor resources
 - Planned maintenance
 - Spare parts
 - CMMS
 - Maintenance documentation
 - Work order management
 - Documentation assessment
 - Technical training program for equipment

Figure 3.4 illustrates the maintenance model.

Figure 3.4: Maintenance Model

Figure courtesy of Arnel N. Cabungcal.



3.3.3 Continual Improvement

Lean management and Six Sigma techniques, discussed earlier, are key elements of a continual improvement program that supports equipment reliability during the Operation phase.

Another key element of a continual improvement program that supports equipment reliability is to define what an equipment bad actor is. There are several factors that should be considered when establishing a bad actor list:

- System/equipment criticality
- OEE
- Downtime (hours, mechanical and operational, cost)
- Mean measures (MTBF (Mean Time between Failures), MTTF (Mean Time to Failure), MTTR (Mean Time to Repair), MTBM (Mean Time between Maintenance))
- Waste and rework
- System utilization
- Budget variance (operating and maintenance)
- Work order count (including maintenance labor hours)
- Spare parts cost
- Repair cost
- Type of equipment
 - Start at a macro level and then drill down to system and asset level; type examples include process, utilities, facilities, laboratory, static equipment (piping, heat exchangers, pressure vessels), rotating equipment, fired equipment (furnaces, boilers), instrumentation, electrical, etc.
 - An example of a type of equipment grouping to identify a bad actor type would be jacketed tanks (when grouped as an equipment type, jacketed tanks in general might be experiencing a high number of failures, downtime, etc.)

A bad actor report will identify opportunities to utilize RCA and FMEA tools to identify mitigation strategies.

Overall Equipment Effectiveness (OEE = Availability × Performance × Quality) is a commonly used KPI across all manufacturing industries. By tracking and improving OEE, organizations have been able to avoid capital investments by increasing the efficiency of their manufacturing processes, thereby increasing their manufacturing capacity with existing equipment.

The Society for Maintenance and Reliability Professionals (SMRP) [22] defines leading and lagging indicators as:

Leading Indicator:

“An indicator that measures performance before the business or process result starts to follow a particular pattern or trend. Leading indicators can sometimes be used to predict changes and trends.”

Lagging Indicator:

“An indicator that measures performance after the business or process result starts to follow a particular pattern or trend. Lagging indicators confirm long-term trends, but do not predict them.”

When considering a leading measure, it is beneficial to express it in terms of what it is a leading measure for (e.g., what is the lagging measure that will be affected?). Whether an indicator is a leading or lagging indicator depends on where in the process the indicator is applied.

A lagging indicator of one process component can be a leading indicator of another process component, for example:

- PM compliance is a leading indicator for equipment reliability (lagging measure)
- Equipment reliability is a leading indicator for maintenance cost (lagging measure)
- Maintenance cost is a leading indicator for profitability (lagging measure).

SMRP identifies three sets of measurable components that make up the maintenance and reliability process. [22]

- Management processes and behaviors (mission and vision, people skills)
- Operational execution (operations, design, and maintenance)
- Manufacturing performance (availability, quality, cost, and benefits)

Production disruptions due to equipment unavailability is an example of a lagging KPI under operational execution. The impact of unreliability is seen when scheduled batches do not get produced and thus this disruption needs to be measured.

KPIs are often used to compare, or benchmark, performance between similar equipment, processes, or sites. Benchmarking is a method of improving performance by measuring and comparing performance against others or “best in class” performance measures. Benchmarking should answer the following questions:

- Who performs better?
- Why are they better?
- What actions do we need to take in order to improve our performance?

Internal Benchmarking: A comparison of internal operations at a site or within the same organization. The aim is to identify “best in organization” processes/practices and then bring the level of performance of the site or the whole organization to the current “best in organization” benchmark.

External Benchmarking: This type of benchmarking can be competitive or generic. Competitive benchmarking is a comparison against specific competitor products, services, or functions. Generic benchmarking is a comparison of business functions or processes that are the same, regardless of industry or country. Generic benchmarking can typically be used when comparing asset management, maintenance, and reliability processes and practices.

