

*Insert Facility/Institute Logo Here*

**FACILITY OPERATIONS AND MAINTENANCE MANUAL *TEMPLATE***

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| Facility: |
| Manual Title: *Facility Operations and Maintenance Manual* |
| Document Number:  | Version Number: *00* |
| Process Leader: | Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this manual (e.g., manuals, SOPs, forms, records):* Biorisk Management Manual (4-00-001)
* Autoclave: Operation and Maintenance SOP (*3-02-006*)
* Biological Safety Cabinet: Operation and Maintenance SOP (*3-02-001*)
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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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INSTRUCTIONS: The Facility Operations and Maintenance Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed when operating and maintaining a facility. These templates are not exhaustive; facilities must customize each document to ensure it is locally applicable and relevant.

* **Black text** can be considered generic text that may be appropriate for inclusion in a facility’s operations manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

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### Maintenance Request Form

### Verification of completed decontamination and safe status form

### Maintenance Completion Form

### Item Supply Request Form

### Sticker for maintenance completion and next maintenance due

### Sticker for calibration completion and next calibration due

### Sticker for “Out of order, cannot be used”

### Sticker for “at present not used, not in calibration scheme, must be calibrated before taken into use”

D. Example Supplier Equipment Information

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# Policies and General Management

##  I. Purpose and Limitations

The purpose of this manual is to describe the basic principles of facility operations and maintenance that are required for the continued operations of *[Insert Facility Name]*. This manual contains information related to keeping the laboratory system in full working condition, such as the critical facility infrastructure and equipment, facility-wide risk assessment, definition of roles and responsibilities, equipment use, and maintenance strategies. This manual will need to be supported by a set of standard operating procedures (SOPs) and attachments that describe specific laboratory operations, detailed work processes, and maintenance strategies related to the principles described in this manual.

Creating a documented strategy for operations and maintenance that all leadership and staff agree to, prior to beginning work in the facility, will enhance the cooperation required to operate efficiently, safely, and with an appropriate use of resources. Such an agreement must occur for current existing facilities and processes or for newly constructed facilities and new procedures.

For a documented strategy to represent the safest and most efficient procedures, it must be based on in-depth risk assessments. These risk assessments will include biological, chemical, and physical safety and security risk assessments *along with any other specialized assessments, such as dealing with radiological hazards, special work conditions based on the surrounding human or animal community, and socio-economic considerations for the surrounding community.* All of these assessments must be completed using the facility’s mission, legal requirements, and risk acceptability as a backbone to inform and interpret the results. The outcomes of these assessments will be used to determine the acceptable amount of time that a facility can be inoperable (also known as down-time) during operations stand-down times to complete the necessary maintenance in order to keep the facility running optimally. By thinking through these concepts and planning ahead, it will be possible to effectively schedule the maintenance down-time to allow for a minimal loss of laboratory activity and loss of valuable work time.

## Principle

The scope of *[Insert Facility Name]*‘s operations and maintenance manual is to define and set requirements to control risks associated with procedures necessary for daily operation. Many of the aspects discussed in this manual relate closely to the information discussed in *[Facility’s Biorisk Management Manual; 4-00-001]*. Because of this, there must be a clear delineation of content between the two. The *[Facility’s Biorisk Management Manual (BRM Manual); 4-00-001]* covers the operational aspects associated with minimizing the risk of exposure to biological agents. In doing that, it discusses a variety of administrative and operational controls such as Disinfectants and Decontamination, Waste Handling and Disposal, and Laboratory Equipment. While this is critical to facilities operation, to avoid duplication it has not been included here. This manual will instead discuss the operational aspects that will support the long-term health of the equipment being used in order to prevent functional issues with the equipment. These two documents should be used together to form a complete understanding of the operational environment in the facility.

From a maintenance perspective, this document covers the variety of maintenance needs of *[Insert Facility’s Name]*. This includes the type of maintenance strategies incorporated within the facility’s overall maintenance system, the maintenance plan and its planning and considerations, and critical systems. Accompanying this manual should be a compendium of log and request forms, signage, standards operating procedures, equipment repair manuals, and other additional supportive materials.

