MANAGEMENT OF CHANGE

AIGA 010/19

Revision of AIGA 010/04

Asia Industrial Gases Association

N0 2 Venture Drive, #22-28 Vision Exchange, Singapore 608526
Tel: +65 67055642 Fax: +65 68633379
Internet: http://www.asiaiga.org

MANAGEMENT OF CHANGE

Acknowledgement

This document is adopted from the European Industrial Gases Association document IGC Doc 51 'Management of Change'. Acknowledgement and thanks are hereby given to EIGA for permission granted for the use of their document.

ASIA INDUSTRIAL GASES ASSOCIATION
No-2 Venture Drive, #22-28 Vision Exchange, Singapore 608526
Tel: +65 67055642 Fax: +65 68633379
Internet: http://www.asiaiga.org

Table of Contents

Amendments to 010/04

Section	Change
All	Editorial revision to include references and latest AIGA style.
3.1	Publications terminology added.
All	Extensive rewrite

1 Introduction

Management of Change (MOC) process forms an important element of a Process Safety Management System (see Element 12 in AIGA 099, *Process Safety Management Framework – Guidance Document*: [1][1]) as well as other management systems. The introduction of any change to a process, process equipment, or component and associated premises, if not appropriately managed, can significantly increase the levels of personal, environmental, security, reliability and process safety risk or impact product quality.

Management shall ensure that risks arising from any form of change are systematically identified, assessed and managed.

2 Scope and purpose

2.1 Purpose

This publication provides guidance on how to establish a MOC process and describes the relevant roles in this process.

2.2 Scope

Formal MOC processes cover changes of plant equipment or components, process, inventory or substances or any associated premises in a given unit, which can impact any safety and health conditions, environmental protection, security, reliability or product quality.

Changes subject to a MOC process should be detailed in a company procedure. Examples of changes subject to MOC processes are:

- Change or addition of equipment, pipelines or control systems;
- Revision or new process parameter, procedure or internal standard;
- Installation or modification of new software;
- Construction of a new building inside a production area, or moving equipment close to occupied buildings;
- Introduction of a new substance.

Examples of changes not subject to MOC processes are:

- Replacement in kind;
- Operating changes within defined safe operating limits.

Processes covered by this document include, but are not limited to:

- ASU production facilities;
- Hydrogen and carbon monoxide (HYCO) production facilities including electrolysis facilities;
- Acetylene production facilities;
- Nitrous oxide production facilities;
- Carbon dioxide production facilities;

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section

- Cylinder and container filling facilities;
- Speciality gas production, package filling and storage facilities;
- Research and Development facilities;
- Distribution depots;
- Pipelines;
- Transportation;
- Customer installations owned or operated by the gas company;
- Temporary supply systems;
- Cylinder testing facilities.

Note: Organisational change is not covered by this publication. EIGA publication Safety Info HF 10 *Organisation - Managing Organisational Change* [2] provides appropriate guidance.

3 Definitions

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

3.1 Publications terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May and need not

Indicate that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

Change is a modification to equipment, processes, procedures, design documents, operating documents, components, inventory or substances or any associated premises in a given unit etc. that is outside previously established specifications or operating limits.

Replacement in kind is a replacement of equipment, processes, procedures, components, inventory or substances etc. that meets the original design specifications and so does not change the hazards in kind or degree.

4 Roles and responsibilities

The following gives guidance on typical roles associated to the MOC process. Some of these roles can be combined to be performed by one person, provided at least two competent persons are involved in the MOC process. Any person who could be involved in a change shall be trained to understand what constitutes a change and how a change shall be addressed and managed.

4.1 Initiator (Applicant)

The initiator can be any person who wishes or needs to put forward a proposal for the modification of a process. The initiator could be someone associated with the work area, such as an operator or instrumentation engineer, or they could be someone in a central operating or engineering role. The initiator of a change shall describe the reason for the change and provide sufficient information to adequately describe the change to a person not familiar with that particular situation. This can be done in an electronic format. It is best practice that the initiator also describes the plan for implementation of the change.

