MANAGEMENT OF CHANGE;
EXPLOSION RISK MANAGEMENT
Prepared for nabim

BY

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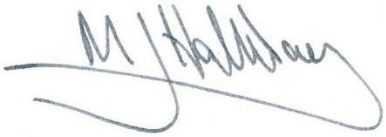

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EXECUTIVE SUMMARY.

HSD Safety Ltd. (HSD) has prepared guidance relating to the management of change in relation to explosion risk management. The purpose of this guidance is to assist nabim members in development of appropriate management strategies and management standards to suit their individual business organisational structures. The guidance attempts to cover how changes, ranging from small simple changes or modifications up to major projects, can be effectively managed.

The structure and layout of this report is explained below;

- Section 1 outlines the concepts used for management of change, including project management. The purpose of this section is to enable “non-specialists” involved in management of flour mills to understand the overall requirements.
- Section 2 explains the lifecycle management approach for managing change throughout the life of a process, or process plant, from initial feasibility through design, installation to operation and explains the links to management of change.
- Section 3 concentrates on management of change to an operational facility, including management of plant / equipment modification, process change, organisational change and decommissioning or disposal.
- Section 4 discusses example management strategies or approaches for a range of illustrative scenarios

Further guidance is provided in the following Appendices

- Appendix A; Example; Preliminary Hazard Assessment
- Appendix B: Equipment Selection / Specification
- Appendix C: Equipment Supply; Key Documentation
- Appendix D; Illustration of different categories of change
- Appendices E – G; Example management of change control forms / checklists
- Appendix H. Illustrative Forms for Section 4.5 Example Changes

To assist with understanding the terminology used in this document or terminology used in published standards and guidance, including terminology that may be used by regulators or other 3rd parties; a detailed glossary of terms is also provided in Section 1.3.

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APPENDICES

1.0 BACKGROUND

Most workplace health and safety legislation contain requirements to carry out appropriate risk assessments;

- Before a new work activity is started
- If it is suspected that the risk assessment is no longer valid
- There has been a significant change

The principles of Management of Change apply across all aspects of a business; this report uses the more familiar context of explosion hazards to convey the ideas. For example, in the UK, the Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) contains a requirement to carry out risk assessment, which should be carried out

- Before any new work activity involving dangerous substances is started up
- If there is a reason to suspect that the risk assessment is no longer valid
- There has been a significant change, including changes to
    - The workplace e.g. plant, equipment, building
    - The work processes
    - Organisation of the work

Similarly, in Ireland, Part 8 of the 2007 Safety Health & Welfare at Work (General Application) Regulations, which relates to explosive atmospheres, contains the following requirements;

- Prepare an explosion protection document, as soon as practicable and before the commencement of work
- Revise the explosion risk assessment a significant change, extensions or conversions takes place to
    - The workplace e.g. plant, equipment, building
    - The work processes
    - Organisation of the work

Explosion hazards are a type of major accident hazard where a single event, e.g. an explosion can have major impact such as life changing injuries or fatality, major environmental impact or which can cause major asset loss or business impact. In order to effectively manage major accident hazards, it is important to understand the differences between Occupational Health and Safety Management and Process Safety Management;

- Occupational Health and Safety Management is focussed on protecting the safety, health and welfare of people and the concept is normally extended to focus on protection of the environment

- Process Safety Management, has the same goal but is focussed on major accident hazards e.g. rare single events with major or catastrophic consequences.

Occupational health and safety incidents occur more frequently than process safety incidents but tend to be much less severe. Many organisations focus a lot of effort on occupational health and safety metric such as injury rates and lost time accident rates and utilise reactive management process such as reporting and investigation.

Due to the potentially greater severity of consequences from fire and explosion events a different set of techniques are used to help view, identify and manage subtle root causes.

For effective process safety management, it is important to recognise the difference between active and latent failures which can lead to incidents

- Active failures are unsafe acts committed by individuals e.g. failure to carry out a task correctly, and the effects are normally felt almost immediately
- Latent failures are embedded in an organisation e.g. poor standards or poor oversight, and lie dormant and hidden waiting for an active failure.

Latent failures can be present for many tens of years, waiting to line up with one or two active failures resulting in a major accident hazard. Due to the rare nature of major accident hazards, many years of “safe operation” can lead to complacency within an organisation or within an entire industry sector. Complacency typically leads to failure to keep focus on the proactive measures needed to ensure latent failures are not present or failure to ensure that they do not creep into an organisation over time. An example could be the removal of an alignment sensor on a tall bucket elevator because it has become obsolete and has never alarmed.

Change, including creeping change (the impact of numerous small changes over time), can lead to the introduction of latent failures within a plant, process, organisation or within an industry sector.

It is therefore vital to ensure that effective management of change systems are followed, and it is beneficial to share knowledge, learnings and good practice between industry sectors. A Management of Change system is not designed to obstruct innovation, improvement or modernisation but to refresh the understanding of why a system was designed and implemented a particular way and test if the proposed changes poses any threats to the established safe design.

The guidance in this document attempts to share knowledge, learnings and good practice on management of change from other industry sectors with major accident

hazards, but in a context, which is appropriate to the limited range of major accident hazards, e.g. dust explosion hazards, that exist in flour milling. The aim is to allow nabim members to review their own management systems and develop appropriate management strategies to suit their individual business organisational structures.

1.1 Assumptions

The following assumptions have been made in this report;

	Assumption	Justification for assumption
1.1.1	The roles and responsibilities defined in this document are generic roles and responsibilities rather than actual job titles or job descriptions	Job titles and job descriptions vary between organisations and sites and it would be impracticable for HSD to consider all the variants that exist between nabim members and sites
1.1.2	It is assumed that sites have appropriate formal documentation that defines the current design limitations and the importance of risk control systems for the equipment and process that are operated.	This is a basic assumption that needs to be in place. It is not possible to effectively manage changes to plant, equipment or process without knowing the current design limitations or the importance of risk control systems
1.1.3	It is assumed that sites have appropriate formally documented explosion risk assessments and hazardous area classifications in place for their current operations	This is a basic assumption that needs to be in place. It is not possible to effectively assess the impact of a change without current explosion risk assessments and hazardous area classifications
1.1.4	It is assumed that managers and engineers involved in managing change keep their competence current, follow appropriate standards and do not carry out work that is outside the bounds of their current competence.	Ensuring the competence of people with key roles or key responsibilities is a requirement of many pieces of health and safety legislation e.g. Provision and Use of Work Equipment Regulations (PUWER). nabim also promotes good practice with regard to health and safety and places focus on enhancing the skills bases within the industry.
1.1.5	It is assumed that organisations and sites have appropriate safety, health and environmental management systems and arrangements in place that cover all aspects and impacts of their operations	Management of change systems are not standalone and need to form part of an overall safety, health and environmental management system

1.2 Limitations

The report and assessments have limitations as follows

Limitation

1.2.1 The standard of safety, health and environmental management systems can vary significantly between organisations and sites. The overall effectiveness of a safety, health and environmental management system, including review and auditing of compliance with essential requirements, has a significant impact on the effectiveness of management of change. Assumptions have been made as described above

1.2.2 The standard of documentation and records that define the current design limitations of equipment and process can vary significantly between organisations and sites. In some cases, there can be over-reliance on the knowledge and experience of a limited number of key individuals, rather than on formally documented corporate knowledge which may have become "lost" in original project files. Assumptions have been made as described above.

1.2.3 The standard of documentation in explosion risk assessments, including the basis for hazardous area classification, can vary significantly between organisations and sites. In some cases, there is reliance on the knowledge and experience of the individuals involved in the original assessment, making it difficult for other people in the future to understand the basis behind decisions made in the assessments. Assumptions have been made as described above.

1.3 Glossary of Terms

The following glossary of terms are provided to assist the reader understand the terminology used in this document and / or used in published standards and guidance, including terminology that may be used by regulators or other 3rd parties;

Term	Definition / Meaning
Accountability e.g. Accountable Person	An Accountable Person is the individual who is ultimately answerable for an activity or decision. This includes "yes" / "no" authority and veto power. Only one Accountable Person should be assigned to an action. *See Responsibility*
As Low As Reasonably Practicable (ALARP)	The concept of "reasonably practicable" risk involves weighing a risk against the trouble, time and money needed to control it. It lies at the heart of the most national health and safety legislation. *See Good Practice*
Assets	Plant, machinery, property, buildings, vehicles and other items that have a distinct value to the organisation
Asset Integrity	The ability of the plant or facility to perform its required function efficiently whilst avoiding harm to people, equipment and the environment
Asset Integrity Management	The process of ensuring assets (equipment) are designed & installed to give the required level of integrity, are operated and maintained to retain the required level of integrity throughout their lifetime.
Asset Life Plan	An Asset Management Plan covering the entire lifecycle of an asset *See Asset Lifecycle, Process Safety Lifecycle and Asset Management Plan*
Asset Lifecycle	The time interval that commences with the identification of the need for an asset and terminates with the decommissioning of the asset or any associated liabilities *The principal stages of an asset's life cycle can include: create/acquire, utilise, maintain and renew/dispose*
Asset Management	Systematic and coordinated activities and practices through which an organisation optimally and sustainably manages its assets and asset systems, their associated performance, risks and expenditures over their life cycles for the purpose of achieving its organisational strategic plan
Asset Management Plan	A document specifying activities and resources, responsibilities and timescales for implementing the asset management strategy and delivering the asset management objectives

Term	Definition / Meaning
Competence	The ability to undertake responsibilities and perform activities to the standards expected. It is a combination of practical and thinking skills, experience and knowledge, plus personal behaviours and understanding e.g. the ability for every director, manager and worker to recognise the risks in operational activities and then apply the right measures to control and manage those risks.
Competence Management	The process of getting staff to be competent, followed by competence assessment and reassessment, and maintaining staff competence
Competency	A description of the knowledge or skills that a person requires to perform a task.
Competent Person	A person who has the competence required to carry out a particular task, activity or role. This term should be used carefully as it is often used in the context of a role defined in either • A specific legislative requirement (a legally defined role) • A specific non-legislative requirement (e.g. a role defined in a standard)
Criticality	A measure of the importance of an asset, item of equipment or risk control system. Criticality is risk based and typically based on the risks of failure or non-performance and is used to develop inspection, maintenance, monitoring and auditing regimes. *See Integrity*
Criticality Assessment	The assessment process used to determine the criticality of an asset, or type of asset.
Good Practice	Standards for controlling risk that Regulators have judged and recognised as satisfying the law, when applied to a particular relevant case, in an appropriate manner. The decision about what is Good Practice is made by consensus through a process of discussion with stakeholders, such as employers, trade associations, other Government departments, trade unions, health and safety professionals and suppliers. Compliance with Good Practice is used to demonstrate risk is ALARP.
Hazardous Area Classification	The classification of areas where potentially explosive atmospheres exist, into zones based on the likelihood and duration of occurrence and the nature of the explosive atmosphere
Inherent Safety	A concept normally used in the early design stages of an industrial process which focuses on the elimination or reduction of potential hazards instead of controlling them.
Inspection	The use of observation, measurement, testing and judgment to evaluate conformity. Inspection results are compared with specified requirements in order to establish whether conformity has been achieved.
Integrity (of an asset or system)	This is the inverse of Criticality and is used to define the Risk Reduction Factor required by a Risk Control System
Intelligent Customer	A term used in high hazard industries in relation to the use of 3rd parties, contractors and service providers; if safety critical work is being contracted out or out-sourced then the company should ensure that it remains an “intelligent customer” e.g. it should retain adequate technical competence to judge whether, and ensure that, work is done to the required quality and safety standards.
Major Accident	Any incident (particularly a major emission, fire or explosion) resulting from uncontrolled developments which could lead to serious danger to human health or the environment, immediate or delayed
Mitigation (Mitigate)	When used in relation to risk control; Mitigation measures are those which; • Control; reduce the severity of the occurring hazard, • Limit; limit consequences of the hazard by emergency planning / response
Nominated Engineer	An internally defined role used to allow for changes in organisational structure or job titles. A competent person, nominated by a Responsible Engineer, who is responsible for a specific technical aspect of asset integrity e.g.; • Site (or Plant) Nominated Process Engineer; responsible for process engineering on a designated site or plant • Site (or Plant) Nominated Electrical Engineer; responsible for electrical engineering on a designated site or plant • Site (or Plant) Nominated Mechanical Engineer; responsible for mechanical engineering on a designated site or plant
OEM Instruction Manual	Own Equipment Manufacturer’s instructions, for safe installation, operation and maintenance of equipment – provision of these by equipment suppliers is a legal requirement under European Machinery and Equipment Directives and the ATEX Equipment Directive.
Process Safety	Prevention of harm to people or the environment with a focus on Major Accident Hazards e.g. freedom from unacceptable risk caused by very rare but very serious incidents.

Term	Definition / Meaning
Process Safety Management	Systematic and coordinated activities and practices through which an organisation optimally and sustainably manages its manufacturing / industrial process, their associated performance, major accident risks and expenditures over their life cycles for the purpose of achieving its organisational strategic plan
Process Safety Lifecycle	Necessary activities involved in the implementation of a new manufacturing process. The lifecycle starts at the concept phase of a project and finishes when the manufacturing process has been halted or is no longer in operation and is fully decommissioned.
Responsible Engineer	An internally defined role used to allow for changes in organisational structure or job titles. The person responsible for maintaining the integrity of assets within a particular aspect of an organisation e.g. • Site Responsible Engineer; responsible for assets on a designated site • Plant Responsible Engineer; responsible for assets on a designated plant • Responsible Electrical Engineer; responsible for electrical safety
Responsibility e.g. Responsible Person	A Responsible Person is the individual(s) who complete a designated task. The Responsible Person is responsible for action/implementation. Responsibility can be shared. The degree of responsibility is determined by the individual with the "Accountability".
Risk Control	Measures, e.g. management processes / systems, equipment, devices or functional systems, that need to be in place to reduce risk
Risk Based Inspection / Maintenance	An inspection or maintenance scheme which is key risk control system based on the criticality of an asset / asset system or a type of asset and which reduces risk to an acceptable level. Typically used for developing inspection / maintenance schemes for Safety Critical Equipment or Systems. *See Criticality, Integrity & Safety Critical Equipment.*
Risk Reduction Factor	A term used in quantified and semi-quantified risk assessments to indicate the factor by which the frequency of an event has been reduced by or the magnitude of the impact of an event has been reduced by Risk Control(s). *See Integrity & Risk Control System*
Safety Critical Equipment / System	There are two main categories of safety critical equipment or systems. An item of equipment or system is safety critical if; • Its failure could cause or contribute substantially to a major accident or • Its purpose is to prevent, or limit the impact of, a major accident *See Major Accident*
Validation	A process which uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is achieved. It can be carried out under realistic use conditions or within a simulated use environment e.g. • Design & Development; validation uses objective evidence to confirm that products meet the requirements which define their intended use or application • Service Provision processes must be validated whenever their outputs cannot be measured, monitored, or verified until after the service has been delivered. In this case, validations use objective evidence to confirm that service provision processes are capable of producing planned results • Installation (e.g. of equipment / systems); validation uses objective evidence to confirm that equipment or systems meet the requirements which define their intended use or application It is often applied to safety critical equipment / assets / systems and is used to demonstrate that an installed design achieves all the safety requirements e.g. before plant, process or equipment is put into use.
Verification	A process which uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved e.g. • Design and development; verification uses objective evidence to confirm that design and development outputs meet specified input requirements. • Purchased Products; objective evidence must be used to verify or confirm that purchased products meet specified purchasing requirements. • Installation (e.g. of equipment / systems); verification uses objective evidence to confirm that equipment or systems have been installed to meet their specified design requirements. This can be done is many ways e.g. • Carry out inspections, tests or measure performance • Carry out alternative calculations • Compare a new design specification with a proven design specification