## Considerations and Requirements

*In developing this manual, the mission of the laboratory must be taken into consideration. Based on the operating requirements of the facility, different maintenance strategies and timings will apply. Some of the considerations to look into for the facility are listed here. This section should outline the requirements for your facility only.*

* 1. *Operational Hours – Depending on the facilities working schedule, routine maintenance can be scheduled after-hours. If the facility does not have times where work isn’t being performed then the type of work being performed must be considered to minimize impact on operations during routine maintenance.*
		1. *Is this facility operational 24 hours a day, seven days a week, all year?*
		2. *Is this facility operational 24 hours a day, seven days a week during specified production times?*
		3. *Is this facility operational during normal business operating hours during the work week?*
		4. *Is this facility operational for extend work days compared to typical business operational hours.*
	2. *Mission Criticality – How critical is it that facility continues to run uninterrupted. What are the consequences of a failure that causes the facility or a specific laboratory to be inoperable?*
		1. *If critical systems fail, will there be irrevocable damage to the product, samples, or other biological materials?*
		2. *If critical systems fail, will there be irrevocable damage to facility infrastructure, equipment, or tools?*
		3. *Can the facility afford to be inoperable for [number] of days?*
	3. *Maintenance Capability – Who will be performing the maintenance? What skills or certifications are required?*
		1. *Does the facility have the expertise within the organization to maintain the equipment or will the facility need to contract with maintenance specialists outside the organization?*
		2. *Which pieces of equipment is it worth gaining the maintenance expertise for, if the facility does not have it currently?*
	4. *Biological Risk Profile – How hazardous are the biological agents and the work the facility is performing with them?*
		1. *If a critical system failure occurred, what is the level of risk to the personnel in the laboratory?*
		2. *If a critical system failure occurred, what is the level of risk to the animals in the laboratory?*
		3. *If a critical system failure occurred, what is the level of risk to the human community surrounding the laboratory?*
		4. *If a critical system failure occurred, what is the level of risk to the animal community surrounding the laboratory?*
	5. *Other Risk Profiles –*
		1. *What are the economic repercussions if there is a critical system failure?*
			1. *Due to loss of product/revenue stream?*
			2. *Due to fines, lawsuits, and penalties?*
		2. *What are the political or public sector (societal) repercussions if there is a critical system failure?*
		3. *What are the impacts on the facility’s reputation if there is a critical system failure?*
	6. *Other considerations for the development of an Operations and Maintenance Manual*

## Definitions and Terminology[[1]](#footnote-1)

* 1. **Accident:** unintended event giving rise to harm
	2. **Biohazard:** potential source of harm caused by biological agents or toxins
	3. **Biological agent:** any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants
	4. **Biorisk:** combination of the probability of occurrence of harm and the consequence of that harm where the source of harm is a biological agent or toxin
	5. **Biorisk management system:** part of an organization’s management system used to develop and implement its biorisk policy and manage its biorisks
	6. **Biosafety:** laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release
	7. **Biosecurity:** laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release
	8. **Calibration:** Is a comparison between measurements – one of known magnitude or correctness made or set with one device and another measurement made in as similar a way as possible with a second device.
	9. **Certification:** Is the confirmation of certain characteristics of an object, person, or organization. This confirmation is often, but not always, provided by some form of external review, education, assessment, or audit.
	10. **Commissioning:** The commissioning process comprises the integrated application of a set of [engineering](http://en.wikipedia.org/wiki/Engineering) techniques and procedures to check, inspect and test every operational component of the project, from individual functions, such as [instruments](http://en.wikipedia.org/wiki/Measurement_instrument) and equipment, up to complex amalgamations such as [modules](http://en.wikipedia.org/wiki/Module), [systems](http://en.wikipedia.org/wiki/System) and [subsystems](http://en.wikipedia.org/wiki/Subsystem).
	11. **Communication:** The exchange of information between people.
	12. **Decontamination:** procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects
	13. **Disinfection:** process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms
	14. **Flexibility:** How the facility operates and is able to change, adapt, or adjust to different needs for maintaining the facility and the type of research happens within the facility.
	15. **Incident:** event with a potential for causing harm (near-miss, accidental or intentional), or any event that deviates from the normal operations.
	16. **Redundancy:** concept of having backup systems and equipment in order to continue normal operations or run under emergency operations in the event of the primary system or equipment failing.
	17. **Standard Operating Procedure (SOP):** an instructional document designed to achieve a single consistent outcome using the same methods regardless of the individual performing the task.
	18. **Sterilization**: A process that kills and/or removes all classes of microorganisms and spores
	19. **Toxin:** substance, produced by a biological organism, which in small or moderate amounts produces an adverse effect in humans, animals or plants. This definition includes substances and materials which may be contaminated with toxins (see also biohazard)
	20. **Validation:** is confirming that a product or service meets the needs of its users.
	21. **Verification:** Confirmation that the facility, system, or equipment is operating as originally tested. Often done on a yearly basis to ensure that the product is working according to the original commissioning requirements.
	22. *Others to be determined*