4.2 Owner

The owner has ultimate accountability for the process or system where the change is being proposed and for the implementation of the change. The owner has the responsibility and experience to evaluate the need of a change and decide on its technical and practical merit. They also define the required assessments to obtain technical approval. Their further responsibility is to decide on the readiness for implementation. In the final step of the MOC process the owner signs off the closure of the change.

For many changes the owner's role may be taken by the plant or facility manager.

4.3 Change manager

The change manager's role is to ensure and to verify that all items identified during the assessment process are in place and complete. These items may include a risk assessment, technical details of the change and supporting documents such as piping and instrumentation diagrams (P&IDs) and other drawings.

It should be ensured correct risk analysis has been used and the results are valid. In some cases, this can involve the application of a check list. The assessment of change includes an analysis of the impact on safety, health, environment, reliability, security and quality and also identifies the applicable standards, local mandatory regulations, codes and laws.

The role of the change manager and the role of the owner can be combined in one.

4.4 Technical approver(s)

Depending on the complexity of the change, a technical review of the change is conducted by one or more technical approvers in their area of competence. This (these) role(s) can be located onsite or within a central function.

When the product involved is under regulatory control, additional specialists may be required to support the other technical approvers.

5 MOC Process steps

The principle for management and control of plant and equipment modification is divided into eight steps.

All of these steps are generally applicable and can be used for all kinds of changes.

5.1 Initiation

The Initiator provides an idea on the change. They describe the reason for the change and its scope and attach supporting documents and may include an implementation plan. The application form for the change is submitted to the owner.

5.2 Appraisal

The owner ensures that the change is evaluated on technical, operational, safety, security, environmental, quality, regulatory and economical aspects. Depending on the complexity and level of risk identified, the owner will determine the level of technical review and risk assessment. The owner will then decide if the project needs a nominated change manager.

In some applications, the change can have an impact on aspects of regulatory or customer authorisations, for example, in medical gases or electronic gases applications. In these cases, additional requirements can apply and the relevant competent person responsible for maintaining the authorisations needs to be aware of any impact on the certification.

5.3 Approval

The owner together with the change manager provides all change documentation to the technical approver(s). The technical approver(s) approves or rejects, with reasons, the change.

5.4 Implementation

After approval has been obtained, the change can be implemented under precondition that necessary resources have been made available.

During the implementation phase, a modification of the original scope may be necessary or be requested. The owner is responsible to ensure the impact of this modification is reviewed and approved again before implementation.

Most changes will require plant documentation to be updated. In some cases, this can cover a number of documents. A selection of important documents that can be impacted is given in 5.7.

5.5 Verification

The implemented change shall be verified to ensure that it is in accordance with the requirements and objectives of the change. This may include an operational readiness and a Pre-Start-up-Safety-Review (PSSR). See Process Safety Management System Element 13 - Operational readiness and process start-up [1].

It shall be verified that all actions required before start-up are closed.

In cases where the change strongly influences a process, the application of a test period can be useful to ensure the process runs in steady conditions. In this period operational performance needs to be monitored more carefully.

5.6 Training and awareness

Ensure that affected employees and contractors are made aware of the impact of the change and, if required, that training is provided prior to the restart of the changed process or closure of the MOC process.

5.7 Documentation

All documents concerning the change should be filed at the unit where the change is being carried out or in a central electronic system accessible for all relevant personnel.

Typical documentation to be updated includes, but is not limited to:

- Plant documentation such as operating procedures, control logic documentation, alarm and trip schedules, drawings and manuals, pressure test certificates, cleanliness certificates, training records, maintenance procedures;
- Regulatory documentation and product specifications.

Typical new documentation to be finalised for the change includes:

- Purpose for the change;
- Records of any reviews and assessments done for the change;
- Records of the change approval which summarise the change including the completion date;
- Possibly an electronic or paper based register of all changes conducted at the site (see basic example in Appendix 4).

5.8 Closure of MOC process

All changes successfully implemented shall be closed. Prior to closure of the MOC process, a review of all important elements of the change should be carried out. This should include all open actions from the Pre-Start-up Safety Review process, document updates, risk assessments and training of personnel.