The key benefits of benchmarking are:

- Focusing improvement efforts on issues critical to success

- Ensuring that improvement targets are based on what has been achieved in practice, which removes the temptation to say “it can’t be done”
- Providing confidence that the organization’s performance compares favorably with best practice

Risk management and review is a key element of the continual improvement process. The following are examples of processes included in a risk management and review program: [21]

- Risk assessment and management
- Contingency planning and resilience analysis
- Sustainable development
- Management of change
- Asset performance and health monitoring
- Asset management system monitoring
- Management review, audit, and assurance
- Asset costing and valuation
- Stakeholder engagement

For best practices associated with operations and maintenance, refer to the following ISPE Good Practice Guides:

- Asset Management [1]
- Operations Management [7]
- Maintenance [2]
- Good Engineering Practice [6]
- A Risk-Based Approach to Calibration Management [4]
- Sustainability [23]

3.4 Decommissioning Phase

The Decommissioning phase applies when the equipment will no longer be used to meet the organization’s objectives. This is commonly referred to as the equipment EOL. During the decommissioning phase, the equipment is removed from operational service and is typically not maintained. The equipment might be maintained in an out-of-service mode for a period of time while waiting for removal and disposal. From the time the equipment is placed out of service to the time the equipment is disposed of, certain activities may need to be performed (e.g., final requalification and calibration close out) to provide the documented evidence that the system was operating as it should at the time of decommissioning, i.e., verifying that the appropriate state has been maintained at the end of the operational life of the system. The decommissioning phase also includes managing the disposition of spare parts maintained in inventory. Prior to the removal of a piece of equipment, it is important to determine if the equipment will require decontamination. The organization may receive salvage value for the equipment and spare parts which might only be scrap value.

Decommissioning should be included as part of the commissioning process. Equipment becomes obsolete as processes change and as the techniques, technology and approaches to meeting process needs change also. Decommissioning obsolete equipment, and recommissioning others where appropriate, is part of the continuous cycle of commissioning.

In order for decommissioning to be effective, it needs to be embedded in the existing approach to commissioning and to take a strategic and holistic commissioning approach.

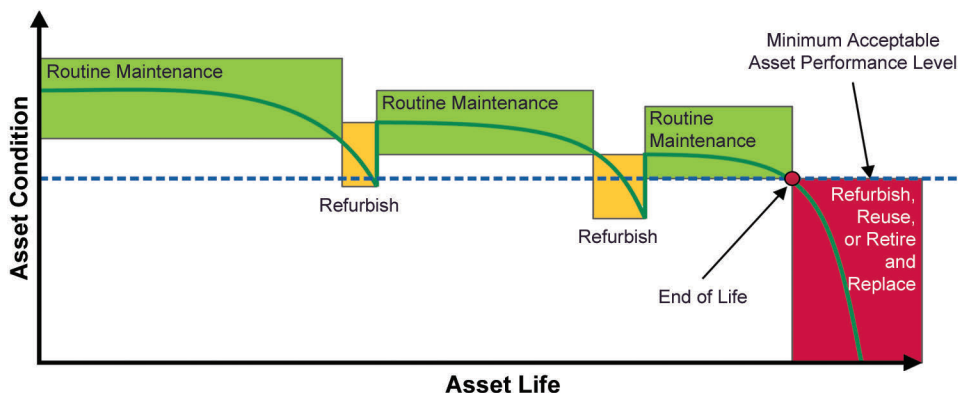
The *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities* [5] provides thorough guidance with respect to the GxP decommissioning process which includes testing responsibilities, employee support, how to properly decommission GMP documents for equipment that is removed from a validated system, asset disposal, remediation and demolition, and roles and responsibilities.