## Roles and Responsibilities

The responsibility for properly maintaining a facility is shared between all personnel from executive management to the laboratory personnel and support staff. These responsibilities are described generally below. More specific duties are outlined within the relevant SOPs. *Personnel roles and responsibilities can be added or deleted based on the specific structure of the organization. Some of the roles listed below may be the same individual. As an example, if the maintenance staff is minimal, and there is not a head of engineering, then the roles of Engineering Management may be included in the Executive Management role. However, if the same person is responsible for multiple roles, the separation of user and maintenance roles should be clarified here.*



*[Insert your facility’s organizational chart here]*

* 1. Executive Management *shall take ultimate responsibility for the organization’s maintenance program to ensure that roles, responsibilities, and authorities are defined, documented, and communicated and to demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain, and improve the maintenance program. Executive management will determine, within the maintenance strategy informed by engineering and maintenance personnel and the Biorisk Management Professional, what equipment will be serviced in-house and what will be contracted out to private companies. For any in-house repairs, it is their responsibility to ensure that the proper individuals, whether that is maintenance personnel, laboratory personnel, management staff or others are fully trained on proper decontamination, shutdown, repair, and startup of the systems being repaired.*
	2. Engineering Management *shall work with executive management and laboratory management to set timelines for operational stoppages, and establish proper roles and responsibilities within the entire laboratory. They must consolidate repair requests to ensure that the schedule is meeting the needs of the laboratory and any immediate actions. Engineering management is responsible to ensure that policies, procedures, and other actions are communicated throughout [Insert Facility’s Name] to ensure widespread communication and coordination of the maintenance program. For any repairs to equipment or systems, it is the Engineering Management’s responsibility to ensure that they are meeting the supplier of the equipment’s recommendations.*
	3. Laboratory (Mid-Level) Management *is responsible for coordinating the [Insert Facility’s Name] technical work with the maintenance schedule to ensure minimal loss of productivity due to operational stoppages without compromising the safety of workers. Laboratory management will also be responsible for collecting data on any problems found by laboratory staff in the workings of equipment requiring attention from maintenance staff.*
	4. Maintenance Personnel *are the primary responsibility holders of maintaining the facility’s equipment. This includes the planning of individual and large-scale maintenance activities and also ensuring that the facility is running according to the specified parameters following maintenance activities. During normal operating conditions, maintenance personnel should take routine measurements of critical equipment to determine the amount of routine wear to inform the maintenance schedule. Maintenance personnel are also required to understand the scope of the risk in the maintenance environment and be trained on how to protect themselves from any biological, chemical, or physical risk that is present in their operating environment. When maintenance personnel are contractors, appropriate oversight by Biorisk Management Professionals or other delegated facility employee is necessary.*

### Biorisk Management Professionals *serve as a primary link between the maintenance personnel and laboratory staff regarding the biological risks associated with the laboratory. They are responsible for ensuring each team understands the work that is being done by the other and its necessity. The Biorisk Management Professional is responsible for ensuring the operating environment has been properly decontaminated to allow for work to be done by the maintenance personnel. In the event the area cannot or should not be decontaminated, they need to train the maintenance personnel to have the proper understanding of the biological risks to properly protect themselves while performing their duties.*

### Laboratory Personnel *serve as the primary users of most laboratory equipment. In that capacity, it is critical for them to understand proper use of the equipment to minimize the stress put on individual parts. Because laboratory personnel are routinely interacting with the equipment, they are able to collect data on the functioning of the equipment and make provide reports and notification to their management of any maintenance issues. In certain situations, the laboratory personnel may be responsible for performing simple repairs on specialized equipment the maintenance staff does not have access to or for repairs that must be made under operating conditions that do not allow for outside personnel to enter.*

### Environmental Health and Safety Professional *shall serve a similar role to the Biorisk Management Professional in keeping the maintenance staff up to date on the risks associated with chemical, physical, and other hazards. As the Environmental Health and Safety Professional manages the preventative medical program for laboratory staff, maintenance staff should be evaluated to be enrolled in a similar program as needed for entering into hazardous areas.*

# Laboratory System

## Planning and Assessment Strategies

*Developing a laboratory system maintenance plan is most effective during the construction and startup of a facility. This will allow for a full inventory of systems that can be provided or developed through consultation with the construction company. If this is not possible and the manual must be developed for an operating facility, as much information should be gathered to ensure the manual is as complete and informed as possible. In order to do this, the following information must be gathered:*

### Risk Assessment

The following risk assessments were completed to inform the development of [*Insert Facility’s Name]* maintenance plan and schedule. Based on the highest risk areas being defined as [*insert the areas of most concern from a biological, chemical, physical, and/or other risk perspective*]the maintenance plan and schedule focuses on ensuring that these systems receive a greater degree of attention to ensure the integrity of the equipment is not compromised through extended use.