The closure is normally carried out by the owner.

6 Temporary changes

Temporary changes are sometimes required because of unforeseen process deviations or equipment malfunction. They have a limited validity and at the end of the period the process or equipment shall revert to the original state or a permanent change shall be implemented. Temporary changes follow the same procedure as permanent changes.

It is good practice that companies define the maximum duration of a temporary change in their procedures.

Temporary changes should be registered with all other changes of the site, but attention shall be given to not exceed the validity date of this change.

7 Emergency changes

An emergency change may be initiated on a true emergency basis if a temporary or permanent change cannot be implemented. The following situations may justify an emergency change:

- To correct a deficiency that would cause a hazardous condition that is an immediate threat to the safety and health of the site personnel or the public.

- To prevent an immediate environmental release.
- In case of jeopardy of not providing product to clients, owing to equipment failure or unforeseen design errors.

An emergency change may initially bypass the use of the written or electronic MOC process but still requires an assessment of the change.

At least two technically competent persons including one designated by senior line management shall review and verbally approve the change. The responsible person for the plant or facility or his nominated deputy should be involved in the decision. All impacted employees shall be notified.

It is good practice that essential elements of the change and approval are documented in some way. This could be done for example by email, text message or recorded conversation and also by an entry in the shift book. Once the change is in place, it shall be validated as soon as possible.

An example MOC application form is represented in Appendix 2 and the complete MOC Process is shown in the Flowchart in Appendix 3.

8 Checklist

Appendix 1 shows an example of a Management of Change Risk Assessment and Control Checklist that may be used in the initial and appraisal stages to ensure that all safety aspects or potential impacts are considered and no omissions have been made. The list is not exhaustive and may be adapted to company experience.

9 References

Unless otherwise specified, the latest edition shall apply.

[1] AIGA 099, *Process Safety Management Framework – Guidance Document*. www.asiaiga.org

[2] EIGA Safety Info HF 10 *Organisation - Managing Organisational Change.* www.eiga.eu

Appendix 1 - Management of Change Risk Assessment and Control Checklist

MOC No.	**Description of change:**
Date:	**Location of change:**
Name of Initiator:	**Signature of Initiator**

1. Space and Location Evaluation		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Ground stability suitable for the new equipment		
Location exposed to flooding (drainage not sufficient)		
The process interacts with neighbouring activities		
The process may expose the third party to the risks		
Location exposed to heavy objects falling down risk		
Location benefits the natural and/or artificial lighting		
"Ex" atmosphere present or potentially generating		
Confined space or non-ventilated zone		
Utilities available (energy, cooling water, air, sewerage)		
Access for vehicles, FLT, mobile cranes, supply		
Working at height and/or falling hazard		
Space for operation and maintenance		
Access to the instrumentation and control equipment		
Possibility to install ladders, mobile platforms, guard rails		
Exit doors/ways not blocked by new equipment /piping		
Two exit ways assured (if necessary)		
Natural air ventilation available		
2. Process Design, Safety and Reliability Assessment		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
2.1. Purchasing		
Purchased material - fit for intended purpose		
Materials are compatible with fluids/environment		
Material specifications available		
Pre-purchase analysis for critical items done		
Cleaning requirements for purchased items		
Wall thickness and/or MAWP[2] requirement fulfilled		
Materials suitable for high/low temperature		
Does equipment comply with applicable codes? • Pressure vessels • Noise and emissions (water, air, soil) • Electrical		
2.2. Parameter control and Safety Critical Device		
The change affects (exceeds) MAWP of the process		
Additional safety (relief) valve necessary		
Thermal relief valve on cryogenic pipe between isolation points		
Thermal relief device on liquefied gas piping/system		
Over pressure protection of the vacuum systems		
Under pressure protection system if necessary		
Fluids through relief devices vented to a safe area		