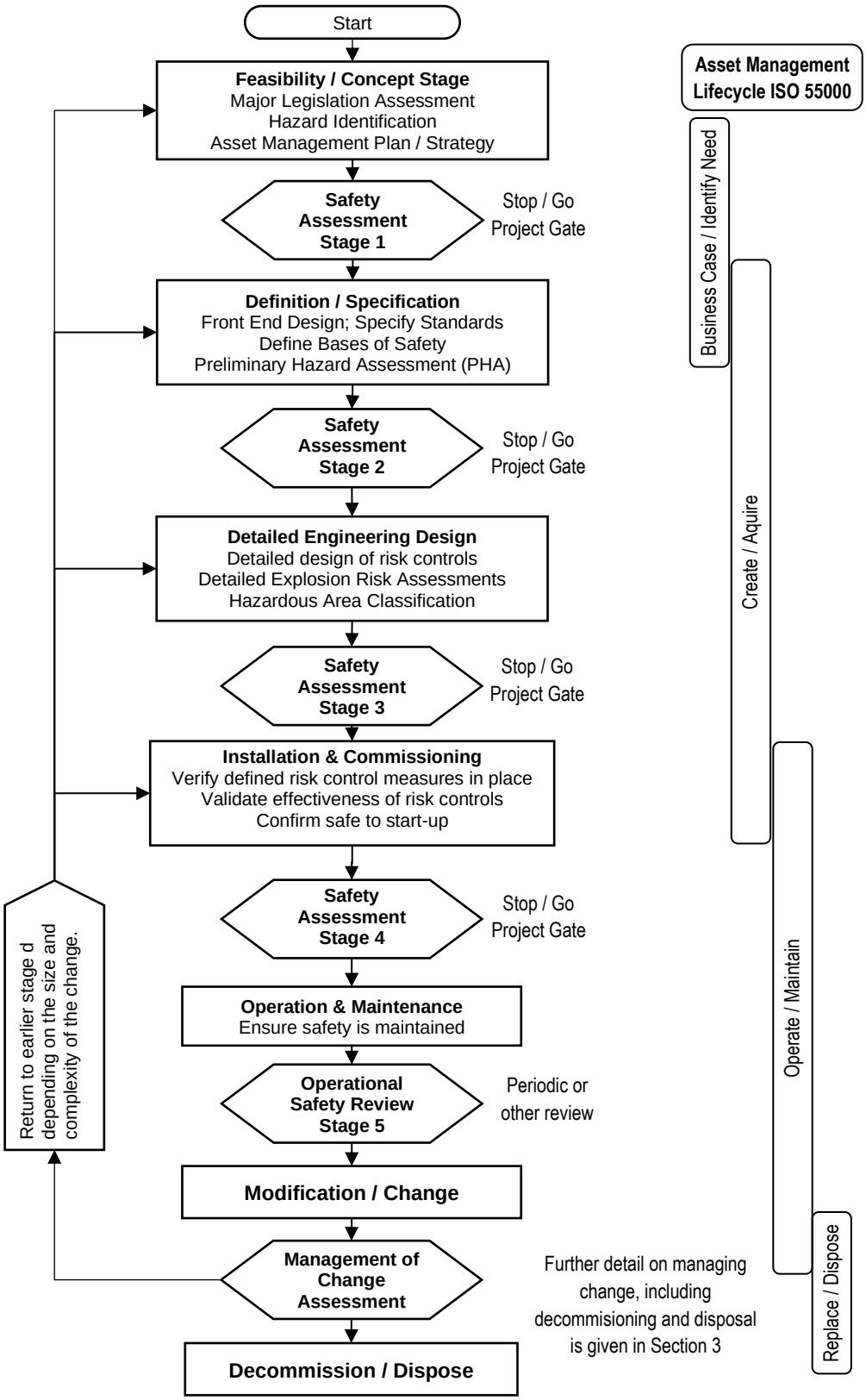
1.4 Workflow; Lifecycle project management

Explosion risk assessment for a new build or expansion project is a lifecycle process that should be carried out and documented at various stages of a project development, from initial concept through to operation and including changes to existing operations and equipment. The overall process is outlined below;

Typical Project	
Lifecycle Stage	**Explosion Risk Assessment**
Stage 1 (Feasibility)	Initial assessment which identifies the basic fire and explosion hazards of the materials involved, identifies the basic hazards of the unit operations, considers inherent safety and sustainability principles and identifies relevant legislative and other requirements. *Note; the basic fire and explosion hazards associated with flour milling are documented in relevant nabim guidance documents.*
Stage 2 (Definition)	Preliminary hazard assessment (PHA) which uses information from Stage 1, identifies the types of risk control measures required to prevent the identified significant hazards or mitigate their effects and identifies where more detailed process hazard assessment is required to define bases of safety. *Note; the types of risk control measures required for flour milling are documented in relevant nabim guidance documents, but risk-based options are available to suit each milling operation*
Stage 3 (Design)	Explosion risk assessment which; • Assesses the risk presented by the identified significant explosion hazards • Assesses the suitability of risk control measures, including hazardous area classification • Defines a basis of safety (basis of safe operation) against each of the identified significant explosion hazards
Stage 4 (Pre-start up)	Verification / validation - a final assessment which; • Verifies the defined risk control measures are in place. • Validates that the defined risk control measures are effective. • Verifies that any assumptions made in earlier stages are valid. • Confirms the defined bases of safety are valid and that risk is managed to the required level.
Stage 5 (Operational)	Final verification / validation – a final assessment which; • Verifies that organisational risk control measures are in place. • Validates that organisational control measures are effective • Verifies the validity of assumptions made during the design stages, which can only be verified once the mill has been commissioned and has been operating for several months

The stages are illustrated in the following workflow

Figure 1.1 — Workflow; Lifecycle project management



2.0 EXPLOSION RISK MANAGEMENT LIFECYCLE

Each of the lifecycle stages of the overall process illustrated in Section 1.4 are discussed below.

- Stage 1; Feasibility / Concept
- Stage 2; Definition / Preliminary Design
- Stage 3; Detailed Design and Installation
- Stage 4; Pre-start up - verification and validation
- Stage 5; Operational – final verification / validation and re-validation

For novel processes or operations there may be a need to carry out an earlier inherent safety and sustainability assessment e.g. Stage 0. However, this is not envisaged frequently and has not been discussed in detail. Management of change for operational facilities is discussed further in Section 3.0.

The requirements for the following process safety assessments should be considered for each project. For simple projects where the risk profile of a site is not significantly changed, several stages can be combined. For large or complex projects or projects which could significantly change the risk profile of an organisation or site all stages should be considered.

Safety Assessment	**Notes / Comments**
Stage 0	This very early stage considering inherent safety and sustainability is only envisaged if novel processes or technologies are being considered
Stage 1	Feasibility assessment for introduction, or major changes to traditional flour milling is likely to be simple as it is a well understood and established process and the basic fire and explosion hazards associated with flour milling are documented in relevant nabim guidance documents. More complex assessment will be required if a project changes the risk profile of an organisation or site e.g. by introducing new hazards.
Stage 2	Preliminary Hazard Assessment is typically required for new facilities or for major changes to existing facilities, primarily to ensure that new hazards are not being introduced and to ensure the bases of safety for the main explosion hazards and the required design standards are formally defined.
Stage 3	Fire and explosion risk assessments, including hazardous area classification is required for new facilities and review and revision is likely to be required for significant changes to existing facilities. The actual requirements should be specified on a project by project basis as part of the Stage 2 work.
Stage 4	Formal sign-off is typically required before start-up to demonstrate and document that all the key safety requirements relating to fire and explosion hazards are in place e.g. essential health and safety requirements are in place and explosion risks are as low as reasonably practicable. The sign-off requirements should be specified on a project by project basis as part of the Stage 3 work.
Stage 5	Formal sign-off is typically required after commissioning and an initial operating period to demonstrate and document that all the key safety requirements relating to fire and explosion hazards are effective. The timing and sign-off requirements should be specified on a project by project basis as part of the Stage 4 work. On-going periodic review is also required during the operational period to demonstrate and document that all the key safety requirements relating to fire and explosion hazards remain effective
Management of Change	Small simple projects can often be effectively managed by a site management of change system – see Section 3.0 for further details.
Decommissioning or Disposal	This is a form of major change – see Section 3.0 for further details.

2.1 Stage 1; Feasibility / Concept

This safety assessment stage is carried out very early in a project and the purpose of this stage is to ensure that the understanding of the project, the process and the materials involved is sufficient to enable safety, health and environmental impacts to be properly assessed.

If the project involves acquisition of an operational process plant the principles of due diligence should also be applied. Published guidance is freely available on this subject; OECD(2018), Guidance on Change of Ownership in Hazardous Facilities, Environment, Health and Safety, Environment Directorate, Organisation for Economic Cooperation and Development.

This safety assessment stage also contributes to key policy decisions (e.g. on siting, design basis) and ensures that contacts are established with the functional groups, site management and the authorities who may contribute to, or impose constraints upon, the development of the project. This stage enables the following;

- Identification of major legislation that could apply to a new or significantly modified facilities
- Identification of any significant changes to the risk profile of the organisation or the risk profile of a site or facility
- Identification of the requirements for further safety, health and environmental risk assessments or other studies
- Development of an Asset Management Plan / Strategy (e.g. ISO 55500)

Traditional flour milling is a well understood and established process and the basic fire and explosion hazards associated with flour milling are documented in relevant nabim guidance documents.

In relation to explosion hazards the following major legislation would generally apply to flour milling, primarily due to combustible dust explosion hazards, but potential explosion hazards from other dangerous substances should be identified at this stage;

- UK; Dangerous Substances and Explosive Atmospheres Regulations (DSEAR)
- Ireland; Part 8 of the 2007 Safety Health & Welfare at Work (General Application) Regulations

The applicability and requirements of design and construction legislation should also be considered as early as possible in a project to ensure that roles

and responsibilities are clearly defined and that risks are effectively managed from start to finish of the project.

- UK; Construction (Design and Management) Regulations (CDM)
- Ireland; Procurement, Design and Management Requirements of the Safety Health and Welfare at Work (Construction) Regulations

The need to apply relevant legal good practice and standards to the design should be considered for the following types of equipment and systems;

- Hazardous area classification and Ex equipment
- Explosion protection systems and devices
- Fire protection systems
- Electrical equipment
- Earthing and lightning protection systems
- Dust aspiration and local exhaust ventilation systems

Transport and siting impacts would typically be considered at this stage e.g.

- Bulk raw material, finished product and co-product movements
- Packaged raw material, finished product and co-product movements
- Internal movements of materials within a site

The impact of normally rare external events should also be considered, but due to the limited types of dangerous substances typically handled, the need for lightning protection risk assessment is expected to be the only consideration likely to be required in relation to dust explosion hazards. Other rare external events may be considered in relation to business risks e.g.

- Earthquake, subsidence or landslide
- Flooding, dam burst, storm surge, rising water courses, storm water run-off
- Storm and high winds
- Aircraft crash
- Breach of security

The availability of suitably qualified and experienced in-house staff for, or the use of 3rd parties, should be considered for each project step such as; front-end design, detailed design, construction / installation, commissioning, operation and maintenance.

When utilising the services of 3rd parties to carry out safety critical work; it is important that nabim members act as Intelligent Customers e.g. they should retain adequate technical competence to judge whether, and ensure that, work is done to the required quality and safety standards.

Due to the wide range of historic backgrounds, cultures and sizes of nabim members' businesses generalised titles for roles have been used in this report; we are certain individual businesses will identify the corresponding titles and individuals within their organisation. Typical roles that may need to be considered for inclusion in a project team at the design stages, depending on the size and complexity of a project, include;

- Project Manager
- Plant Operation
- Plant Maintenance
- Scientist / Technologist
- Process Engineer
- Mech. Engineer
- Elec. Engineer
- Control / Instrument Engineer
- Civil / Structural Engineer
- Process Safety
- Occ. Health & Safety
- Environmental

Typical roles that may need to be considered for inclusion in a project team at later stages e.g. construction / installation, commissioning and operation include;

- Commissioning Manager
- Plant Technicians
- Mech. Technicians
- Elec. Technicians
- Control / Instrument Techs.

At this initial stage a simple assessment can be carried out considering the following simple measures;

- Not applicable; the staff type, or role is not applicable
- Sufficient availability; sufficient in-house competent staff are available
- Limited availability; competent in-house staff are available, but their time availability may be limited, or staff are available, but they may not be fully competent (limited knowledge or experience)
- Not available; sufficient competent staff are NOT available

For example, in most cases, it is expected that civil / structural engineering support will not be available in-house and the need to identify suitably competent 3rd party resources should be highlighted at this early stage.

An illustrative list of the types of further assessments or studies that could be required depending on the size and complexity of a project is as follows;

Assessment Type	**Notes / Comments** Food Safety / HACCP requirements not included
Explosion risk assessment	This is expected for flour milling due to dust explosion hazards, but other explosion hazards may exist in ancillary areas
Hazardous area classification	This is expected for flour milling due to combustible dusts, but with good design and good housekeeping standards the extent of hazardous area zones in the workplace should be limited in extent
Reaction risk assessment	Not expected for most flour milling operations, but in the UK other reactive dangerous substances may fall under DSEAR and / or the potential for decomposition of materials may need to be considered for novel processes
Fire risk assessment	This is expected for flour milling, significant fire hazards should be identified at Stage 2
Pressure systems and pressure relief assessment	Likely to be required if pressure systems are present as part of a new facility. Significant pressure hazards should be identified at Stage 2
Substance health assessment	Significant hazards should be identified at Stage 2
Noise risk assessment	Significant hazards should be identified at Stage 2
First Aid Needs	A formal first aid needs assessment should be carried out for the installation / construction phase
Env. Impact Assessment	The requirements of the environmental protection legislation and the applicability and requirements of the environmental permitting legislation should be considered at Stage 2
Manual Handling / Ergonomics	Significant hazards should be identified at Stage 2 assessment
Construction / Demolition	The applicability and requirements of design and construction legislation should be identified at Stage 2 assessment
Machinery / Equipment Safety	Machinery and equipment standards should be specified at Stage 2 Risk assessments for the use of machinery and work equipment may be required before start-up
Lifting equipment	Lifting equipment should be identified as part of the machinery / equipment safety assessment

2.2 Stage 2; Definition / Preliminary Design

The purpose of this safety assessment stage is to identify significant hazards and ensure that there are suitable bases of safety and appropriate risk control measures in the preliminary design to eliminate the risk or reduce the risk from the significant hazards to tolerable levels.

Preliminary Hazard Assessment (PHA) should use a structured approach to identify consider and document the following types of hazardous events using prompts and guidewords;

- **External Fire;** fires outside equipment in the workplace, these can escalate to lead to explosions
- **Internal Fire**; fires inside equipment, these can escalate to lead to explosions
- **Internal Explosion**; explosions inside equipment
- **Confined Explosion**; explosions outside equipment, but confined by buildings structures etc., where pressure effects could occur.
- **Unconfined Explosion**; explosions outside equipment, in open, un-confined areas, where pressure effects will not occur.

- **Violent Release of Energy**; other forms of violent energy release that have similar hazards to explosions.