1. Biosafety – *Insert the results of the biosafety risk assessment here. In the results, identify the highest risk areas of work based on the likelihood and consequences of exposure, infection, or accidental release of the biological pathogens. Indicate in this section the role of engineering controls in place to mitigate the risk and if those controls need to be deemed “mission critical”.*
2. Biosecurity - *Insert the results of the biosecurity risk assessment here. In the results, identify the highest risk areas of work based on the likelihood and consequences of theft, loss, and misuse of the biological pathogens. Indicate in this section the role of engineering controls/physical security in place to mitigate the risk and if those controls need to be deemed “mission critical”.*
3. Chemical Safety - *Insert the results of the chemical safety risk assessment here. In the results, identify the highest risk areas of work based on the likelihood and consequences of exposure or accidental release of the chemical agents used in the laboratory. Indicate in this section the role of engineering controls in place to mitigate the risk and if those controls need to be deemed “mission critical”.*
4. Chemical Security - *Insert the results of the chemical security risk assessment here. In the results, identify the highest risk areas of work based on the likelihood and consequences of theft, loss, and misuse of the chemical agent. Indicate in this section the role of engineering controls/physical security in place to mitigate the risk and if those controls need to be deemed “mission critical”.*
5. General Safety – *Insert the results of the general safety risk assessment. In the results, identify the highest risk areas of work based on the likelihood and consequences of injury in the workplace. Indicate in this section the role of engineering controls in place to mitigate the risk. Some aspects of general safety to be included in the assessment are risks associated with:*
	1. *Steam*
	2. *Heat*
	3. *Electrical*
	4. *Ergonomics*
	5. *Slips, Trips, and Falls*
	6. *Other hazards*
6. General Security – *Insert the results of the general security risk assessment. In the results, identify the highest risk areas of work based on the likelihood and consequences of theft, loss, misuse of laboratory and administrative equipment, or sabotage of the facility’s mission. Indicate in this section the role of engineering controls in place to mitigate the risk.*
7. *Other necessary risk assessments, as needed*

## Impact Assessment Analysis – In order to ensure that the system is working properly, an impact assessment must be completed. This is done to identify which are critical and which are non-critical systems. To determine this, consider the impact equipment has on *exposure, laboratory protection, environmental protection, decontamination, access, accountability, etc.* For critical systems, the following questions need to be answered:

* *Do they work according to their intent?*
* *Can we trust the engineering controls?*
* *What does it take to create a safe system?*
* *What does it take to keep the system safe?*
* *What other systems are interconnected with this one?*

## The above assessments must be taken into consideration in order to determine what the priorities of the facility are holistically and what areas will be the focus areas. Decisions on identifying critical systems and equipment should be made based on an understanding of the risk assessments and determination of allowable down time in the event of failure. The equipment included in this section is that which cannot be inoperable, must have the shortest operational stoppage during failure or maintenance, or in the event there are no such systems, that which require the highest priority and attention. For these pieces of equipment, international, regional, national, and civic regulations must be included to determine necessary level of maintenance.

## *Highlighted below are examples of the types of systems that could be deemed to be either Critical or Non Critical systems. A facility is responsible for making the determination between its Critical and Non-Critical systems and equipment.*

* 1. Identifying Critical Systems and Equipment
	2. Identifying Non Critical Systems and Equipment

C. Example Systems to be Considered When Identifying Critical and Non-Critical Systems

### *Airflow System – Include the major points of failure and focus points of this system, including critical equipment and how it will be maintained. This information will be fed into the maintenance schedule for routine maintenance.*

### *Heating, Ventilation, and Air Conditioning (HVAC) Systems*

### *High Efficiency Particulate Air Filters*

### *Filter Housings*

### *Pre-filters*

### *Airflow Regulators*

### *Fans*

### *Dampers*

### *Ducting*

### *Fixed Air Handling Equipment – Include within this, key equipment that draws air from the room or the HVAC system to protect the worker, the sample, or the environment.*