[2] MAWP – Maximum Allowable Working Pressure

Temperature control necessary		
Alarms necessary for high/low process conditions		
Protection against low temperature embrittlement		
Flow control and protection systems		
Safety interlock systems installed		
Safety Instrumented Systems identified and installed		
2.3. Electrical equipment		
Electrical system conforms to regulations		
Electrical motors, panels and wiring conform standards		
Electrical back up system provided if necessary		
Overload protection for the main electrical equipment		
Emergency shut-off switch provided if necessary		
Necessary remote start/stop switches		
2.4. Software		
Control loop change necessity		
Additional software module, influence on process		
Removal of software module, necessity and effects		
Temporary removal of an existing loop		
New control loop, influence on the process		
Assessment of changes on critical trips and interlocks		
Software change validation		
2.5. Technology/Operation		
Backup systems provided if necessary		
Manual isolation valve provided and accessible		
Response time for automatic isolation valve sufficient		
Fail safe isolation requirements met		
Fluid composition change during process • Can generate "ex" zone • Can generate oxidising environment • Can generate toxic/ asphyxiating atmosphere		
Purging/venting line directed to a safe area		
Equipment lock-out capability • Electrical • Mechanical • Fluids (shutoff valves)		
Equipment and pipes marked, labelled and colour coded		
3. Workplace Safety Assessment		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Mechanical and machinery guarding		
Guard rails, bumper posts and barriers		
Safeguard personnel from hot/low temperature		
Noise reduction / insulation		
Oxygen flash protective shields		
Electrical grounding of electrical equipment		
Electrical isolation performance considered		
High voltage equipment adequately isolated		
Electric equipment protected against collision		
Release of flammable, toxic, asphyxiating, oxidising gas		
Forced ventilation at work place necessary		
TLV/LEL[3] values identified and considered (e.g. CO_2, C_2H_2)		
Air monitoring required at work place (e.g. O_2, CO_2)		

[3] TLV/LEL – Threshold Limit Value / Lower Explosion Limit

Safety shower / eyewash necessary		
Safety signalization in place : • Warning signs (“ex”, flammable substance) • Mandatory signs (wearing PPE) • Restriction signs (access, smoking)		
Labelling (piping, valves, storage, equipment, chemicals)		
Tripping hazards (piping, conduits, valves, floor openings)		
Walkways free of obstacles		
Sharp edges and protruding obstacles secured		
Clearance of overhead obstacles (pipes, valves, boxes)		
Valve handle direction away from exposed persons		
Personal Protective Equipment (PPE) suitable/reviewed		
Special PPE needed: • Self-contained respirators • Flame resistant clothing • Chemical protecting garments		
Portable gas analysers		
Lifting equipment registered and authorised		
Lifting equipment operators authorised and trained (FLT)		
4. Fire Control and Emergency Procedures		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Additional safeguards for new sources of fire		
Update the fire permit/authorisation		
Update the “ex” zone for new flammable gas sources		
Review the smoking policy (new area, signs)		
Emergency fire procedure change (signage, lightning)		
Revision of fire alarm and annunciator system.		
Fire extinguisher number or/and type changed		
Fire hydrants number or/and location changed		
Fire hose length and position vs. the new equipment		
New fire detectors necessary (number, type, locations)		
New flammable gas sensors necessary		
New sprinkler system, hydrants and drainage necessary		
New extinguishing agent necessary		
Spread of fire by floor/wall openings		
Access for fire trucks		
5. Environmental Aspects		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Noise exceed the acceptable value at the boundary		
Air affected by emissions; update the legal permit		
Area atmospheric monitoring necessary		
Contamination of local sewer by water discharge		
Contamination of soil and groundwater		
Process generates (dangerous) waste. Permit update		
Waste disposal procedure and route disposal in place		
Chemical reaction in a common drain (e.g. carbide)		
New substance under specific environmental regulation • REACH (registration, information, reporting)		