The decommissioning and the EOL evaluation process include a refurbish, repurpose or replace decision process. The following are considerations for this decision process:

- Evaluating needs, past and present—have the needs changed?
- What are the risks associated with extending the life of the asset? Decline in performance, lack of vendor/manufacturer support (i.e., software, obsolescence, etc.), physical condition, new technology of replacement equipment is superior from both cost and functionality aspects, etc.
- Determining the value of the equipment in its current state—what is the residual value of the equipment? (actual and/or remaining book value)
- Determining the cost to refurbish the equipment—what will the equipment be worth after a successful repair is made?
- Can the equipment be reused in a different capacity and replaced?
- Determining the cost of new equipment—what are the repair versus replacement factors? Considerations include repair cost as a percentage of new cost, features, reliability, installation costs, energy costs (standard versus high efficiency), time frame, warranty protection, availability of spare parts, protection from obsolescence, regulatory/health/safety/environmental considerations, CAPEX versus OPEX funds availability, etc.

Figure 3.5 illustrates the asset lifecycle, showing the EOL stage.

Figure 3.5: Example of Equipment Reaching End-of-Life [1]



Spare parts obsolescence is unavoidable and is not a result of how inventory is managed or how well storeroom personnel are trained. It is inevitable that any spare part will become obsolete at some point. Technology changes, designs change, equipment changes, and processes change; these changes can be difficult to influence. Conversely, how organizations plan for and respond to these changes can be managed.

The MRO spare parts removal process needs to take into account two types of obsolescence: vendor and owner.

- **Vendor Obsolescence:** Occurs when the Original Equipment Manufacturer (OEM) no longer sells the spare part or when the OEM is purchased by another OEM and the physical parts remain with the same, but the manufacturer/model information changes. The vendor may or may not have an alternative spare part to take the place of the old part. The alternative spare part may require modifications to fit the existing application.
- **Owner Obsolescence:** Occurs when an organization decides to replace or upgrade existing equipment. The existing spare parts in inventory will no longer be needed, so the spare parts become obsolete.

Begin with the End in Mind: Few organizations think about the future obsolescence or useful life of spare parts. This can result in either not having the parts when they are needed or ending up disposing of parts that were bought and never used.

Managing Spare Parts Obsolescence: It is important to understand and manage vendor and owner obsolescence.

- Vendor obsolescence may or may not be communicated to the owner in advance of the change. Vendor-owner relationships are critical to ensure the vendor provides the owner with advanced notification.
- Owner obsolescence visibility is under the control of the owner. The owner has control of the impending change that will result in the spare part being obsolete.

Project Spare Parts Evaluation: Engineering and maintenance personnel need to communicate to the storeroom when equipment is being upgraded and the existing equipment is being decommissioned. This allows the storeroom to reduce the stocking levels and determine the size of the final order. Typically, a capital project has a cost line item to account for disposal of obsolete spare parts.

EOL Evaluation Process for Spare Parts: The best way to manage spare parts obsolescence is by adopting a lifecycle approach to asset management. Lifecycle analysis takes into account the entire asset life, including the EOL plan. Proactively managing spare parts obsolescence can save significant costs in both procurement and equipment availability.

For best practices associated with decommissioning, refer to the *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities* [5].

4 Risk Management

4.1 Overview

This chapter reviews the application of risk management to equipment assets with the goal of improving its reliability and maintenance. Risk management is the systematic application of policies, procedures, and/or practices that are used to assess, analyze, evaluate, and control risk. A risk management process is an enabler to making informed decisions, being proactive, and pursuing continual improvement throughout the equipment lifecycle.

Ideally, risk management is applied throughout the lifecycle of an asset. Risk evaluation is relevant to both new and existing equipment in an asset portfolio. Risk management should also extend from the asset to the components. Periodic evaluation allows for the adjustment of priorities based upon changes to the asset mix, design, usage, performance, and issues.