### *Biological Safety Cabinets*

### *Different Classes of Biosafety Cabinets (ex. Class II A2, Class II B2, Class III*

### *Chemical Fume Hoods*

### *Laminar Flow Benches*

### *Waste Disposal and Decontamination – Include within this section systems that are responsible for the removal and decontamination of biohazardous waste.*

### *Autoclave*

### *Incinerator*

### *Gaseous Decontamination Systems*

### *Piping, Valves*

### *Pumps, Heating Devices, Others*

### *Chemical Decontamination Methods*

###  *Chemical decontamination drive in basins*

### *Effluent decontamination system*

### *Research Equipment*

### *PCR Machine*

### *Centrifuge*

### *ELISA Washer*

### *Incubator*

### *Freezers/Refrigerator*

* + - 1. *Water Bath*
			2. *Heat Blocks*
			3. *Dry Oven*
			4. *Etc.*

### *Security Equipment*

### *Access Control Devices*

### *Proximity Reader*

### *Card Reader*

### *Pin Pad*

### *Finger Print Reader, Hand Geometry, other Biometric Scanners*

### *Keyed Entry Systems*

### *Intrusion Detection Devices*

### *Cameras*

### *Infrared Detection*

### *Microwave Detection*

### *Safety Systems*

### *Fire Suppression Systems*

### *Sprinkler System*

### *Fire Extinguisher*

### *Fire Alarms*

### *Other Building Equipment- Any other piece of equipment or physical infrastructure that will require maintenance. These tend to be lower priority items that will have less impact on the mission, safety, and security of the facility.*

### *Windows and Bars*

### *Doors, Handles, Locks, and Automatic Door Openers*

### *Sinks, Plumbing, Faucets, and Carts*

### *Cabinets and Shelves*

### *Walls and Floors*

### *PAPR Chargers*

### *Security Alarms*

# Operations

## Creating an Operational System to Support Mission Critical Activities

As mentioned in Section II, many operational aspects that are related to the use of the equipment and systems are included in the *[Facility’s Biorisk Management Manual; 4-00-001]*. Within the *[Facility’s Biorisk Management Manual; 4-00-001], operational aspects such as waste treatment, decontamination, and other biorisk related mitigation measures are discussed.* The topics below will supplement this documentation by adding procedures for the proper treatment of the equipment to guarantee that it remains functional and able to meet its needs for the mission, safety, and security.

### Equipment Use and Laboratory Protection

### *Where do specific pieces of equipment need to be placed to prevent damage or loss of function? This should include room layouts/diagrams, possible interference, and related workflows.*

### *Is a sensitive piece of equipment in a high traffic area?*

### *Is the equipment subject to unnecessary damage from opening doors, moving carts, or other routine activities?*

### *Does the airflow or personnel movement disrupt the function of the equipment?*

* + - 1. *Does the location fulfill local regulations regarding natural disasters (flooding, earthquake, tornado, etc.)?*

### *Are there specialized usage requirements for specific pieces of equipment that will ensure that it functions in the way that intended to minimize the possibility of malfunction?*

### *Is there a need to minimize certain types of equipment or supplies in the near area because of heat, vibration, or other concerns?*

### *Is specialized placement of supplies in, on, or near the equipment required for optimal functionality? For example, will the placement of supplies within a biosafety cabinet, or the placement of a biosafety cabinet near air ducts or doors adversely impact the airflow?*

### *Are there certain chemicals, supplies, or equipment that cannot be used in conjunction with a particular piece of equipment? For example, are certain chemicals used in biological laboratories that cannot be safely passed through an autoclave (i.e. bleach)?*

### *Does the equipment have any particular restrictions or requirements on the types of decontamination practices it requires?*

### *Have the proper disinfection agents been selected that effectively disinfects the equipment from contamination, but also avoids or minimizes damage to the equipment?*

### *Are the methods of decontamination acceptable to the electronic systems found within the system?*

### Operational Stand-Down Times

### *What are the standard operating hours of the facility? Is this a facility that remains functional 24 hours a day and7 days a week, runs only during a typical work week, or does it have extended hours each day?*

### *What are the procedures necessary for starting up the systems and equipment after each shut-down? Is there an order the equipment and systems need to be started to synchronize systems or avoid damage?*

### *Will turning on one system increase the pressure (air pressure, water pressure, etc.) that could have an impact on the balance of other systems utilizing those functionalities?*