• F-gas, VOC[4]'s		
Safety Data Sheets available for new substances		
New substance used affect Seveso site inventory		
Effluents, emissions or waste treatment necessary		
6. Change Accomplishment		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Change approved by the Technical Approvers		
Change allowed by the manufacturer /possible without losing warrantee		
Change documentation available		
Contractors selected vs. competence and liability criteria		
Contractors have qualified and certified welders		
QRA[5] available for change accomplishment		
Contractors assign a local coordinator/supervisor		
Contractor training on specific hazards: • Confined space, asphyxiating, oxidising, "ex"; • Gas pressure, fire, walkways, PPE • Emergency procedures • Housekeeping rules etc.		
Work permit necessary for change accomplishment		
Welding/brazing procedure available		
Written agreement signed with contractors		
Cleaning for oxygen service if appropriate		
Purging of undesired particles		
Non oxidising environment for welding (inertisation)		
Pressure/ tightness tests performed if appropriate		
Certification by appropriate bodies		
Welding certificates and radiographic inspection records		
Adequate safety level performance for Safety Instrumented Systems installed		
Reception performed by an authorised person		
7. Operational Readiness and Implementation		
Note: If in doubt or uncertain - consult with Technical Specialists as appropriate.	**Y/N/NA**	Comments / Date
Installation checked, tested and prepared for start up		
Updated working/operating procedures available		
Key operating personnel trained on: • Start-up/shut down procedure • Normal operating, parameter control • Emergency procedure		
Indirect involved personnel informed and/or aware of change and of start-up		
Workplace risk assessment/ JSA[6] available or performed		
Updates of the technical documentation • Construction drawings • P&I diagrams • Instrumentation/electric diagrams etc.		
Necessary spare parts identified and available		

[4] VOC – Volatile Organic Compound
[5] QRA – Quantitative Risk Assessment
[6] JSA – Job Safety Analysis

Change performance requirements identified		
Impact on quality product to the customer		
Impact on GMP for medical products		
Change needs to be communicated or approved to/by an authority (e.g. medicinal agencies, Seveso, environmental)		

Appendix 2 – Example of a Management of Change Application Form

MOC No:		**Date:**	**Site/Location:**
Plant/Process/Section:		**Initiator (Applicant) Name:**	
Description of Proposed Change:			
Objective(s) of Proposed Change:			
Category of change: Planned / Temporary / Emergency		**Who will conduct the work?** Site / Department / Contractor	
Estimated Start Date:		**Estimated Completion Date:**	

Section 1: Assessment Record and Local Application Signatures

	Y/N/ NA	Comments	Person Responsible Action Completed by/Date
Risk Assessment & Hazard Checklist considered?			
Do Documents require updating / creating? • HAZOP / Risk Assessments • P&IDs • Standards and Work Instructions • Electrical Details / Wiring Diagrams • Instrument Details / List / Loop Diagrams • Control Documents / Software • Equipment design records • Spare Parts Inventory Records • Any other documents, e.g. site plan, fire protection drawings / records etc.			
Are Equipment / Material Specifications / Part Numbers fully defined?			
Are Work and Execution Plans / Method Statements written?			
Are Inspection / Test Procedures written?			
Is there any Regulatory / Legal impact?			

Signed: **Date:**		**Change Manager** **Recommending this MOC application**
Signed: **Date:**		**Owner of this MOC application**

Section 2: MOC Review and Approval Record

MOC No:	**MOC APPLICATIONS SENT FOR COMMENT / APPROVAL** (Sections below to be completed by Change Manager)

Required Approval / Technical Specialist Review (Name and Title)	**Signature / Date**

MOC Status / Actions Required: (Tick where relevant)

Approval Without Conditions/Restrictions ☐	Approved with Conditions/Restrictions (see below) ☐	Rejected ☐