The approach should be used to;

- Formally identify significant explosion hazards associated with each main plant item or unit operation.
- Review the proposed the risk control measures defined to prevent or mitigate those explosion hazards.
- Define viable bases of safety to protect against each significant explosion hazards.
- Identify equipment or operations that require preliminary explosion risk assessment e.g. to consider risk levels associated with design options

An example PHA for a typical raw wheat intake is given in Appendix A and the bases of safety summarised below;

Equipment	Flammable Atmosphere	Ignition Source	Basis of Safety
Grain Intake Pit	Flammable dust cloud not expected in normal operation due to relatively low dust content of grain. In abnormal circumstances, a load may contain significant quantities of dust	Electrostatic; unearthed metal equipment items. Electrical equipment. Non-electrical equipment. External sources.	Explosion prevention by avoidance of flammable atmospheres and control of ignition sources. This is a viable option.
Conveyors	Flammable dust cloud very unlikely in en-masse conveyors. Dust can accumulate in bearings, dead zones, and on internal surfaces.	Electrostatic; unearthed metal equipment items. Electrical equipment. Non-electrical equipment. External sources. Transmission from upstream	Explosion prevention by avoidance of flammable atmospheres and control of ignition sources. This is a viable option
Bucket Elevators	Flammable dust cloud can occur due to foreseeable malfunction, which can be cause a co-incidental ignition source	Electrostatic; unearthed metal equipment items. Electrical equipment. Non-electrical equipment. External sources. Transmission from upstream	Explosion prevention is NOT a viable option on raw wheat. **Explosion protection by explosion relief or suppression is required**. Flameless explosion relief or suppression may be required depending on the location of the elevator. Explosion isolation may be required depending on upstream or downstream risks
Raw Wheat Silos	Flammable dust cloud not expected in normal operation due to low dust content of pre-cleaned grain and gravity filling. Dust can accumulate on silos walls above the normal fill level.	Electrostatic; unearthed metal equipment items. Electrical equipment. Non-electrical equipment. External sources. Transmission from upstream	Explosion prevention by avoidance of flammable atmospheres and control of ignition sources may be a viable option, depending on the type and location of the silos. **Preliminary Explosion Risk Assessment Required**

To assist in the detailed design stage, international, European or national standards and guidance that should be followed during the detailed design relating to explosion prevention and protection should be identified and defined at this Stage e.g.

Subject	Standards / Guidance
Explosion Relief	EN 14491:2012 Dust explosion venting protective systems EN 14460:2006 Explosion resistant equipment
Explosion Isolation	EN 15089:2009 Explosion isolation systems
Bucket Elevators	CEN/TR 16829:2016, Fire and explosion prevention and protection for bucket elevators
Fans	EN 14986:2017 Design of fans working in potentially explosive atmospheres

The concept for hazardous area classification should be defined at Stage 2 of the project, for flour milling this would typically involve specifying good controls to eliminate or minimise dust releases into the workplace such as dust tight seals / connections and good dust aspiration, which combined with good housekeeping standards will generally confine hazardous area zones to the internals of processing equipment and a limited number of localised hazardous area zones in the workplace.

Further detailed guidance is given in Appendix B relating to equipment selection / specification e.g. equipment for use in hazardous areas and explosion protection systems.

The Stage 2 PHA should be considered as a key controlled project document and be subject to review and revision if significant changes occur to the design. For ease of management as a project develops, the Stage 2 PHA can form the basis for, and an introductory section within Stage 3 explosion risk assessment documentation.

2.3 Stage 3; Detailed Design and Installation

The purpose of this safety assessment stage is to carry out a detailed review of a firm design in order to verify that all relevant hazards have been identified and assessed, that all relevant risk control measures have been included in the design and to demonstrate that the plant and process have been designed to reduce risk to as low as reasonably practicable (ALARP).

Explosion risk assessment, including hazardous area classification, should be carried out at the detailed design stage. A structured assessment approach should be used to identify the risk of an explosion occurring within each major plant item or process stage and to document the chosen "Basis of Safety" for

that item or stage. The proposed control measures through which the Basis of Safety is to be implemented are reviewed and an assessment made of the residual risk to people. Where the Basis of Safety cannot be demonstrated to be sufficiently robust and residual risks are intolerably high, additional control measures are recommended to secure the Basis of Safety. The assessment therefore needs to address the following questions:

- Can a flammable (explosive) atmosphere arise in normal or reasonably foreseeable abnormal operation and if so, how extensive is it likely to be and how likely is it to occur?
- Can ignition sources arise within the possible flammable atmosphere? How likely are they to arise in normal or reasonably foreseeable abnormal circumstances and are they likely to be sufficiently energetic to ignite the flammable atmosphere?
- What are the consequences in the event of ignition of the flammable atmosphere? In relation to health and safety legislation, the concern is for the safety of people and the nature and extent of the hazard, how many people may be in the affected area and how likely they are to be present should all be considered.
- What is the most appropriate Basis of Safety and are the proposed control measures sufficient to reduce risks to tolerable levels?
- If the proposed control measures are not considered sufficient then what additional controls are required to reduce further the residual risk?

HSD recommend use of a simple semi-quantitative risk ranking system as part of the above approach. This is intended to assist in the comparison of relative risks between different equipment items or process stages and to give an approximate indication of the tolerability of the risks in relation to broad risk category bands. It is also of assistance when determining overall priorities for implementing additional control measures.

Ratings are determined by assigning an individual rating for each of the following elements:

- Likelihood of a flammable atmosphere;
- Likelihood of credible ignition sources of sufficient energy becoming active and effective;
- The hazard nature and extent;
- The number of people in the affected area.

Each rating should take account of the effectiveness of the proposed control measures. The individual ratings should be combined to give an overall risk rating which can fall within three broad categories:

- **Broadly Acceptable** - risks are sufficiently low that no further controls need to be pursued.
- **Tolerable if shown to be as low as reasonably practicable** (TIFALARP) - further controls to reduce risk should be implemented unless they are shown to be grossly disproportionate (in terms of practicability and / or cost) to the resulting risk reduction. Demonstrating TIFALARP is outside the scope of work.
- **High Risk** - risks cannot be justified. Additional controls measures must be implemented to bring the risks down into the broadly acceptable region or as a minimum into the TIFALARP region.

It should be noted that once the Stage 3 (design stage) explosion risk assessment and hazardous area classification has been completed, it should be considered as a key controlled document and be subject to review and revision if significant changes occur to the design.

In many industrial process operations, risk falls into the TIFALARP (tolerable if as low as reasonably practicable) region and further controls to reduce risk should be implemented unless they are shown to be grossly disproportionate (in terms of practicability and / or cost) to the resulting risk reduction.

Unlike many other countries where working or designing to comply with “norms” is a common approach, the UK and Irish health and safety legal frameworks, are driven by the need for risk assessment and demonstration that risk has been reduced to as low as reasonably practicable (ALARP). The UK regulatory approach is explained below, the Irish regulatory approach is similar.

In the UK, there are two means of demonstrating risk is ALARP, the simplest is by demonstration with relevant legal “good practice” e.g. standards or codes of practice deemed by Regulators and relevant industry bodies or associations to reduce risk to as low as reasonably practicable. Where relevant “good practice” does not exist then additional risk assessment and cost benefit analysis are required to determine if gross disproportionality can be applied.

Good practice in flour milling is generally well understood within the industry but may not be formally documented in relation to explosion hazards. nabim may wish to consider formally documenting and discussing and agreeing good practices in key topic areas with regulators so that these can be better shared with nabim members. An industry led co-ordinated approach will minimise the

need for members to carry out detailed assessment and cost benefit analyses on projects in the future.

2.4 Stage 4; Pre-start up - verification and validation

This safety assessment stage is carried out before start-up of the process and on major projects is often carried out in two separate stages

- At the end of the construction stage, where hardware, e.g. plant and equipment, is checked to ensure that it has been build and installed as intended and the original design intent from Stage 3 has not been violated. It also confirms that all relevant actions from the Stage 3 safety assessment have been completed
- Before the introduction of dangerous substances, where the non-hardware aspects of the design are considered and covers aspects such as suitability of the commissioning plan, training, operating procedures and confirms systems related function testing e.g. of interlocks and similar safety systems have been carried out. It also confirms compliance with company and legislative standards.

The overall purpose is to ensure that the plant and process are safe for the introduction of, or generation of, dangerous substances. The assessment can be documented as a form of Pre-start-up Safety Review (PSSR) with key sections of a checklist form signed off by the relevant project team members.

In relation to explosion hazards the following prompts can be used to develop and appropriate PSSR checklist form, with appropriate signatories;

- Verify that all relevant actions from the Stage 3 Explosion Risk Assessment and Hazardous Area Classification been be implemented and closed out
- Verify that all relevant assumptions made in the Stage 3 Explosion Risk Assessment and Hazardous Area Classification remain valid.
- Verify that the impact of all changes made to the design after the initial Stage 3 Explosion Risk Assessment and Hazardous Area Classification have been suitably assessed and the Explosion Risk Assessment and / or Hazardous Area Classification have been revised accordingly
- Ensure that the Ex electrical equipment verification document as defined by EN 60079-14 has been completed, with all initial inspection records and relevant documentation required to demonstrate that all Ex electrical equipment complies with relevant requirements. See HSD Report Ref. 181157-B for further guidance relating to management of electrical equipment in hazardous (Ex zoned) areas.

- Ensure that there is suitable documentation relating to all Ex non-electrical (mechanical) equipment to ensure it meets the specified requirements and standards and to ensure that it has been installed and inspected / commissioned according to the Original Equipment Manufacturer (OEM) Manual for installation, operation and maintenance.
- Ensure that there is suitable documentation relating to all explosion protection systems and devices to ensure it meets the specified requirements and standards and to ensure that it has been installed and inspected / commissioned according to the Original Equipment Manufacturer (OEM) Manual for installation, operation and maintenance.
- Ensure there is suitable documentation relating to other key systems and equipment to ensure they meet the specified requirements and standards and to ensure they have been installed and inspected / commissioned according to the Original Equipment Manufacturer (OEM) Manual for installation, operation and maintenance. Examples include;
    - Dust aspiration / LEV systems
    - Earthing / bonding systems required for ignition protection
    - Non-Ex electrical equipment and primary earthing systems
    - Lightning protection systems
    - Fire alarm and detection systems
    - Sprinkler or fire suppression systems
- Ensure other risk controls are in place and suitable e.g.
    - Means of escape are suitable and provide clear egress
    - Fire alarm call points are suitable and have clear access
    - Fire extinguishers are in place and have clear access
    - Appropriate safety signs and labelling is in place
- Ensure that all key documentation has been extracted from project files and handed over to the relevant commissioning and / or operational role holders.
- Ensure that appropriate commissioning and training plans have been developed and have reached the appropriate stage required for introduction of dangerous substances.
- Ensure that suitable operating procedures are available for all stages of the process and / or operation of all equipment.
- Ensure that a suitably prioritised snagging list has been developed and has been handed over to the overall project Commissioning Manager.

2.5 Stage 5; Operational – final verification / validation and re-validation

This safety assessment stage is carried out after commissioning and an initial operational period. The actual time after start-up will vary depending on the size and complexity of the project but would typically occur between 3 to 6 months after start-up on a major project.

The overall purpose is to formally review operating experience against the design concept to ensure that the plant and process(es) have been safely commissioned and are operating safely and confirm that all assumptions made during earlier stages remain valid. The assessment can be documented as a form of final handover from the project / commissioning team to the operational functions, with key sections of a checklist form signed off by the relevant team members.

In relation to explosion hazards, the information is required for this stage includes

- Reports from previous safety assessment stages
- Explosion risk assessment and hazardous area classification report
- Commissioning report(s) and records
- List and details of any changes or modifications since start-up
- Details of accidents, incidents and near misses since start-up
- Results of any workplace monitoring, safety reviews and audits
- Reactive maintenance / equipment breakdown history
- Records of planned preventive maintenance and inspection
- Feedback from people who operate the process(es)
- Feedback from people who inspect and maintain the equipment.

In relation to explosion hazards the following prompts can be used to develop and appropriate final handover checklist form, with appropriate signatories;

- Verify that all relevant actions from the Stage 4 Explosion Risk Assessment and Hazardous Area Classification been be implemented and closed out
- Verify that all relevant assumptions made in the Stage 4 Explosion Risk Assessment and Hazardous Area Classification remain valid.
- Verify that the impact of all changes made to the design after the “as built” Stage 4 Explosion Risk Assessment and Hazardous Area Classification have been suitably assessed and the Explosion Risk Assessment and / or Hazardous Area Classification have been revised accordingly

- Verify that all equipment and explosion prevention and protection systems are operating as their design intent and within safe operating limits
- Verify that planned preventive maintenance and inspection regimes are in place for all equipment, particularly for Ex equipment and explosion prevention and protection systems
- Confirm that all key documentation and records have been extracted from project files and handed over to the relevant operational function(s) e.g.
    - Key design documentation and records such as equipment specifications, design standards and design limitations
    - Ex electrical equipment verification document, inspection records and other key documentation
    - Ex non-electrical (mechanical) equipment installation, commissioning / inspection records and OEM manuals
    - Explosion protection systems and devices installation, commissioning / inspection records and OEM manuals
- Confirm all accidents, incidents and near misses have been investigated and analysed appropriately and that relevant improvement actions have been implemented or have been included in the snagging work list (see below)
- Confirm all snagging list work has been completed or confirm that there is suitable resource available to complete snagging work according to an action plan that has been agreed with the operational function(s) or confirm and justify that remaining work on the snagging list relates to low risk areas and implementation is not reasonably practicable
- Confirm that all people involved in the management, operation and maintenance / inspection of the process(es) and equipment have received appropriate training and that appropriate on-going refresher training plans are in place
- Ensure that operating procedures are suitable for use at all stages of the process and / or for operation of all equipment.

On-going periodic review (re-validation) is also required during the operational period to demonstrate and document that all the key safety requirements relating to fire and explosion hazards remain effective.

3.0 MANAGEMENT OF CHANGE

Management of change forms an integral part of the overall lifecycle discussed in Section 2. Discussion in this section focusses on management of change during the Operational and Maintenance lifecycle phase of a process or plant; however, the same principles can be used to manage changes during the design, installation and commissioning phases of a project.

Each operational site or organisation should have formal systems to manage the following types of change;

- Plant and equipment modification
- Process changes
- Organisational changes.

A common question considered when managing change is “what is a change?” e.g. “do we need to follow a formal management of change system”. The simplest answer is “anything which isn’t like-for-like replacement is a change”. The problem with this response is that if it is not carefully considered when defining the scope of applicability of management of change systems; those systems can become swamped with minor simple changes which causes two significant problems;

- It stifles the ability to implement improvements
- It loses focus on the significant changes which require careful management.

The overall concept for effective management of change is that a change should be managed by the simplest management system that can effectively manage the change that is being considered. This concept is explained below and illustrated in the workflow in Appendix D with several examples discussed in Section 4.

- **Management Procedures**; many minor simple changes can be effectively managed by suitable procedures. However, these procedures require appropriate limitations to their scope and require prompts to ensure that a change does not introduce a significant change to risk. Examples of such procedures include
    - Raw material change / Introduction of new substances
    - Recipe change
    - Changes to control systems, including temporary defeats
- **Management of Change Systems;** these are formal management systems which are discussed in further detail below. These systems should be designed to manage most significant changes but have appropriate prompts to escalate major or complex changes to the appropriate stage of a process safety management system
- **Process Safety Management Systems;** these are formal lifecycle management systems as discussed in Section 2

In order to demonstrate changes are managed safely; systems and procedures should be in place to ensure that the following essential components are covered:

- Each change follows an appropriate system involving;
  - Definition of the scope of the change and justification for the change
  - Assessment of the potential impact(s) of the change
  - Approval of the change
  - Implementation and handover of the change
  - Closure and review of the change
- Suitable assessments are carried out to identify and manage potential adverse effects on;
  - The basis of safety of the plant or process
  - The environmental impact of the plant or process
  - The current design basis of the plant or process
  - Process and manufacturing operations
  - Service and utility operations
- Documentation is generated for all changes to demonstrate that;
  - The scope of the change is clearly defined
  - The justification for the change is clearly defined
  - Appropriate assessments have been carried out to assess the impact of the change
  - The correct approvals have been given for the change
  - Relevant actions have been completed before the change is implemented / handed over
  - A review of the effectiveness of the change is carried out
- Changes, and their impact, are communicated to all people affected by the change;
- Appropriate training is given to all people affected by the change;

3.1 Change Management Stages

For effective change management, a staged process should be followed and managed by an appropriate team of competent people. Each stage should be considered as an individual plan, do, check, act process. The stages should be carried out in their defined order ensuring that the check and act steps of each cycle are not skipped. The check and act steps are important as they verify that the stage has been carried out as intended.