### *What are the procedures necessary for shutting down the systems and equipment at the end of an operational period? Is there an order the equipment and systems need to be turned off to avoid impacting other equipment and systems?*

### *Will turning one system off create an offset that could adversely affect the functioning of another system? Could the shut-down result in a reversal of pressures causing a release of hazardous materials or a lack of water flowing to a critical component?*

# Maintenance

## Types of Maintenance

## The maintenance program is designed around the principles of a reliability centered maintenance strategy. This incorporates different types of strategies in different conditions. Reactive maintenance can be used for items that have a low impact on operations, low cost of repair, and that are affected minimally by maintenance intervention. A majority of the maintenance being done in the facility will be completed using a preventative maintenance strategy, resulting in a regular upkeep of the equipment. This can be used for equipment that can have an expanded lifespan when regularly maintained, for pieces of equipment where additional funds can be utilized to avoid failure, and may be hard to regularly inspect due to access or availability. The final group of equipment will undergo a predictive maintenance strategy. These are pieces of equipment with a lifespan that can be significantly increased by regular monitoring and repair with parts that are nearing the end of their functional life, and/or are mission critical pieces of equipment. By taking regular measurements, failure can be predicted and prevented while still allowing for the maximum use of the parts in question. For a full explanation of these strategies, see Attachment A.

## Considerations for a Maintenance System

## There are many considerations that went into the design of [*Insert name of Institution*]’s maintenance plan. In order to properly maintain the facility, these factors and their impact on operations were considered. The below considerations can be organized into the master Maintenance Schedule (see Attachment C) to allow for a complete understanding of the maintenance needs.

* 1. Facility Operational Timelines
		1. *Who is responsible for the maintenance of each piece of equipment identified in Section VII A and B?*
			1. *Is this done by [Insert name of Institution] staff or contracted out to external experts?*
		2. *Are the service contracts in place for the equipment requiring external expertise?*
		3. *What are the facility requirements for shut down? Does this facility run 24 hours a day, 7 days a week, all year? Does this facility run during normal business hours during the week? Does it have a regular hybridized schedule with set shut down times every week? Does it run constantly for a certain number of months before being shut down?*
			1. *Are service contracts arranged to meet the needs of the facility’s shut down schedule? Do special accommodations need to be put in place to allow for the maintenance to take place? Partial shut downs? Full shut downs?*
	2. Hazard Environment
		1. *Using the risk assessments included in Section VI. A, as built construction documents, and room functions assign each area in the laboratory to a hazard environment. These environments can be described into various levels such as low, high, and extreme. (Additional designations can be developed and documented here as necessary.) Hazard environments will help to determine what level of protection is required, when different areas can be accessed, level of training necessary to enter the area, and special considerations.*
			1. *Low Hazard conditions have few to no special safety considerations and work is relatively unhindered by the operational environment. This means that there is little restriction on when maintenance can be performed on the equipment. It requires minimal decontamination and disposal constraints and equipment preparation is minimal. This all results in being able to, under most circumstances, have both planned and unplanned operational shut downs.*
			2. *High Hazard conditions have greater limitations to access, maintenance scope during operations, and increased preparation for maintenance. The safety and security measures are greater than low hazard situations and there are often procedures for entering, exiting, and transporting tools through a high hazard area. These areas often require greater preparation for maintenance, either through a shutdown, additional training for the maintenance staff, of alternate sample processing locations.*
			3. *Extreme Hazard conditions have strict access requirements for either safety or security reasons. These areas require strict protection and have very limited opportunity for maintenance under normal operations. As with high hazard, there are complex entry and exit procedures and great restrictions on moving maintenance equipment into or out of an extreme hazard environment. These situations require significant planning prior to an operational shutdown to allow for maintenance to occur.*

 *When assigning these categorizations to areas within the institution, certain caveats must be taken into account. First these are hazard environments under operational conditions. In most extreme hazard conditions, for example, in shutting down the facility operations, the hazard environment could drop to a low hazard environment due to the decontamination protocols in place. Working in this area under shut down could have significantly relaxed safety regulations because of that. These must be considered as the plan is developed. Additionally, as everything in this manual is designed off of initial risk assessments, dividing the hazards into three groups may be seen as negating the validity of the risk assessment. This categorization helps to organize maintenance strategies throughout a variety of situations within an institution. When actual maintenance occurs, the room/laboratory/department specific information will serve as the primary source of information on the necessary practice and procedures to follow while interacting with it.*

* 1. Maintenance Categories

Maintenance is a critical component of a successfully operating facility. *[Insert Director’s name]* supports the full integration of a maintenance plan into *[Insert mission, research, diagnostic, etc]* functions. In order to minimize the impact of the maintenance, the work will be well coordinated so that time and resource loss will be reduced to a reasonable level. To do this, the systems and equipment identified for repair will be categorized into *four different subsets* of operational impact. These categories will designate the varying levels of interruption that maintenance will cause on operations. These categories will take into account its impact on operational safety and security, operation, availability of infrastructure, expected stand down times, need for disinfection, how far in advance they must be planned, and start up times post stand down.