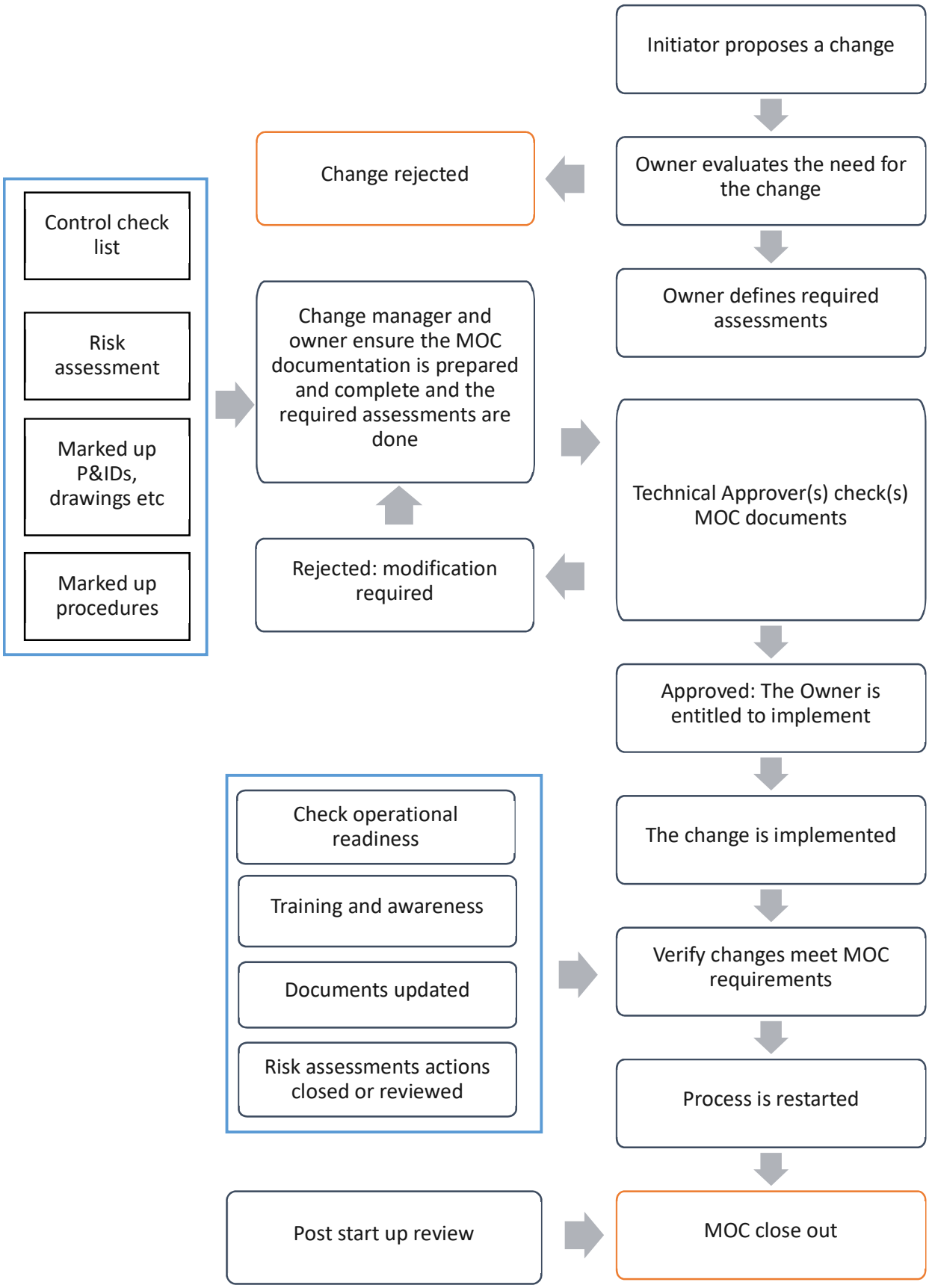
Conditions/Restrictions	Initiator / Applicant to confirm Resolution of conditions	
	Signature	Date

Owner / Change Manager Approval Ready for Implementation

Signed: Date:

Signed: **Date:**		**Owner Sign-off for MOC Completion** (when Change Manager notifies that all actions are complete)

Appendix 3 – Management of Change Process Flowchart



Appendix 4 - Example of Management of Change (MOC) Register

Date Received	Register Sequential Number	MOC No#	Description of Proposed Change (Summary)	Location / Region	Plant / Plant Type	Medical Yes/No	Forwarded for Review: Name(s)	Comments / Conditions / Restrictions	Approved?