Stage	Purpose
Definition & Justification	To define the scope and purpose of the change in sufficient detail to allow the impact of change to be assessed.

Stage	Purpose
Assessment	To carry out suitable and sufficient assessment(s) to identify potential adverse effects that the change may have and to manage them by identifying safety measures that are required before the change can be implemented
Approval	To provide the appropriate level(s) of approval for the change to be implemented and confirm the competence of the team of people involved in assessing and implementing the change
Implementation & Handover	To ensure that all relevant safety measures have been put in place and have been checked before the change is put into place or used
Closure & Review	To ensure that any assumptions made at earlier stages remain valid and to ensure all outstanding actions and any implementation or commissioning issues have been closed out and to review the effectiveness of the change after an extended commissioning or operational period.

3.2 Key Roles and Responsibilities

Managing Change relies on "Team Competence" and the roles and responsibilities are likely to vary between individual member sites depending on their management / organisational structure, however the following two key points apply in all situations;

- Everyone involved needs to understand their role
- Everyone involved needs to understand their responsibilities

The following key roles and responsibilities should apply on most sites or in most departments within an organisation, noting that an individual can often carry out two or more roles and that some roles e.g. department or plant manager will not apply on smaller sites.

Site Responsible Manager; overall responsibility for safety on their Site

- Ensure Management of Change systems operate safely & effectively on their site
- Ensure people involved in Management of Change understand their roles & responsibilities
- Obtain support / resource from other departments or 3rd parties when required

Department Manager; overall responsibility for safety in their Department

- Ensure no changes are made without following appropriate systems
- Ensure change does not occur until it is safe to put the change into place
- Ensure procedures are updated when change occurs
- Ensure staff are trained when change occurs

- Obtain support / resource from other departments or 3rd parties when required

Plant Manager; overall responsibility for safety on their Plant;

- Ensure no changes are made without following appropriate systems
- Ensure plant / process is not restarted after change until it is safe to restart
- Ensure procedures are updated when change occurs
- Ensure staff are trained when change occurs
- Obtain support / resource from other departments or 3rd parties when required

Site Responsible Engineer; overall responsibility for safety of plant / equipment on their Site

- Ensure Plant Modification systems operates safely & effectively on their site
- Ensure engineering aspects of change carried out to correct standards
- Ensure people involved in design are competent for their role(s)
- Ensure people involved in installation are competent for their role(s)
- Obtain support / resource from other departments or 3rd parties when required

Site Responsible SHE Manager; responsibility for safety on their Site

- Ensure the site has safe & effective Management of Change systems
- Ensure the site has a monitoring / auditing system for its Management of Change systems
- Ensure people involved in Management of Change understand their roles & responsibilities
- Provide support to other people in the Management of Change system when required
- Obtain support / resource from other departments or 3rd parties when required

Process Responsible Scientist / Technologist; overall responsibility for the safety on their Processes

- Ensure Process Change systems operate safely & effectively on their processes
- Ensure scientific / technological aspects of change carried out to correct standards
- Ensure people involved in scientific / technological aspects are competent for their role(s)

- Ensure people who define scientific / technological aspects of processes are competent for their role(s)
- Obtain support / resource from other departments or 3rd parties when required

As discussed previously in Section 3.1, nabim members need to act as Intelligent Customers when utilising the services of 3rd parties to carry out safety critical work e.g. they should retain adequate technical competence to judge whether, and ensure that, work is done to the required quality and safety standards.

3.3 Plant / Equipment Modification

The purpose of a plant / equipment modification system is to provide an effective method of controlling and managing changes to plant and equipment by ensuring that any intended modification to plant and equipment is risk assessed and managed adequately so that its safety is not compromised following the modification, that people are not exposed to unacceptable risk and that environmental protection is maintained.

It should be used to manage any change, both permanent and temporary, that is not a “like-for-like” replacement. Note; replacement of a piece of equipment (e.g. a valve or instrument) with an equivalent make and model which is already documented for the required duty within an approved engineering standard classes as “like-for-like”. Examples of temporary changes include;

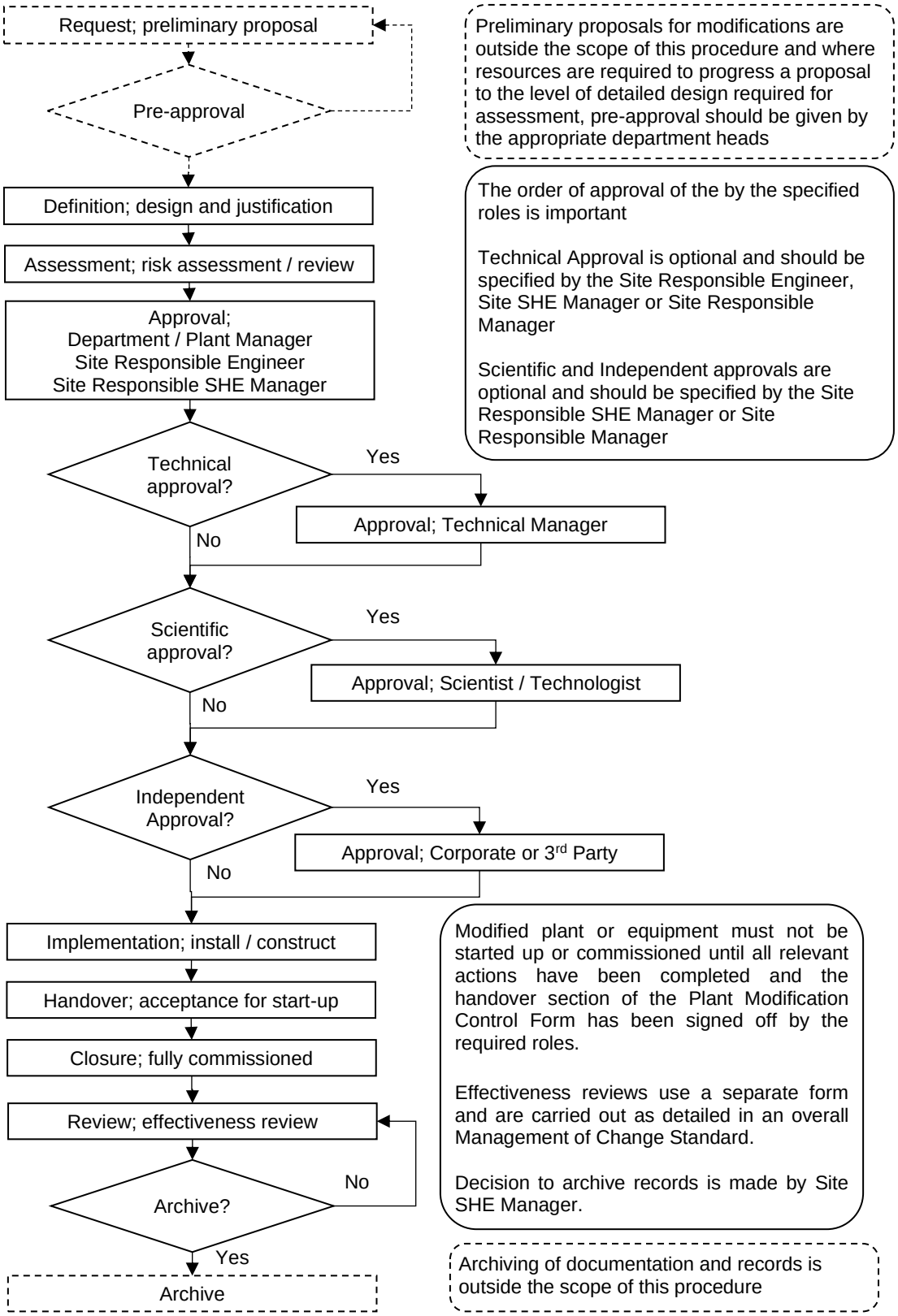
- Use of trial equipment
- Use of equipment that has been subjected to a temporary repair
- Use of equipment with part of its control system defeated or bypassed

It should also be used for the restarting of any plant or equipment which has not been operated in the last 2 years, to ensure that an assessment is made of any potential changes to the process, legislation or standards which could have taken place.

For sites or organisations without formally controlled engineering standards; all changes to engineering standards should be controlled and managed using a Plant Modification system until formal systems are in place for controlling and managing changes to engineering standards.

The overall workflow for managing plant / equipment modification is illustrated in Figure 3.1 on the following page.

Figure 3.1 Illustrative Example Plant Modification Workflow;
Managed by a Plant Modification Control Form – see Appendix E



3.4 Process Change

The purpose of a process change management system is to provide an effective method of controlling and managing changes to processes by ensuring that any intended change to a process is risk assessed and managed adequately so that its safety is not compromised following the change, that people are not exposed to unacceptable risk and that environmental protection is maintained.

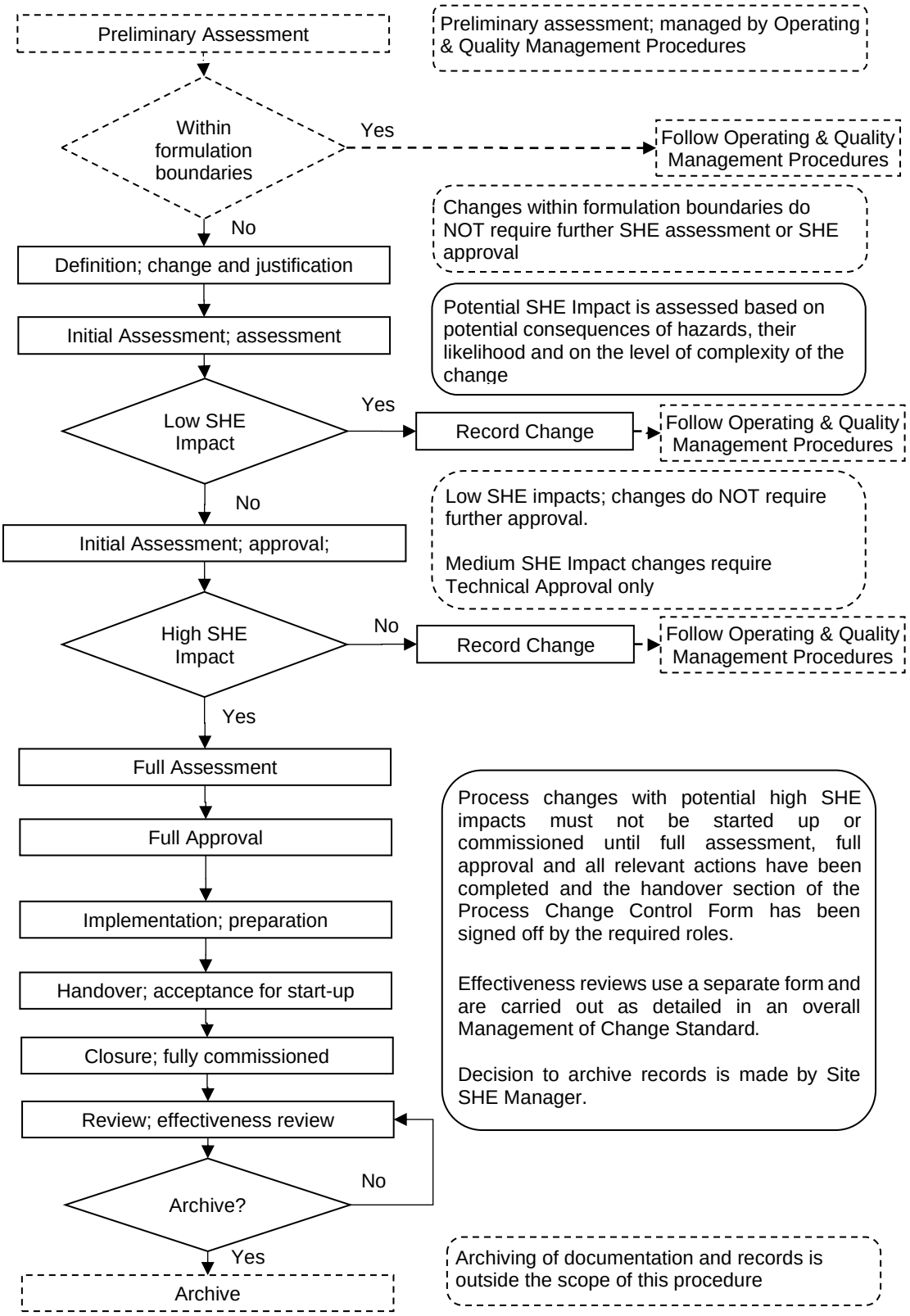
It should be noted that flour milling processes are generally limited to straightforward unit operations such as particle size reduction, simple sieving / screening, transfer and blending / mixing operations, which limits the types of fire and explosion hazards. Heat treatment introduces an element of thermal processing which can introduce a different set of fire and explosion hazards.

Process changes outside of normal formulation boundaries are not common within flour milling e.g. most changes are likely to be minor and should be managed effectively by operating or quality management / HACCP procedures or systems.

A process change management system should also be used for the restarting of any process which has not been operated in the last 2 years, to ensure that an assessment is made of any potential changes to the plant, equipment, legislation or standards which could have taken place.

The overall workflow for managing process change is illustrated in Figure 3.2 on the following page.

Figure 3.2 Illustrative Example Process Change Workflow;
Managed by Process Change Control Forms – see Appendix F



3.5 Organisational Change

The purpose of an organisational change management system is to provide an effective method of controlling and managing organisational changes by ensuring that any intended change is risk assessed and managed adequately so that its safety is not compromised during and following the change, that people are not exposed to unacceptable risk and that environmental protection is maintained.

Changes within an organisation can vary widely in terms of depth and complexity and can have a wide range of impacts to major accident hazards, other process hazards as well as occupational health, safety and environmental hazards.

The procedure outlined below utilises a staged approach to analyse the potential impacts of each organisational change and develop a risk-based approach to manage each individual change based on the following categories.