Some equipment will require different types of maintenance. Each type of maintenance will be categorized individually to ensure that unexpected operational interruption does not occur. When categorizing a maintenance procedure, it is likely that some procedures will categorize into different categories in different criteria. When this occurs, it must be categorized into the higher category and the reasons documented so that it is not accidentally reduced. The table below gives the criteria for determining where each type of maintenance falls. For a full description of the maintenance categories, please see Attachment B.

|  |
| --- |
| **Overview of Maintenance Categories and Their Characteristics**Table adapted from Salerno and Gaudioso, 2015) |
| **Category** | **A** | **B** | **C** | **D** |
|  | **No impact on safety and availability**  | **Impact on safety and availability**  |
| **Type of maintenance work**  | Inspection and small services | Shorter, less extensive activities with maintenance interval ≤ 1 year | Extensive work on important systems maintenance interval ≥ 1 year | Very extensive work on whole facility  |
| **Stand-down time\*** | None | Days to weeks | Several weeks | Months |
| **Planning horizon** | None | Months | 1 year | Several years |
| **Implementation of maintenance work** | Continuously | At predetermined intervals,once every 3 or 6 months. | At predetermined intervals,1x per year | As needed |
| **Time needed to return to normal operations** | None | Possibly one day | Several days | Time consuming, functionalities may be newly defined |
| **Continued Analysis possible** | Yes | Only if lab still in operation  | no | no |
| **Examples** | Observe system parameters, refilling working materials, exchange wear parts  | Periodic controls, service/repair of lab equipment, cleaning  | Maintenance HVAC, ETP\*\*, autoclaves, breathing air supply | Rare, larger modifications and renewal  |
| \*not including time for prior decontamination\*\*Effluent Treatment Plant |

##

* 1. Facility Maintenance Procedures
		1. Pre-maintenance shut down procedures – *Describe initiatives and procedures that needs to be undertaken to ensure that critical equipment or system is safe to handle. This will include any methods of decontamination, the ability of the equipment to be moved for maintenance or its need to stay on site, or other considerations.*
		2. Maintenance Activities – *Describe the needs of the equipment to undergo maintenance during this maintenance period. Operations and Maintenance SOPs can be developed for this step to be included as attachments to this manual. There are several template SOPs that can be used to help facilitate the development of these such as those for the Autoclave (3-02-006) and the Biological Safety Cabinet (3-02-001) templates.*
		3. Post Maintenance – *Describe how the equipment can be checked for safe and optimal performance before being released for reentry into the operating environment.*

## Maintenance Plan

## *A maintenance plan can be developed as a hard copy document, file card system, electronic generic system, or specialized commercially available software. To select the correct system for [Insert facility’s name], the standard form of documentation used in the facility should utilized. Whatever system is selected, all the pertinent data should be included. Key methods for capturing the maintenance plan should include a Maintenance Schedule, Spare Parts Inventory System, and Adjustment of Maintenance Frequency.*

### Maintenance Schedule

### The maintenance schedule includes all pieces of equipment and systems that need to undergo maintenance, and the pertinent information that determines when the equipment must be maintained. *A draft maintenance schedule can be found in Attachment C.4*. Timing issues include if there are specific times of day that the maintenance needs to be performed, last completed maintenance on that specific piece of equipment or system, and any relevant reference numbers to other aspects of the maintenance strategy.