The risks and impacts pertinent to equipment reliability are influenced by operational context. In the pharmaceutical industry, equipment failure has the potential to impact business, safety, and compliance standing. The risk priority of an asset should reflect and address the severity of impact, including:

- Asset management strategy
- Reliable supply
- Product safety and effectiveness (identity, strength, quality, purity, potency)
- Profit/loss
- GMPs
- HSE

Furthermore, risk elements and mitigation may be elicited from risk assessments driven by other management systems and/or compliance requirements where equipment assets are implicated. These other types of risk assessment include:

- Quality risk assessment, Quality Risk Management
- Process hazard analysis, Process Safety Management (PSM)
- Environmental risk assessment, environmental risk management plan

Risk evaluation is pertinent to critical equipment components. Practical methods and tools used in establishing and sustaining a maintenance strategy have risk management as a base; these include:

- RCM
- FMEA
- FMECA
- Calibration management
- Critical spares analysis

Asset Criticality is related to risk, and the Asset Criticality analysis develops a relative priority of equipment assets within an asset set or portfolio. Asset Criticality is beneficial in prioritizing activity and resources, including but not limited to:

- Asset improvement
- PM optimization
- Critical spare parts
- Engineering effort
- Maintenance execution

Note: The focus of risk assessment applied for C&Q activities is on manufacturing process failure modes and are out of the scope of this Guide.

4.2 Risk Management Process

While the practice of formal risk management is not covered here in detail (refer to ICH Q9 [16]), the process generally develops the risk evaluation with the following facets:

- Likelihood
- Severity (of impact)
- Detectability
- Mitigating actions

4.2.1 Engagement

The key to an effective evaluation is to include the perspectives necessary to incorporate the causes and effects of risk. Kickoff of a risk management process begins with identifying and involving stakeholders, including representatives from the following functions:

- Operations
- Engineering (e.g., facility, utility, process)
- Maintenance
- Quality Assurance (QA)
- HSE

4.2.2 Identify Targets

Prior to launching a risk evaluation, it is crucial to define the scope and objects of evaluation. Facilitation with respect to the scope is critical to make effective and efficient use of stakeholders' time.

As suggested previously, risk assessment in the context of equipment reliability may be applied at multiple levels throughout an asset's lifecycle. In each case, preemptively define the boundaries of the systems or components under consideration.

Prompt the stakeholders to engage and assemble evidence of equipment failures and impact to feed the evaluation process. The basis of the evidence may include:

- Operational issues
- Maintenance and calibration issues
- Repeat failures
- Incidents/deviations/atypical events
- Equipment or process changes

For the implementation of a new asset without history or explicit evidence, equipment failure assumptions may be collated based upon an existing asset base, network experience, or manufacturer's data. In addition, equipment considerations catalogued in parallel assessments may be reviewed and presented. These assessments may include:

- Quality risk assessment
- Process hazard analysis
- Environmental risk assessment
- Value stream mapping
- Business continuity

4.2.3 Evaluate Targets

To quantify or qualify risk, the elements of risk are determined for each object under evaluation. The basis of calculated risk are:

- Likelihood of failure
- Severity of failure impact
- Detectability of failure

The targeted objects are dependent upon the scope of the risk assessment. The level of detail corresponds to the method and specific risk being evaluated. Suitable risk assessment tools for example assets include:

- RCM: Equipment (functions) of a pumping skid
- FMEA: Equipment components within a sterile product boundary
- Facility quality risk assessment: HVAC equipment supporting graded space
- Process hazard analysis: Instruments and safety devices within a pressurized system

Developing and aligning on rating scales for each factor serves as a best practice. The scales should be developed with functional experts experienced in evaluating equipment risk and with an understanding of the operating context. Determine the number of brackets (e.g., 1–5) and the range boundaries for each bracket necessary to encompass the anticipated ranges of each element. Well-developed scales aid with the following:

- Comparable, relative scores across asset groups and business units
- Consistent interpretation among stakeholders
- Effectiveness of facilitation by clearly defined boundaries
- Evaluation efficiency through reduction of subjective debate