Table 3.5.1; Categories of Change

Category	Definition Major accident hazard e.g. fire / explosion or violent release of energy
Insignificant	Change in a function or department or individual post with little or no impact on major accident hazard safety
Minor	Change within a department with major accident hazard safety responsibilities, that has a minor impact on management or emergency response arrangements
Significant	Change with potential significant impact on major accident safety e.g. • Significant downsizing • Wide ranging change resulting in significant transfer of roles, responsibilities and accountabilities • Organisational change due to significant changes to the site risk profile e.g. expansion of a hazardous process plant
Major	Change with potential major impact on major accident hazard risk e.g. • Large scale downsizing • Outsourcing of a major accident hazard significant function • Organisational change due to major changes to the site risk profile e.g. introduction of a new, or major expansion, of a hazardous process plant

Table 3.5.2; Assessment Levels based on Category

Category	Assessment Level See notes following this table to explain terminology
Insignificant	Simple checklist assessment e.g. • Parts 1-3 of the Change Control Form in Appendix G
Minor	Simple checklist assessment e.g. • Parts 1-3 of the Change Control Form in Appendix G
Significant	Detailed assessment e.g. uses Parts 4 onwards of the Change Control Form in Appendix G • Mapping of tasks and individuals • Training Needs Analysis / Competence Assessment
Major	Detailed assessment e.g. uses Parts 4 onwards of the Change Control Form in Appendix G • Mapping of tasks and individuals • Training Needs Analysis / Competence Assessment • Workload & Resource Assessment • Emergency Response Assessment

Table 3.5.4; Assessment Methods - Terminology	
Method	**Explanation – in the context of managing change**
Mapping of tasks and individuals	Use information from the Part 2 of the Organisational Change Control Form to identify all roles with major accident hazard responsibilities that could be affected by the change should be identified in the current organisation and in the proposed organisation. Identify the persons who carry out those roles, their responsibilities and the tasks they carry out which relate to major accident hazards.
Training needs analysis	Use information from the Part 2 of the Organisational Change Control Form and the findings from the mapping of tasks and individuals to carry out a training needs analysis for the persons in the proposed organisation who carry out new or changed roles, who have new or changed responsibilities or who carry out new tasks.
Workload & Resource Assessment	Use information from the Part 2 of the Organisational Change Control Form and the findings from the mapping of tasks and individuals to identify roles where there will be a significant reduction in the number persons, a significant increase in duties or workload or a significant increase in responsibilities. Ensure that there are sufficient resources for; • Normal operation • Start-up and shutdown • Process upsets and emergencies
Emergency Response Assessment	Specialist methods tailored to consider staffing requirements for responding to hazardous incidents are available However, it is unlikely that these will need to be used in flour milling operations

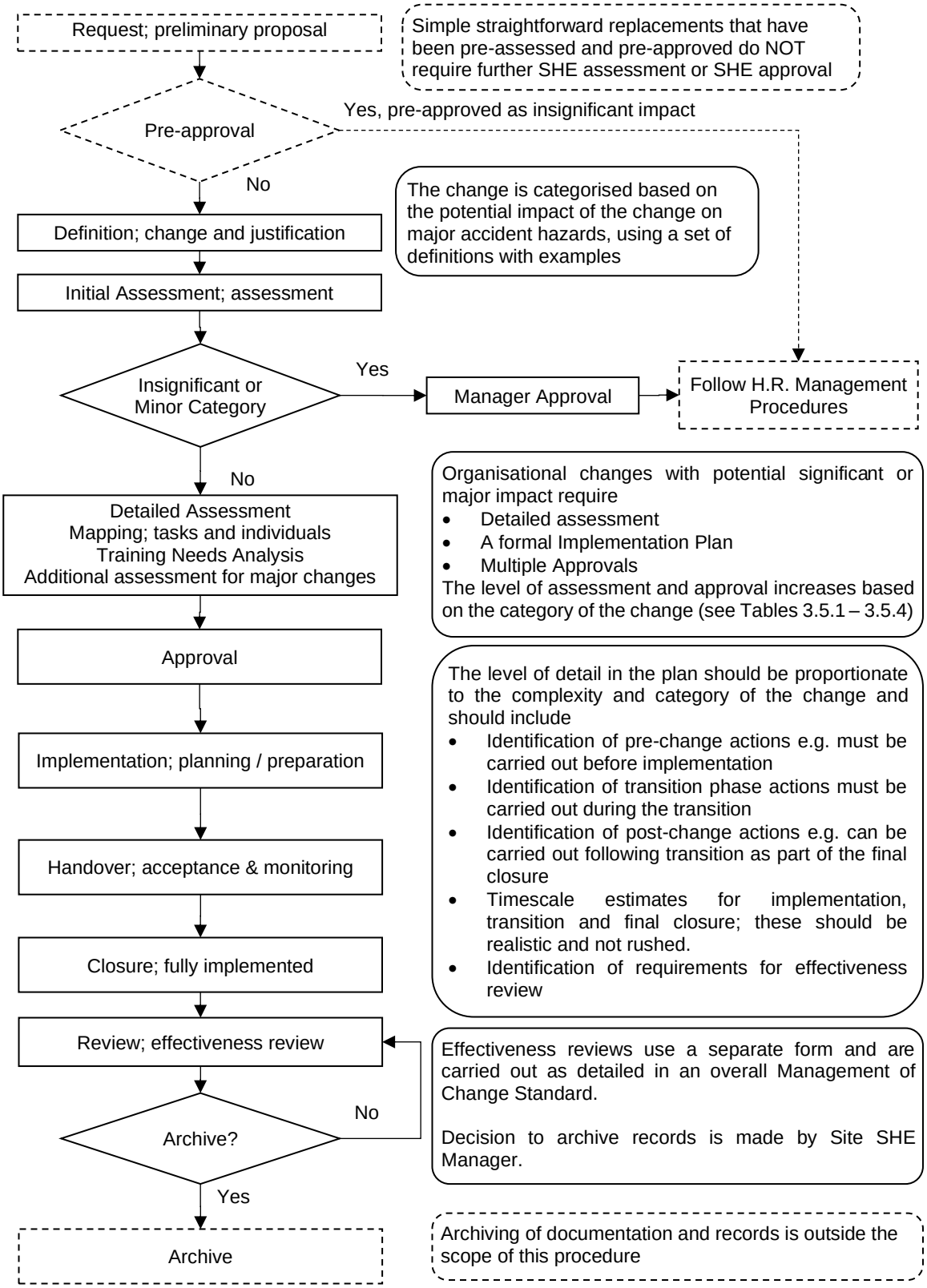
Table 3.5.4; Approval Levels based on Category	
Category	**Approval Level**
Insignificant	Manager above the Line Manager responsible for the change *Note; changes in individual posts at this category of change can often be pre-assessed and pre-approved then managed by HR Procedures.*
Minor	Manager above the Line Manager responsible for the change *Note; changes at this category of change require assessment and approval on a case by case basis e.g. they should not be pre-assessed or pre-approved*
Significant	Approval by; • Corporate (see notes following this table) • Site Responsible Manager • SHE Manager *Note; Regulatory Authorities may require informing of the change*
Major	Approval by; • Corporate (see notes following this table) • Site Responsible Manager • SHE Manager *Note; Regulatory Authorities may need to review the change*

The overall principle is that the responsible Line Manager(s) would normally be involved in the change process and the approval would be from the level of management above the involved Line Manager(s). For smaller organisations where there is limited scope for high level corporate approval it is recommended that some form of independence is introduced for significant and major changes e.g.

- Significant changes; approval by Executive Directors
- Major changes; approval to include at least one Non-Executive Director

The overall workflow for managing organisational change is illustrated in Figure 3.3 on the following page.

Figure 3.3 Illustrative Example Organisational Change Workflow;
Managed by an Organisational Change Control Form – see Appendix G



3.6 Decommissioning or Disposal

It is difficult to give detailed guidance relating to decommissioning and disposal due to the significant differences between sites and organisations. However, the following points should be noted;

- Decommissioning should be managed as a significant project and Organisational Change Management should be followed for decommissioning to effectively manage the transition from normal operation, through cleaning and decontamination and removal of equipment. Task specific explosion risk assessments may be required for cleaning and decontamination activities until all potential explosion hazards have been removed from the site.
- Demolition activities should be managed as a major project according to legislation and guidance relating to demolition.
- Disposal of an operational process plant should be managed as a major organisational change following the principles of due diligence. Published guidance is freely available on this subject; OECD(2018), Guidance on Change of Ownership in Hazardous Facilities, Environment, Health and Safety, Environment Directorate, Organisation for Economic Cooperation and Development.

4.0 ILLUSTRATIVE EXAMPLE SCENARIOS

Illustrative example scenarios are discussed below for the following;

- Consideration at Stage 1 (Feasibility / Concept)
  - Introduction of flour heat treatment to a site
  - Introduction of gluten free flour milling to a site
  - Introduction of a novel process e.g. to produce “low dust” flour
- Consideration at Stage 2 (Preliminary Design)
  - Design decision; type and location of silos
  - Design decision; choice of explosion protection of bucket elevators
- Consideration at Stage 3 (Detailed Design)
  - Ex equipment selection / specification
  - Design of explosion relief
- Consideration at Stage 4 (Pre-start-up)
- Consideration at Stage 5 (Operational)
  - Final verification / validation
  - Re-validation
  - Replacement of a wheat cleaning sieve
  - Change in gluten supply
  - Replacement of an experienced engineer

4.1 Stage 1 (Feasibility / Concept)

The following example scenarios illustrate the need for some changes to be considered very early in a project.

Ref.	Scenario
4.1.1	Introduction of flour heat treatment to a site that has previously only carried out bread making flour milling e.g. introduction of new hazards changes the site risk profile
4.1.2	Introduction of gluten free flour milling to a site that has previously only carried out bread making (wheat) flour milling e.g. potential change to the fire / explosion properties of the materials used which could affect the bases of safety for some operations / equipment
4.1.3	Introduction of a novel process, e.g. to produce low dust flour, with potential hidden or unforeseen changes to explosion hazards

4.1.1 Introduction of flour heat treatment to a site

If the site has not previously carried out heat treatment, the project will be a major expansion with impact of new hazards e.g. change in site risk profile.

By carrying out a formal structured assessment at Stage 1, which can be done with a small number of experienced competent people, the following will be identified and formally documented;

Major legislation relating to fire and explosion hazards applies e.g.

- UK; Dangerous Substances and Explosive Atmospheres Regulations (DSEAR)
- Ireland; Part 8 of the 2007 Safety Health & Welfare at Work (General Application) Regulations

Major legislation relating to design and construction likely to apply e.g.

- UK; Construction (Design and Management) Regulations (CDM)
- Ireland; Procurement, Design and Management Requirements of the Safety Health and Welfare at Work (Construction) Regulations

Relevant legal good practice and standards apply relating to the following e.g.

- Hazardous area classification and Ex equipment
- Explosion protection systems and devices
- Fire protection systems
- Electrical equipment
- Earthing and lightning protection systems
- Dust aspiration and local exhaust ventilation systems

The project is too large and complex to be managed by a simple Management of Change System. Further formal safety assessments are required at each key stage of the project, with formal sign off at the following stages before proceeding to the next stage;

- Stage 2; Definition / Preliminary Design
- Stage 3; Detailed Design e.g. before installation
- Stage 4; Pre-start up e.g. before introduction of dangerous substances / process hazards
- Stage 5; Operational e.g. after commissioning and an initial operational period

The change is significant and may affect the workload of existing site personnel during the project and may affect the ongoing operational plant once commissioning is completed. Specialist 3rd parties may also be required for key project roles. Formal organisational change should

be started as soon as practicable to assess the impact of the project and of the ongoing new plant and process.

A formal structured assessment at Stage 1 will also identify what further assessments are required – see discussion below;

Assessment Type	Notes / Comments
Explosion risk assessment	Yes, new explosion hazards introduced to site. Preliminary Hazard Assessment required to define bases of safety at Stage 2
Hazardous area classification	Yes, to be carried out as part of explosion risk assessment. Hazardous Area Classification concept, including design standards and housekeeping standards to be defined at Stage 2
Reaction risk assessment	Yes, thermal decomposition of flour during heat treatment is a known fire hazard, but this may be a new hazard to the site. This hazard could be assessed as part of fire and explosion risk assessment
Fire risk assessment	Yes, general fire risk assessment will be required and further fire risk assessment of process fire hazards e.g. dangerous substances, will be required. This could be done in conjunction with explosion risk assessment
Pressure systems and pressure relief assessment	Limited pressure hazards may be introduced. Significant pressure hazards should be identified at Stage 2
Substance health assessment	Significant hazards should be identified at Stage 2
Noise risk assessment	Significant hazards should be identified at Stage 2
First Aid Needs	A formal first aid needs assessment should be carried out for the installation / construction phase. Review the existing site first aid needs assessment. This could be done as part of Organisational Change Management
Env. Impact Assessment	The requirements of the environmental protection legislation and the applicability and requirements of the environmental permitting legislation should be considered at Stage 2
Manual Handling / Ergonomics	Significant hazards should be identified at Stage 2 assessment
Construction / Demolition	Major installation project; expected to fall under design and construction legislation. Details should be identified at Stage 2 assessment
Machinery / Equipment Safety	New installation; machinery and equipment standards should be specified at Stage 2. Risk assessments for the use of machinery and work equipment required before start-up
Lifting equipment	Lifting equipment should be identified as part of the machinery / equipment safety assessment

4.1.2 Introduction of gluten free flour milling to a site

Introduction of gluten free flour milling to a site designed for wheat milling could be a major project, similar to that discussed in Section 4.1.2, except that the unit operations carried will be similar to those carried out at the site for wheat milling. The most significant aspect of the change is associated with the differences between the fire and explosion properties of the flours. In some cases, the differences are significant enough to require a basis of safety, or equipment specification, that is different to that for wheat.

Rice dust has been compared with wheat dust to illustrate the potential implications;

- Minimum Ignition Energy (MIE); rice dust can have minimum ignition energy below that of wheat dust, making a rice dust cloud slightly more prone to electrostatic ignition than wheat dust. However, rice dust has MIE greater than 30 mJ which means that there are no special requirements for eliminating low energy static discharges from people or non-conductive items e.g. equipment with earthing and bonding designed for use on wheat dust should be suitable for use on rice dust.
- Minimum Ignition Temperature; the minimum dust cloud ignition temperature of rice dust is typically in the range 380 – 390°C which is below that for wheat dust which is typically in the range 420 – 480°C. This means that a rice dust cloud may be slightly more prone to ignition from hot surfaces, but the implications for equipment selection are minimal e.g. a temperature class T3 (200°C maximum surface temperature) would be specified for both materials
- Layer Ignition Temperature; the layer ignition temperature of rice dust can be as low as 290°C which is below that for wheat dust which is typically greater than 300°C. This means that a rice dust layer may be slightly more prone to ignition from hot surface, but the implications for equipment selection are minimal e.g. a temperature class T3 (200°C maximum surface temperature) would be specified for both materials
- Explosion Indices; there is only limited data for rice dust however this indicates that the explosion indices for rice dust are lower than those for wheat dust. Equipment with explosion relief designed for wheat dust should therefore be suitable for a change of duty to rice. However, the project should consider if new equipment with explosion relief should be “future proofed” and designed to allow a change of duty to wheat or materials with higher explosion indices.
- Combustibility Rating (BZ); rice dust can have a slightly higher combustibility rating that wheat dust, but this property is significantly affected by material properties such as particle size and moisture. Although rice dust may burn slightly faster than wheat dust, the implications for bases of safety for grain handling and cleaning are minimal.

Rice flour has been compared with wheat flour to illustrate the potential implications;

- Minimum Ignition Energy (MIE); rice flour has minimum ignition energy below that of wheat flour, making a rice flour cloud slightly more prone to electrostatic ignition than wheat flour. However, rice flour has MIE greater than 100 mJ which means that there are no special requirements for eliminating low energy static discharges from people or non-conductive items e.g. equipment with earthing and bonding designed for use on wheat dust should be suitable for use on rice flour.
- Minimum Ignition Temperature; the minimum dust cloud ignition temperature of rice flour can be as low as 360ºC which is below that for wheat dust which is typically 430ºC. This means that a rice flour cloud may be slightly more prone to ignition from hot surfaces, but the implications for equipment selection are minimal e.g. a temperature class T3 (200ºC maximum surface temperature) would be specified for both materials
- Layer Ignition Temperature; the layer ignition temperature of rice flour, like wheat flour, is relatively high (typically greater than 450ºC). The implications for equipment selection are minimal as the maximum surface temperature is determined by the minimum dust cloud ignition temperature.
- Explosion Indices; there is only limited data for rice flour however this indicates that the explosion indices for rice flour are lower than those for wheat flour. Equipment with explosion relief designed for wheat flour should therefore be suitable for a change of duty to rice flour. However, the project should consider if new equipment with explosion relief should be “future proofed” and designed to allow a change of duty to wheat flour or other flours with higher explosion indices.
- Combustibility Rating (BZ); Wheat flour has the lowest combustion rating of 1 indicating that it does not catch fire under the test and fire does not spread. It does not produce flames or incandescent particles and it is concluded that the likelihood of ignition of a wheat flour cloud caused by smouldering wheat flour is very low. However, rice flour has a higher combustion rating and behaves differently when dispersed in air. Careful consideration of the bases of safety for equipment such as roller mills and equipment downstream of them is required.

Dusts from other raw materials used for gluten free flour milling, and other types of gluten free flour, may have limited published data;

Sampling and testing may be required to check key properties before defining bases of safety and equipment selection / specification.