### Spare Part Inventory System

### The spare part inventory system is a secondary process to the maintenance system that allows for the tracking, availability, ordering, and stocking of spare parts for maintenance. This system allows for both the unpredictable short term requests for parts and longer term, planned maintenance activities. Parts that require frequent use should be held on hand in order to expedite the maintenance process where as parts that are either rarely used, can expire, or have predictable maintenance use can be ordered in time for their need. An inventory log should be kept of all parts on hand so that a determination can be made if the part is present or needs to be ordered. *An example of an inventory log can be found in Attachment C.1.*

### Adjustment of Maintenance Frequency

### Following the completion of a maintenance activity, an assessment of the statue of the removed parts will be completed. This assessment, in regards to the parts maintained through preventive measures will help to determine the appropriateness of the removal of the part on that timeframe. If the part does not show significant wear and the facility shut down requirements allow for it, the part may be considered for extended use before future repairs. This will allow for the preventive maintenance plans to be adjusted according to the specific operating environments. When considering these adjustments, it is important to consider the manufacturers specifications and warranty. If the desired change of action invalidates the warranty, then careful consideration must be used to determine if the changes are of significant enough value to implement. Detailed maintenance records are valuable to have available for analysis by others, as well as useful for identification of predictive maintenance intervals for scheduled maintenance.

## Critical Systems and Equipment Maintenance Considerations

## Non-Critical Systems and Equipment Maintenance Considerations

## *Each piece of equipment, system, and infrastructure’s maintenance requirements must be carefully considered. This will include all critical and noncritical systems within the facility. In most cases, when taking ownership of a building, the contractor is able to provide a complete list of manufacturer’s specifications. This will include both critical and noncritical systems. If this information is not provided then researching it to acquire the information is critically important. This will give the most information about the products being used, company of manufacture, technical specifications, warranty information, usage information, maintenance and troubleshooting, and specified repair parts.*

 *This information will be the key outside information for developing the maintenance schedule. This should be by far the largest section of the manual with information on every piece of equipment that will undergo repairs. This includes major laboratory equipment such as biosafety cabinets, centrifuges, and refrigerators; major building infrastructure systems such as HVAC and electrical systems; and minor features like lighting, automatic door closers, and hinges. This information will help to determine if the repair will be included in the preventive, predictive, or reactive maintenance categories. For an example of supplier equipment information that should be included for each item, please see Attachment D.*

## References

* + 1. Salerno, R. and J. Gaudioso. *Laboratory Biorisk Management: Biosafety and Biosecurity*. 2015. CRC Press.
		2. R. M. Salerno and J. Gaudioso, Laboratory Biorisk Management: Biosafety and Biosecurity, CRC Press, Boca Raton, FL, 2015
		3. Sullivan, G.P., R. Pugh, A.P. Melendez, and W.D. Hunt. 2010. Operations & Maintenance Best Practices: A Guide to Achieving Operational Efficiency. Washington, DC: Pacific Northwest National Laboratory for US Department of Energy. Pg. 5.1 <http://www1.eere.energy.gov/femp/pdfs/omguide_complete.pdf>
		4. K. S. Cole, D. Fisher, and S. Westfal, Management Principles for Building and Operating Biocontainment Facilities, Dockside Sailing Press, Newport Beach, CA, 2013
		5. *Insert Local/National Regulations and Guidelines*

## Additional Reading

* + 1. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>
		2. CEN Workshop Agreement 15793:2011, Laboratory biorisk management, ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793\_September2011.pdf

## CEN Workshop Agreement 16393:2012, Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008, ftp://ftp.cen.eu/CEN/Sectors/List/ICT/Workshops/CWA%2016393.pdf

## CDC, WHO, and Clinical and Laboratory Standards Institute, “Purchasing and Inventory,” Laboratory Quality Management System Training Toolkit, <http://www.who.int/ihr/training/laboratory_quality/purchasing/en/index.html>

## Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf>

## WHO, Laboratory Quality Management System Handbook, 2011, <http://www.who.int/ihr/publications/lqms_en.pdf>

## WHO Laboratory Biosafety Manual, 3rd Edition, <http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/>

## WHO Biorisk Management: Laboratory Biosecurity Guidance, September 2006, <http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf>

# ATTACHMENTS

A. Maintenance Strategies (This section is an excerpt from Salerno and Gaudioso, 2015)

* 1. Maintenance Categories (This section is an excerpt from Salerno and Gaudioso, 2015)
	2. Template Documents

### Inventory Log

### Master Maintenance Log

### Individual Maintenance Log

### Maintenance Schedule

### Maintenance Request Form

### Verification of completed decontamination and safe status form

### Maintenance Completion Form

### Item Supply Request Form

### Sticker for maintenance completion and next maintenance due

### Sticker for calibration completion and next calibration due

### Sticker for “Out of order, cannot be used”

### Sticker for “at present not used, not in calibration scheme, must be calibrated before taken into use”

* 1. Example Supplier Equipment Information
1. Revised from CEN Workshop Agreement 15793:2011, Laboratory biorisk management [↑](#footnote-ref-1)