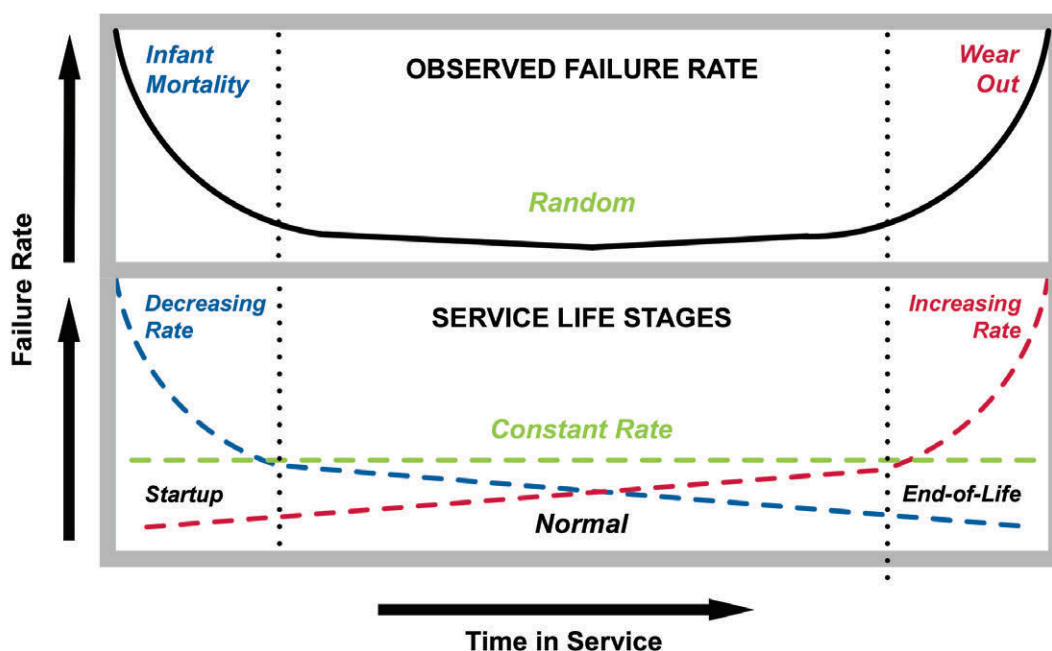
4.2.3.1 Likelihood of Failure

The likelihood of failure is the thrust of risk in equipment reliability. Multiple sources of information may be used as an indication of equipment's likelihood to fail, for example:

- Operating experience
- Maintenance experience
- Calibration and corrective work order history
- Safety events
- Quality deviations
- Environmental incidents
- Equipment change history

A key consideration for equipment is the lifecycle stage of an asset and the failure profiles that apply to the equipment and components. Conceptualization of the failure profile in equipment reliability is presented by the Bathtub curve, as shown in Figure 4.1.

Figure 4.1: Bathtub Curve



The curve plots failure rate versus time, with three major failure rate segments:

- Decreasing: Early “infant mortality” failure
- Constant: Random failures
- Increasing: Wear-out failures

In practice, the curve should represent the specific attributes and failure modes of the equipment or component. For example, an electronic device may have a very steep decreasing failure rate for infant mortality, after which it remains at a constant failure rate with no increase due to wear. Conversely, a mechanical device may begin with a constant failure rate and end with a steep, increasing failure rate, but with no initial decrease due to infant mortality.

4.2.3.2 Severity of Impact

The severity of impact should reflect the effects of equipment failure. Severity is independent of the potential or frequency of failure. Severity dimensions that reflect the business’s priorities should be selected, with impact that may include:

- Personnel safety
- Environment
- Product quality, safety, and efficacy
- GMPs
- Product supply
- Financial
- Resources/effort

The facets of impact should be considered independently and holistically. For example, “supply” may capture the scheduled impact to the supply chain due to downtime, whereas “financial” expresses the expense of repair and/or the cost (loss) of the product. The rating of severity should be based upon experienced or expected values.