4.1.3 Introduction of a novel process

The implications of introducing a novel process has potential to introduce hidden or unforeseen changes to explosion hazards. One example is the introduction of “low dust” flour, e.g. low dust release flour for health protection of workers, which may initially appear to have potential benefits in relation to explosion hazards. However, when considered carefully at the start of the design of a new process; the processing method used to produce low dust flour can have potential to affect explosion hazards in several ways. Even if the changes are minimal, it is important to document these so that they are fully understood by the project team and then final operational team.

If simple methods are used to remove the finest fractions of dust from the flour, then careful consideration needs to be given to what happens to the removed fine fraction. Depending on the method of downstream handling, the fine fraction could concentrate up in the downstream system e.g. dust filters or cyclones and could alter the fire and explosion properties of flour dust. In general, fine dusts are easier to ignite as a dust cloud and the resulting dust cloud explosion is more violent, than for coarser dusts e.g. minimum ignition energy is lower and explosion indices are greater.

If more complex processing methods such as hydro or thermal treatment designed to agglomerate the particles by electrostatic interaction are used; this may initially appear to make the flour coarser with the potential for making it less likely to be ignited as a dust cloud and resulting in a less violent explosion. However, the agglomeration process may only rely on relatively weak electrostatic forces and only assist in preventing the fine, e.g. respirable fraction, of dust from being roused in the relatively gentle conditions found in dusting operations. In processing equipment where dust clouds are formed at explosible concentrations the forces which rouse the dust cloud are greater and the minimum ignition energy and explosion indices are likely to be unchanged, however thermal processing may affect the thermal stability of the flour and lower the minimum dust cloud ignition temperature and layer ignition temperature.

4.2 Stage 2 (Preliminary Design)

The following example scenarios illustrate the need for some changes to be considered in detail at the preliminary design stage to enable key design decisions to be made e.g. which could have a significant impact on bases of safety and / or capital or operational costs;

Ref.	Scenario; Design Decision
4.2.1	Type and location of wheat silos; factors to consider when deciding on the type and location of raw wheat silos e.g. large silo block with joint walls or weak roofed individual corrugated steel silos
4.2.2	Bucket elevator explosion protection; factors to consider when deciding on the need for explosion protection on bucket elevators, including explosion isolation.

4.2.1 Type and location of wheat silos

The type and location of wheat silos has very little influence on the likelihood of a dust explosion inside the silo, which should be a very rare event assuming with good ignition prevention controls in place. The only significant influence is that corrugated silo walls can allow dust to accumulations on horizontal surfaces in the headspace above the normal fill level. These dust accumulations can be roused by impact or vibration and as the silo may require periodic cleaning, rousing during cleaning activities presents a significant risk.

The main impact that the type and location have on explosion hazards relate to the consequences of an internal dust explosion which can be serious.

- Silos in blocks with shared walls introduces a significant increase in the nature of the hazard, which is greater if the silo block forms part of the mill building structure. An explosion inside one silo can lead to failure of shared walls, rousing dust in adjacent silos and subsequent ignition in adjacent silos leading secondary explosions causing failure of the entire silo block. This type of escalation hazard can affect a wide area as pressure piling can occur making each subsequence secondary explosion more violent and large missiles from the failure of the silo structure can affect a wide area of a site and can have potential to harm people in buildings nearby.
- Individual corrugated silos with weak roofs remove the escalation hazard as shared silo walls do not exist. The cylindrical silos walls are relatively strong and failure of the silo roof, generally by peeling of roof panels, limits the nature and extent of the hazard. The consequences of an internal explosion are likely to be limited to upwards flame and pressure release at high level into a relatively low occupancy area and potential for missiles affecting a localised area of the site immediately

surrounding the silo e.g. caused by damaged silo roof panels or damaged equipment such as conveyors and inlet chutes.

- The location of silos in relation to areas of higher occupancy such as wheat intake, flour outloading, co-product outloading, control rooms, offices needs careful consideration and may influence the choice of silo type and in some cases may even lead to the need for explosion protection e.g. explosion relief, to be included in the design. As illustrated above, a silo block with shared walls can affect a far wider area and potentially put more people at risk than individual corrugated silos with weak roofs.

If factors such as those discussed above are not considered in detail at the preliminary design stage, it could lead to significant increases in capital costs later in the project when explosion risk assessment carried out at the detailed design stage identifies a significant risk e.g. where risk is not as low as reasonably practicable.

4.2.2 Bucket elevator explosion protection

Bucket elevators require special attention since they have been involved in dust explosions and they have many potential ignition sources. Clear definition of explosion protection requirements is the responsibility of the equipment user, rather than the equipment supplier**.** This definition is needed at the preliminary design stage based on a range of factors including;

- Likelihood of forming an explosive dust cloud inside the elevator, which is mainly based on the dust content of the bulk material being conveyed
- Location and size of the elevator, which can vary on an elevator by elevator basis
- Occupancy of the area surrounding the elevator, which may vary by location and floor level / elevation
- Likelihood of dust layers in the area surrounding the elevator, which may vary significantly depending on location inside or outside a building or depending on maintenance and housekeeping standards
- Potential explosion propagation risks which include
    - Propagation to upstream equipment or operations
    - Propagation to downstream equipment or operations
    - Propagation through dust aspiration ductwork

European harmonised guidance for bucket elevators is published in Technical Report CEN/TR 16829:2016 Fire and explosion prevention and protection for bucket elevators, which is available from national standards bodies.

Two example elevators are described in the PD CEN/TR 16829:2016, along with guidance relating to materials such as grain, and clearly states that ignition sources related to other influences should be considered by the **user**:

- Ignition sources introduced from connected equipment e.g. hot, glowing and burning product, embers, explosion from connected equipment etc.
- External ignition sources due to smoking, maintenance, welding, cutting etc. (hot work) - these should be prevented by organisational measures.
- Ignition sources that may arise from the conveyed product e.g. by self-heating deposits inside the bucket elevator

PD CEN/TR 16829:2016 also states that the **user** normally selects a bucket elevator based upon the category (related to internal zone) and should perform a risk assessment based upon the local circumstances. The risk analysis should include the probability that ignition sources enter from outside and consider the potential consequences of an explosion.

Differences exists between sites and explosion risk assessment is required on a case by case basis considering factors such as;

- The effectives of upstream pre-cleaning / aspiration at removing fine material from grain significantly affects the likelihood of forming an explosive atmosphere.
- Cleaning of grain typically involved a high degree of screening and aspiration designed to remove fine material from grain.
- Screenings can contain a mixture of materials from different sources, including recovered dust e.g. from dust aspiration systems.
- Pellets can be prone to breakdown if not manufactured effectively and pelletising can occasionally be bypassed allowing un-pelletised materials to be used on pellet handling equipment.

PD CEN/TR 16829:2016 lists detailed requirements and guidance for bucket elevators of each category as summarised below;

- All bucket elevators e.g. Category 3 or higher integrity
- Additional requirements for bucket elevators with internal Category 2
- Additional requirements for bucket elevators with internal Category 1

PD CEN/TR 16829:2016 states it is not possible to give general precautions for Category 1 equipment; if ignition sources cannot be prevented during rare malfunctions, explosion mitigating measures are required in addition to Category 2 requirements. PD CEN/TR 16829:2016 also gives detailed guidance on mitigation measures (explosion protection and / or isolation) for bucket elevators.

4.3 Stage 3 (Detailed Design)

If the correct staged approach has been followed many of the key design decisions will have been made at Stage 2 making Stage 3 more straightforward.

Ref.	Scenario; Design Decision
4.3.1	Ex equipment specification; detailed specification before procurement and installation
4.3.2	Design of explosion relief; detailed specification before procurement and installation

4.3.1 Ex equipment specification

As discussed in Section 2.2, the overall concept for hazardous area classification should have been defined at Stage 2. It is important to ensure that the standard of aspiration, and the standard of connections and seals on the grain, flour, gluten and co-products handling equipment is specified such that dust releases into the workplace are minimal and at low rate, but with potential to cause dust layers in the workplace.

It is important that the standard of housekeeping to be employed is defined to meets the Good standard defined by EN 60079-10-2 throughout most areas, with a number of areas possibly only meeting the Fair standard defined by EN 60079-10-2.

Preventive maintenance and housekeeping standards can vary between sites and organisations and preliminary hazardous area classification should be carried out as early as possible in the detailed design stage noting;

- Hazardous areas within equipment are classified as part of the explosion risk assessment process
- Hazardous areas outside equipment in the workplace are significantly influenced by the factors discussed above. This cannot be fully demonstrated until the equipment is installed and the process is operational; many organisations prefer to apply a safety margin to assumptions and apply a conservative approach, with slightly larger zone extents which can be relaxed at later stages of the project
- The hazardous area classification process considers the equipment, the operations and their location within the workplace is often an iterative process which changes as the detailed design progresses
- Hazardous area classification drawings should be produced as soon as possible and then managed carefully if layout or design changes.

Detailed equipment selection guidance is given in Appendix B, which should be followed when specifying or procuring equipment for use in hazardous areas. The following points should be noted;

- Over-conservatism can lead to extensive Zone 2 areas in the workplace, making location of large items, such as control panels or blowers, difficult or introducing excessive costs for using Ex equipment which may not be required if appropriate design, maintenance and housekeeping standards are applied to prevent dust releases and prevent dust layer accumulations
- Under-conservatisms can lead to assumptions that workplace Zone 2 areas will not exist in most areas and costs can be reduced by using non-Ex equipment throughout. This can cause future problems if housekeeping standards do not meet the standards required for this approach.
- One common sense approach that can be used in the early stages of a project e.g. for budgeting purposed before the design stage hazardous area classification is finalised, is to specify equipment management areas in the workplace close to the powder handling plant equipment e.g. within 1m of powder handling equipment so that any equipment is suitable for use in a Zone 22 area. This allows large items such as control panels or blowers to be located well outside zoned areas.
- There are many methods of ignition protection available, particularly electrical equipment, and a site (or organisation) may have preferred choices of protection methods for different types of Ex equipment e.g. Ex “d” motors. It is important that these preferred methods are defined, or agreed, by the site (or organisation) rather than by 3rd party project engineers.
- It is important that those involved understand that Ex equipment is specified for both of the following;
    - The zones in which the equipment is located, which can differ if equipment such as instrumentation is located partly inside equipment and partly outside equipment
    - The zones that the equipment is connected to e.g. through inlet or outlet connections

4.3.2 Design of explosion relief

The need for explosion protection (mitigation) such as explosion relief for an item of equipment should have been determined during the preliminary hazard assessment carried out at Stage 2 (preliminary design). Preliminary explosion risk assessment may also have been carried out to determine the practicability of different types of mitigation

such as explosion relief or explosion suppression, traditional explosion vents or flameless vents etc.

The detailed design process can often be iterative as there are many interlinked factors which can cause changes to be introduced. For equipment which needs explosion relief, it is important to understand the key factors which have a significant influence on the design of explosion relief. These are outlined and discussed below.

The materials handled can have a significant influence, for example;

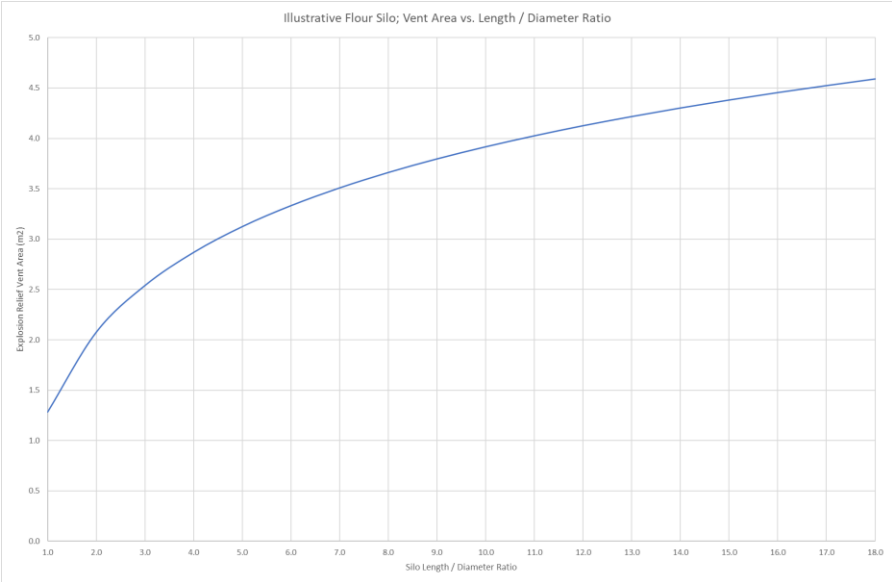
- Changes in material handled by the equipment can have a major influence on the explosion indices (K_{st} and P_{max}); it is vital to use values that are representative of the material handled. These should be specified by the equipment user and would normally be defined at the Stage 2 preliminary hazard assessment stage. Data for most common materials is published by nabim "The Explosibility of Flour, Gluten and Wheat Dust", First edition January 2004. Use of this data is preferable to older generic data which is available from several other published sources. For example; old published data for Gluten indicates values for K_{st} in the range 74 -105 bar.m/s, whereas test data published by nabim indicates a value of 149 bar.m/s. A review of a range of supplier's safety data sheets indicate Kst in the range 77 – 129 bar.m/s, illustrating the wide range of data. When designing a new installation, it is preferable to "future proof" the design and use values for K_{st} and P_{max} at the upper end of the range.
- Change in duty of equipment during detailed design, e.g. change from pelletised screenings / wheatfeed to un-pelletised material, may mean that equipment that previously did not require explosion protection will now need explosion protection.

Equipment dimensions have a significant influence, for example;

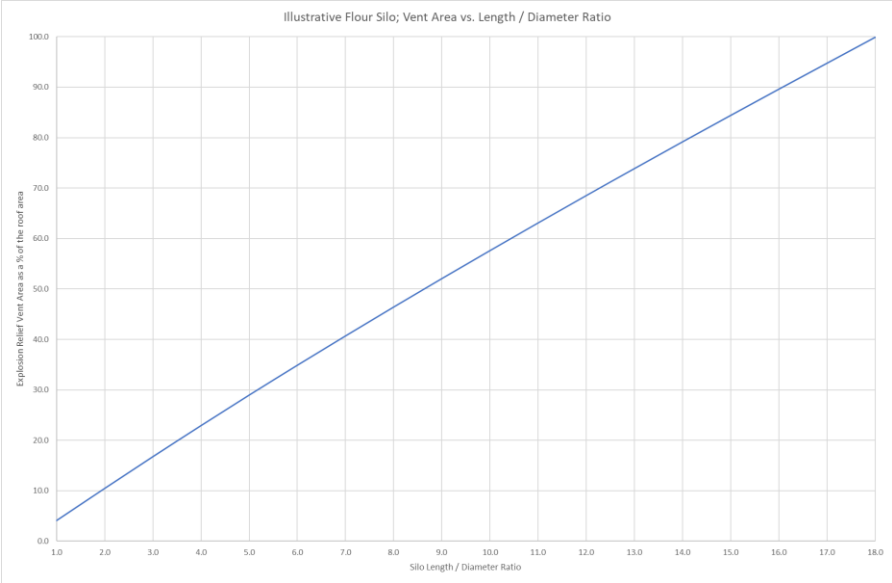
- Changes in equipment volume has a significant effect on the design of explosion relief. Equipment volume has a direct effect on the vent area required.
- Changes to equipment length (height) to diameter ratio (L/D ratio) has a significant effect on the design of explosion relief; increasing L/D ratio leads to increased flame acceleration and causes a more violent explosion. For a typical silo, explosion relief is installed on the silo roof and for a given silo volume the area available for the relief reduces as the L/D ratio increases. The effect is illustrated in Figure 4.1 on the following page.

Figure 4.1 Illustration of the effect of increased L/D ratio

a) Explosion Relief Vent Area vs. Length / Diameter ratio



b) Explosion Relief Vent Area as a % of the Silo Roof Area



Equipment location can have a significant influence, for example;

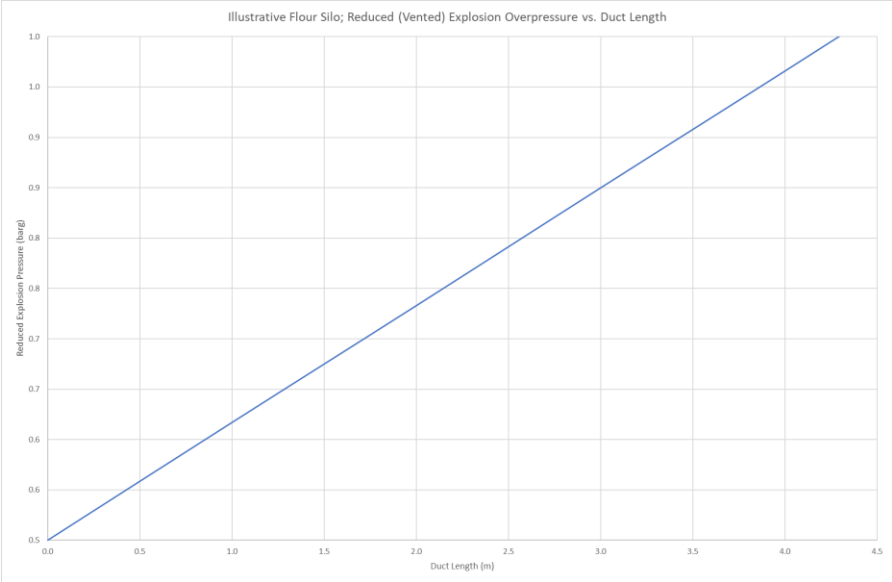
- The occupancy of the area surrounding an explosion vent has a direct influence on the level of risk. Ideally explosion relief should discharge into unoccupied areas and low occupancy areas with formal access restrictions may also be acceptable. Typical flame dimensions vented explosions are illustrated;

Equipment	Length	Width
Small bucket elevator	6 – 8 m	2.0 – 2.5 m
Large bucket elevator e.g. raw wheat intake	10 – 13 m	3.0 – 3.5 m
Large Dust Filter e.g. main dust aspiration	15 – 25 m	5.5 – 7.0 m
Large Silo or Bin	35 – 60 m	12 – 16 m

- For equipment located indoors, the distance between the explosion vent and a safe outdoor location determines the explosion relief duct length, which should ideally be straight. The effect is illustrated below;

Figure 4.2 Illustration of the effect of explosion relief duct length

Reduced (Vented) Explosion Overpressure vs. Duct Length



The main European harmonised standards relating to design of dust explosion relief are summarised below;

- EN 14491:2012 Dust explosion venting protective systems, which specifies the basic requirements of design and covers the following;
    - General methodology that can be used for a wide range of enclosures (silos, vessels etc.) which has a wide range of applicability
    - Specific methods that can be applied under special dust cloud conditions, based on how product is introduced, including;
        - Pneumatic conveying, with axial introduction into vessels and silos
        - Pneumatic conveying, with tangential introduction into vessels and silos
        - Free fall filling e.g. with gravity feed from a rotary valve or screw feeder
    - Flame and pressure effects outside the enclosure
    - Recoil forces e.g. exerted on the vented equipment
    - Influence of vent ducts

    - Hybrid mixtures (gas and dust – unlikely to be present in flour milling)
- EN 14460:2006 Explosion resistant equipment, which specifies the requirements for explosion-pressure-resistant and explosion pressure shock-resistant equipment. Two design concepts are covered;
    - **Explosion-pressure-resistant;** designed to withstand the expected explosion pressure without becoming permanently deformed
    - **Explosion-pressure-shock resistant;** property of vessels, and equipment designed to withstand the expected explosion pressure without rupturing, but allowing permanent deformation

It is important to understand which design concept is being applied. For example, it is common for a silo to be pressure resistant to withstand the maximum pressure that could be caused by the conveying air stream in the event of a dust filter blockage, but only by pressure shock resistant to withstand the pressure in the event of a vented dust explosion. For a silo fitted with explosion protection, to avoid confusion both the pressure resistant design pressure the pressure-shock resistant design pressure should be clearly indicated on design drawings and / or design documentation.

Other European harmonised standards, mainly aimed at designers of explosion relief devices are summarised below;

- EN 14797:2006 Explosion venting devices, which specifies the requirements for venting devices used to protect enclosures against the major effects of internal explosions arising from the rapid burning of suspended dust, vapour or gas contained within. It includes the requirements for the design, inspection, testing, marking, documentation, and packaging.
- EN 16009:2011 Flameless explosion venting devices, which defines types of flameless venting devices designed to avoid the transmission of flames into the surroundings and specifies requirements for the design, inspection, testing, marking, documentation, and packaging.

nabim members should note the documentation requirements specified in these standards and ensure they receive all relevant documentation from the original equipment manufacturers.

4.4 Stage 4 (Pre-start-up)

It is difficult to provide detailed example scenarios for this stage as there is too much variation between projects, organisations and sites and the management structures used. However, a formal sign off is required, as discussed in Section 2.4, before the introduction of dangerous substances. For larger or more complex projects this can be split into two separate stages;

- At the end of the construction stage
- Before the introduction of dangerous substances

The overall concept that should be employed involves "Team Competence". It is recommended that formal structured sign off forms are used, and the following roles and responsibilities should be assigned to relevant competent people representing both the site (end user) and the project (design and construction / installation). Depending on the size and structure of an organisation these roles may be part a corporate function or support may be provided to the site by people based at larger mills. Support may also be provided by 3rd party specialists. Typical handover / sign off requirements for start-up are illustrated below for a major project;

Responsibility	Handover / Sign off Requirements
Management of Change	**Project Manager** to state; • All changes since the Stage 3 (design stage) Explosion Risk Assessment and Hazardous Area Classification have been assessed and approved using a formal management of change system and all relevant actions have been completed • All assumptions made in the Stage 3 (design stage) Explosion Risk Assessment and Hazardous Area Classification relating to design and installation are valid • Design documentation has been updated to reflect the current as built installation • The Stage 3 (design stage) Explosion Risk Assessment and Hazardous Area Classification documents have been updated to reflect the current as built installation. • Design documentation, Explosion Risk Assessment and Hazardous Area Classification documents have been handed over to the Site Responsible Person(s). **Site Engineering Manager** to state; • Design documentation has been received in a useable format **Site SHE Responsible Person** to act as an independent verifier to verify that appropriate management of change system(s) have been followed.

Responsibility	Handover / Sign off Requirements
Management of Electrical Equipment in Zoned Areas	**Project Responsible Electrical, Control, Instrument Engineer** to state that; • All electrical equipment installed in hazardous areas has been installed and inspected according to EN 60079-14 • An Ex electrical equipment verification document as defined by EN 60079-14, has been completed, with all initial inspection records and relevant documentation required • The Ex electrical equipment verification document has been handed over to the Site Responsible Engineer, with all initial inspection records and relevant documentation required **Site Responsible Electrical, Control, Instrument Engineer** to state that; • The Ex electrical equipment verification document has been received, with all initial inspection records and relevant documentation required
Management of Non-electrical Equipment in Zoned Areas	**Project Responsible Mechanical Engineer** to state that; • All non-electrical equipment installed in hazardous areas has been installed and inspected according to OEM instructions. • Installation and initial inspection records for all non-eelectrical equipment in hazardous areas have been completed • Declarations of Conformity and OEM Manuals for installation, operation and maintenance and any other relevant documentation are available for all non-electrical equipment in hazardous areas • The documentation listed above has been handed over to the Site Responsible Engineer, with all initial inspection records and relevant documentation required **Site Responsible Mechanical Engineer** to state that; • The documentation listed above for non-electrical equipment has been received in a useable format e.g. similar to a verification document for electrical equipment
Management of Explosion Protection Devices and Systems	**Project Responsible Mechanical Engineer** to state that; • All explosion protection devices have been installed and inspected according to OEM instructions. • Installation and initial inspection records for all explosion protection devices have been completed • Declarations of Conformity and OEM Manuals for installation, operation and maintenance and any other relevant documentation are available for all n explosion protection devices • The documentation listed above has been handed over to the Site Responsible Engineer, with all initial inspection records and relevant documentation required **Project Responsible Electrical, Control, Instrument Engineer** to state that; All electrical, control and instrumentation elements of explosion protection devices have been installed and inspected according to OEM instructions *continued on following page*

Responsibility	Handover / Sign off Requirements
Management of Explosion Protection Devices and Systems	*Continued from previous page* **Site Responsible Mechanical Engineer** to state that; • The documentation listed above for explosion protection devices has been received in a useable format **Site Responsible Electrical, Control, Instrument Engineer** to state that; • The documentation related to electrical, control and instrumentation elements listed above for explosion protection devices has been received in a useable format
Management of other key systems and equipment	Sign off responsibilities should be defined on a similar basis to those above for other key equipment and systems e.g. • Dust aspiration / LEV systems • Earthing / bonding systems required for ignition protection • Non-Ex electrical equipment and primary earthing systems • Lightning protection systems • Fire alarm and detection systems • Sprinkler or fire suppression systems
Commissioning	Sign off responsibilities should be defined – for example; **Commissioning Manager** to state; • An appropriate commissioning plan has been developed using competent people **Site Engineering Manager** to state; • An appropriate commissioning plan has been developed using competent people **Production Manager** to state; • An appropriate commissioning plan has been developed using competent people **Site SHE Responsible Person** to act as an independent verifier to verify that an appropriate commissioning plan has been developed
Training	Sign off responsibilities should be defined – for example; **Commissioning Manager** to state; • An appropriate training plan has been developed for each relevant group of people and has been implemented to the appropriate point for introduction of dangerous substances **Site Engineering Manager** to state; • An appropriate training plan has been developed for each group of engineering people and has been implemented to the appropriate point for introduction of dangerous substances **Production Manager** to state; • An appropriate training plan has been developed for each group of production people and has been implemented to the appropriate point for introduction of dangerous substances **Site SHE Responsible Person** to act as an independent verifier to verify that an appropriate training plan has been developed for each relevant group of people and has been implemented to the appropriate point for introduction of dangerous substances

Responsibility	Handover / Sign off Requirements
Snagging	Sign off responsibilities should be defined – for example; **Project Manager** to state; • Appropriate snagging lists(s) have been developed and handed over to the Commissioning Manager **Commissioning Manager** to state; • The snagging list(s) have been received in a useable format
Overall Explosion Safety	Sign off responsibilities should be defined – for example; **Project Manager** to state; • All relevant actions from the Stage 3 Explosion Risk Assessment and Hazardous Area Classification been be implemented and closed out • The installation is safe for the introduction of dangerous substances **Commissioning Manager** to state; • The installation is safe for the introduction of dangerous substances **Site Engineering Manager** to state; • The installation is safe for the introduction of dangerous substances **Production Manager** to state; • The installation is safe for the introduction of dangerous substances **Site SHE Responsible Person** to act as an independent verifier to verify that the installation is safe for the introduction of dangerous substances

For small projects, it may be possible to use management of change system handover forms for this stage e.g. to control the handover from installation stage to commissioning / start-up stage.

4.5 Stage 5 (Operational)

The following example scenarios are used to illustrate the need for the factors that need consideration during the operational phase;

Ref.	Scenario
4.5.1	Final verification / validation; review after commissioning and an initial operational period, to ensure plant and process(es) have been commissioned and are operating safely
4.5.2	Re-validation; periodic review, to confirm key safety requirements relating to fire and explosion hazards remain effective e.g. the process(es) and plant remain safe
4.5.3	Example Plant Modification; Replacement of wheat cleaning sieve
4.5.4	Example Process Change; Change in gluten supply
4.5.5	Example Organisational Change; Replacement of an engineer

4.5.1 Final verification / validation

The requirements for final verification and validation after commissioning and an initial operational period should be defined at Stage 3 and form the end of the Commissioning Plan. A formal sign off is required as discussed in Section 2.5, before final closure of a project and the overall concept that should be employed is similar to that discussed in Section 4.4 involving "Team Competence".

Typical sign off requirements for project closure are illustrated below for a major project;

Responsibility	Handover / Sign off Requirements
Management of Change	**Project Manager (or Commissioning Manager)** to state; • All changes since the Stage 4 (as built) Explosion Risk Assessment and Hazardous Area Classification have been assessed and approved using a formal management of change system and all relevant actions have been completed • All assumptions made in the Stage 4 (as built) Explosion Risk Assessment and Hazardous Area Classification relating to design and installation are valid • The Stage 4 (as built) Explosion Risk Assessment and Hazardous Area Classification documents have been updated to reflect the commissioned installation. **Site SHE Responsible Person** to act as an independent verifier to verify that appropriate management of change system(s) have been followed.
Electrical, Control and Instrumentation	**Site Responsible Electrical, Control, Instrument Engineer** to state that; • Electrical, control and instrumentation devices and systems are operating as their design intent and within safe operating limits • Appropriate planned preventive maintenance, inspection and testing regimes are in place for electrical, control and instrumentation devices and systems • All key documentation and records have been extracted from project files and handed over to the relevant operational function(s)
Mechanical	**Site Responsible Mechanical Engineer** to state that; • Mechanical equipment and machinery are operating as their design intent and within safe operating limits • Appropriate planned preventive maintenance, inspection and testing regimes are in place for mechanical equipment and machinery • All key documentation and records have been extracted from project files and handed over to the relevant operational function(s)

Responsibility	Handover / Sign off Requirements
Commissioning and Operation	**Project Manager (or Commissioning Manager)** to state; • All accidents, incidents and near misses have been investigated and analysed appropriately • Relevant improvement actions have been implemented or have been included in the snagging work list **Site SHE Responsible Person** to state; • All accidents, incidents and near misses have been investigated and analysed appropriately • Relevant improvement actions have been implemented or have been included in the snagging work list
Commissioning	Sign off responsibilities should be defined – for example; **Commissioning Manager** to state; • An appropriate commissioning plan has been completed using competent people • An overall commissioning report has been compiled and issued to the relevant operational managers **Site Engineering Manager** to state; • An appropriate commissioning plan has been completed using competent people **Production Manager** to state; • An appropriate commissioning plan has been completed using competent people **Site SHE Responsible Person** to act as an independent verifier to verify that an appropriate commissioning plan has been completed
Training and Procedures	Sign off responsibilities should be defined – for example; **Commissioning Manager** to state; • An appropriate training plan has been completed for each relevant group of people **Site Engineering Manager** to state; • An appropriate training plan has been completed for each group of engineering people and on-going refresher training plans have been developed • Appropriate maintenance procedures are in place for all equipment **Production Manager** to state; • An appropriate training plan has been completed for each group of production people and on-going refresher training plans have been developed • Appropriate operating procedures are in place for all operations • **Site SHE Responsible Person** to act as an independent verifier to verify that an appropriate training plan has been developed for each relevant group of people, on-going refresher training plans have been developed

Responsibility	Handover / Sign off Requirements
Snagging	Sign off responsibilities should be defined – for example; **Project Manager (or Commissioning Manager)** to state; • Appropriate snagging lists(s) have been developed and handed over to the Operational Manager **Operational Manager** to state; • The snagging list(s) have been received in a useable format and resources are available to implement snagging work
Overall Explosion Safety	Sign off responsibilities should be defined – for example; **Project Manager (or Commissioning Manager)** to state; • All relevant actions from the Stage 4 (as built) Explosion Risk Assessment and Hazardous Area Classification been be implemented and closed out • The process(es) and equipment are operating safely and effectively. **Site Engineering Manager** to state; • The process(es) and equipment are operating safely and effectively **Production Manager** to state; • The process(es) and equipment are operating safely and effectively **Site SHE Responsible Person** to act as an independent verifier to verify that the process(es) and equipment are operating safely and effectively.