To represent risk fairly, the assessment team may consider both common and worst-case failures when establishing severity. Critically important to an effective assessment is to rate severity based upon a single, independent failure. Risk facilitators must carefully screen multi-failure scenarios for dependency, feasibility, and scope of evaluation. Accounting for dependent or cascading failures will inflate the severity and overall risk score.

4.2.3.3 Detectability

Detectability in the context of risk assessment represents the ability to recognize a failure or its effects, given that a failure has occurred. The measure of detectability is inversely proportional to risk.

The key to detectability is time relevance. Depending on the failure mode and immediacy of impact, detectability can be determined by various means:

- Operational observation
- PM

- Performance measurement
- Monitoring (predictive)

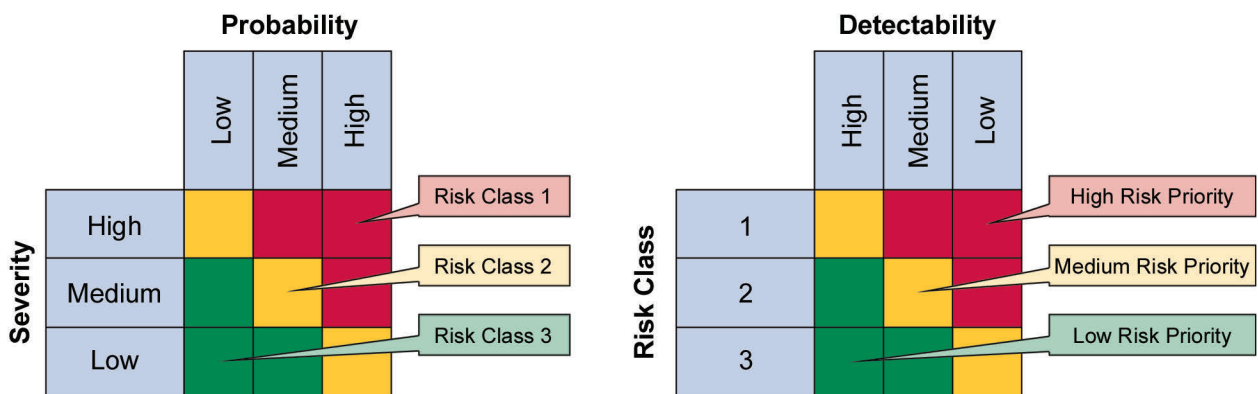
With respect to equipment reliability strategies (e.g., RCM, PdM, PMO), detectability can also provide meaningful indicators for design or program effectiveness. While elimination or prevention of failure modes is an obvious target in risk mitigation, improving failure detection is a powerful aspect of equipment reliability.

If detectability is not applicable or not factored, the outcome of the evaluation is risk versus risk priority.

4.2.4 Risk Assessment

Depending on the type of assessment, risk scores fall into one of two classifications, risk or risk priority, as shown in Figure 4.2. Within each classification, a matrix or group of ranges (e.g., High, Medium, Low) may be developed to aid in sub-classifying the objects assessed. The risk process and/or assessment team should pre-define what level of risk will require mitigation.

Figure 4.2: Risk Assessment Matrices [24]



Risk is the product of the Likelihood and Severity of failure(s). Detectability is not considered.

Risk priority is the product of Likelihood, Severity, and Detectability. A Risk Priority Number (RPN) is used to quantify/qualify the risk of an identified failure and its effects.

4.3 Mitigating Risk

The primary benefit of risk management is the drive for improving equipment performance and reliability. The risk or risk priority scores developed during evaluation provide the organization with a measured mechanism to prioritize and focus resources. The intended outcome is reduction in the overall risk to the business, with attention aimed toward the highest potential risk(s) presented by the most critical asset(s).

In practice, and complementary to equipment maintenance, mitigation may include corrective, preventive, and proactive elements. Consider improvements along with the factors of likelihood, severity, and detection, for example:

- Likelihood: Redesign or replace a component to eliminate a failure mode
- Severity: Add system redundancy to reduce downtime exposure
- Detection: Implement monitoring to detect failure early warning