For small projects, it may be possible to use management of change system closure and effectiveness review forms for this stage e.g. to control the final closure of the project.

4.5.2 Re-validation (periodic review)

On-going periodic review (re-validation) is required during the operational period to demonstrate and document that all the key safety requirements relating to fire and explosion hazards remain effective e.g. the process(es) and plant remain safe. It is important that effective management of change systems, as discussed in Section 3, are in place to enable this periodic review / re-validation.

Explosion Risk Assessment and Hazardous Area Classification documents should be managed as live controlled documents and should be reviewed, and revised if required, periodically e.g. every 3 to 5 years or if there is a reason to suspect that the risk assessment or classification is no longer valid. Factors which could invalidated them include;

- Changes in legislation or relevant good practice e.g. standards or codes of practice.
- Changes in site, corporate or industry knowledge including;

    - Findings from accident, incident or near miss investigations, including significant equipment breakdowns or failures.
    - Knowledge about materials, processes, equipment and other factors, including shared knowledge within nabim
- Significant changes including
    - Changes to the workplace e.g. plant, equipment, buildings
    - Changes to the process
    - Organisational changes
    - Creeping change caused by numerous less significant changes
- Reduction in the capital and/or operational costs of risk control measures that had previously been deemed impracticable on ground of gross cost disproportionality.

A simple checklist approach can often be taken for an established process plant involving use of a formal checklist sign off form which can used by an assessment team to document the findings of the review, justify the decisions made and list the actions required. A typical assessment team could include;

- Engineering Manager, supported by discipline engineers e.g. Electrical, Control, Instrument and / or Mechanical as required
- Production Manager, supported by technical specialists if required depending on the process(es) involved
- Site SHE Responsible Person, supported by specialists if required, to facilitate the assessment.

Example prompts and questions that could be used for this checklist approach are outlined below;

Incident / Near Miss Review

Ask questions such as those below and record the responses;

- Since the last review, has a review of incidents with significant impact been carried out?
- Since the last review, has a review near misses with potentially significant impact been carried out?
- Have the above reviews included incidents / near misses from similar process / technologies?

Summarise any significant incidents / near misses that have been identified

Inherent Safety Review

Ask questions such as those below and record the responses;

- Avoid; has any work been done since the last review to avoid any significant hazards?

- Substitute; has any work been done since the last review to replace hazardous substances or operations with less hazardous ones?
- Minimise; has any work been done since the last review to reduce the quantity of hazardous substances?
- Simplify; has any work been done since the last review to reduce complexity?
- Moderate; has any work been done since the last review to introduce new or improve existing prevention or mitigation measures?
- Since the last review, have there been any changes to Best Available Technique?
- Do all elements of the process comply with current Best Available Technique?
- Since the last review, have there been any changes to product registration / REACH / product stewardship requirements?
- Since the last review, have any risk control measure improvements that were previously ruled out as not practicable on cost benefit grounds been re-assessed?

Summarise any inherent safety work that has been carried out since the last review.

Substances / Materials Review

Ask questions such as those below and record the responses;

- Since the last review have any new substances / materials been introduced, or have there been any changes to the quantities, physical properties, composition or methods of handling of any existing substances / materials?
    - Raw Materials
    - Intermediate process streams or recycle streams
    - Co-Product, by-product or waste streams
    - Products / Finished products
    - Wastes / Trade Effluent
    - Ancillary Chemicals / Services / Treatment chemicals
- Since the last review have any new hazardous substances / materials been introduced or has the hazard classification of any existing substance / material changed? e.g. have any new hazards been introduced or have any existing hazards significantly changed
- Since the last review have there been changes to;
    - Special practices / REACH exposure scenarios
    - Storage or Transport
    - Problems in Handling
    - Process Conditions
    - Materials of Construction Corrosion / Erosion etc.
    - Decontamination
    - Emissions / Releases (gases, aqueous, particulate)
    - Effluent / Waste Disposal
    - Abatement Systems
- Quality Control / HACCP
- Emergency Procedures
- Plant Layout, Spacing, Access
- Hazardous Area Classification
- Provision of Services
- Other Codes of Practice

Legislation and Other Requirements Review

Ask questions such as those below and record the responses;

- Since the last review, have there been any changes in major accident / process safety, e.g. fire / explosion, legislation?
- Since the last review, have there been any changes in occupational health and safety legislation?
- Since the last review, have there been any changes in environmental legislation?
- Since the last review, have there been any changes in environmental legislation?
- Since the last review, have there been any changes in legally binding contracts or agreements? e.g. specialist maintenance contracts, waste trade agreements
- Since the last review, have there been any changes in relevant legal good practice and standards? e.g.
    - Explosion prevention and protection systems
    - Hazardous area classification
    - Fire protection systems
    - High voltage and low voltage electrical equipment
    - Earthing and lightning protection systems
- Since the last review, have there been any regulatory process safety recommendations, improvement actions?
- Since the last review, have there been any relevant 3rd party process safety audit recommendations?
- Since the last review, have there been any relevant internal process safety audit recommendations?

Plant / Equipment Modification Review

Ask questions such as those below and record the responses;

- Since the last review, have there been any plant or equipment modifications?
- If so – was a plant / equipment modification management process followed?
- Has there been numerous minor “non-significant” plant / equipment modifications? e.g. could creeping change have occurred

Process Change Review

Ask questions such as those below and record the responses;

- Since the last review, have there been any process changes?
- If so – was a process change management process followed?
- Has there been numerous minor “non-significant” process changes? e.g. could creeping change have occurred

Organisational Change Review

Ask questions such as those below and record the responses;

- Since the last review, have there been any organisational changes e.g. changes in organisation or resources or changes in the competence (training & experience) of any of the following groups?
    - Production / Operations Management
    - Production Operators
    - Maintenance Management
    - Maintenance Technicians

    - Discipline Engineers e.g. Process, Mechanical, Electrical, Control, Instrumentation
- If so – was an organisational change management process followed?
- Has there been numerous minor "non-significant" organisational changes? e.g. could creeping change have occurred

The above approach and results should then be used to determine the requirements for risk assessment review or other assessments / reviews and to justify or explain the reasoning for the decisions made.

Formal detailed lifecycle reviews

Ask questions such as those below and record the responses;

- Is there need for further formal detailed lifecycle reviews? e.g.
    - Stage 2 (Preliminary Hazard Assessment)
    - Stage 3 (Explosion Risk Assessment / Detailed Design Review)
    - Stage 4 (Pre-start-up Re-verification / Re-validation)

Formal reviews of risk assessments

Ask questions such as those below and record the responses;

- Is there need for further formal reviews of risk assessments? e.g.
    - Explosion risk assessment
    - Hazardous area classification
    - Fire risk assessment
    - Preventive maintenance, inspection or testing regimes
    - Emergency response

The assessment team members should review the assessment form to confirm it is a valid representation of the discussions.

4.5.3 Example Plant Modification; Replacement of wheat cleaning sieve

In most cases replacement of an old wheat cleaning sieve with a new sieve with the same throughput and duty can be effectively managed using a management of change system and control form as described in Section 3.3. The process is illustrated for this example in Appendix H and the key findings are summarised below;

- Minor changes to explosion risk assessment and hazardous area classification, but no change to the basis of safety e.g. slight reduction in risk as the new sieve will be Ex equipment
- Reduction in risk of dust release into the workplace e.g. slight reduction in health hazard exposure and explosion risks
- Minor changes to machinery / equipment use risk assessment
- New CE Ex equipment and machinery and control system(s), with changes to preventive maintenance and inspection regimes
- Changes to operating instructions and new training needs
- Changes to maintenance instructions and new training needs

4.5.4 Example Process Change; Change in gluten supply

In most cases it should be possible to change gluten supply without the need to follow the full scope of a process change management procedure of the type discussed in Section 3.4. However, there is potential for the design basis of the explosion relief on a gluten silo to be exceeded. As discussed in Section 4.2.3 regarding the design of explosion relief; old published data for Gluten indicates values for K_{st} in the range 74 -105 bar.m/s, whereas test data published by nabim indicates a value of 149 bar.m/s and supplier's safety data sheets indicate K_{st} in the range 77 – 129 bar.m/s.

There is potential for newer grades of gluten to have explosion indices that could exceed the current design bases for explosion relief particularly for older gluten silos, which may have been designed using old published data. Three scenarios exist;

- If the gluten silo has explosion relief designed using the published nabim data for explosion indices, it is highly unlikely that the basis of safety for the gluten silo will be exceeded and a simple preliminary assessment will indicate that the change has low impact in relation to explosion hazards. The change needs to be formally recorded but can then be effectively managed by following Operating and Quality Management Procedures.
- If the gluten supplier provides explosion indices for the specific grade of gluten to be used; if the explosion indices are below the values used to design the explosion relief then it is highly unlikely that the basis of safety for the gluten silo will be exceeded and a simple preliminary assessment will indicate that the change has low impact in relation to explosion hazards. The change needs to be formally recorded but can then be effectively managed by following Operating and Quality Management Procedures.
- If the explosion indices exceed those used for the design of explosion relief, or if there is uncertainty in the explosion indices, the full scope of the process change management procedure should be followed and include a full basis of safety review and explosion risk assessment review and revision.

The process is illustrated for this example in Appendix H showing;

- If it can be demonstrated that the design basis for gluten silo explosion relief are not exceeded using a simple initial assessment; the change can be effectively controlled using Operating and Quality Management Procedures.
- If there is uncertainty in the explosion indices, then sampling and testing should be considered as soon as possible to enable a meaningful review of explosion risk assessments.
- If the explosion indices exceed the design basis for explosion relief; detailed explosion risk assessment, including cost benefit analyses for potential improvements to other risk controls, should be carried out ideally before approval of the change, but as a minimum before the change is introduced to the plant.

4.5.5 Example Organisational Change; Replacement of an engineer

As discussed in Section 3.5, changes within an organisation can vary widely in terms of depth and complexity and can have a wide range of impacts to major accident hazards, other process hazards as well as occupational health, safety and environmental hazards. It is therefore difficult to give detailed examples for complex changes, however the example scenario discussed below illustrated how an organisational change management system can be used in a common situation.

The example covers the replacement of an experienced electrical engineer and the approach taken will vary depending on how well an organisation or site has developed and implemented management systems (standards, procedures etc.) such as;

- Formal management systems for key risk control systems e.g. management of electrical equipment in hazardous areas
- Formal documentation of key roles and responsibilities relating to management of key risk control systems
- Formal competence management, training / development and recruitment systems

Initially, replacement of an experienced electrical engineer may appear to be a “like-for-like” change. However, the following points should be noted and carefully considered;

- The current experienced electrical engineer is likely to have many years of experience that is relevant to flour milling e.g. underpinning knowledge and understanding of explosion hazards and risk controls and how they apply in flour milling

- The replacement engineer may not have the underpinning knowledge and understanding of explosion hazards and risk controls and how they apply in flour milling
- The current experienced electrical engineer is likely to have developed the behavioural skills (e.g. managerial skills, communication or interpersonal skills and professional commitment) required for management of explosion hazards
- The replacement engineer may have the required technical competence; however, it must be noted that the behavioural skills required for management of explosion hazards are not covered by the technical training
- In lean organisations, it is common for an experienced engineer to take on other key management roles and responsibilities that are not directly related to his technical discipline. It is important to identify these and ensure that they are transferred to another experienced person within the organisation.

The process for managing this organisational change is illustrated for this example in Appendix H. The illustrative example assumed that the site / organisation currently relies heavily on the knowledge and experience of engineers and managers, rather than having formally defined management systems.

Part 2 of the change control form is used to identify the points raised above which mainly relate to the loss of many years of experience in a role that is key to management of explosion hazards.

In Part 3 of the form, the change is categorised as Significant e.g. it has potential significant impact on major accident hazard (explosion) risk. However, if the organisation had an appropriate set of management systems and standards with, formally documented roles and responsibilities as discussed above, the change could be classified as Minor e.g. minor impact on major accident hazard risk.

If in doubt, it is best to assign the higher category to a change and use Part 4 of the form to develop a relatively straightforward implementation plan, which is summarised below;

- Map the key roles and responsibilities carried out by the current engineer and those to be carried out by the new engineer
- Develop competence requirements for each of the key roles and responsibilities

- Carry out a competence assessment / training needs assessment for the new engineer
- Finalise the implementation plan depending on the findings of the competence assessment / training needs assessment e.g.
    - Training and development of the new engineer
    - Supervision and support needs for the new engineer
    - Transfer of other roles or responsibilities to another experienced person

APPENDIX A; EXAMPLE PRELIMINARY HAZARD ASSESSMENT

RAW WHEAT INTAKE SYSTEM (illustrative example only)						
HAZARDOUS EVENT		CAUSED BY	CONSEQUENCE	PREVENTION MEASURES	MITIGATION MEASURES	COMMENTS / NOTES
1	External Fire	Ignition of combustible materials including grain and grain dust	Fire escalating at slow – medium speed with potential to spread or for smouldering / burning material to enter grain intake system	Housekeeping to prevent build-up of combustible materials, grain or dust. General controls on external ignition sources, hot work etc.	Fire detection, alarm and means of escape. Emergency fire-fighting procedures.	Fire hazards should be assessed by carrying out a fire risk assessment
2	Internal Fire	Ignition of grain or grain dust inside intake pit, conveyors, elevator or silos	Smouldering fire, slow escalation but with potential to spread downstream and become an ignition source for a dust explosion	Preventive maintenance / inspection of equipment according to OEM instructions.		Ignition and internal fire within equipment and potential for ignition source transmission downstream to be considered further in explosion risk assessments
3	Internal Explosion (deflagration)	Rousing of dust and ignition within the grain intake pit	Dust explosion within the intake pit, flame release into the grain offloading bay and secondary explosion (see below)	Gravity discharge and relatively low dust content of grain. Hazardous area classification, with Ex equipment and earthing of metallic parts	Open nature of intake pit will minimise any pressure effects. Housekeeping to prevent dust layer accumulation is important to prevent more serious secondary explosion in the grain offloading area	Significant hazard; requires explosion risk assessment.
4	Internal Explosion (deflagration)	Rousing of dust and ignition within grain conveyors	Dust explosion within the conveyor, flame release into the area. Potential for secondary explosion (see below)	En-masse conveying and relatively low dust content of grain. Hazardous area classification, with Ex equipment and earthing of metallic parts	Housekeeping to prevent dust layer accumulation is important to prevent more serious secondary explosion	Significant hazard; requires explosion risk assessment
5	Internal Explosion (deflagration)	Rousing of dust and ignition within grain bucket elevators	Dust explosion within the elevator, flame release into the mill building and secondary explosion (see below)	Dust aspiration on the elevators Relatively low dust content of grain. Hazardous area classification, with Ex equipment and earthing of metallic parts	Explosion relief on bucket elevators, venting to safe outdoor location.	Significant hazard; requires explosion risk assessment
6	Internal Explosion (deflagration)	Rousing of dust and ignition within raw wheat silos	Major dust explosion within the silo, potential to propagate to adjacent silos in silo block	Hazardous area classification, with Ex equipment and earthing of metallic parts	Weak roofed silo design minimises pressure effects. Outdoor location means minimal impact on the mill building	Significant hazard; requires explosion risk assessment.
7	Unconfined Explosion (deflagration)	Rousing of dust and ignition outdoors	Flash fire, no pressure effects.	Outdoor location and housekeeping prevent dust layer accumulation, making dust cloud formation very unlikely.	Open uncongested area prevents pressure effects	Hazard not expected to be significant – review when carrying out explosion risk assessment
8	Violent release of energy	No other sources of significant energy made known or identified				

APPENDIX B: EQUIPMENT SELECTION / SPECIFICATION

Equipment in hazardous areas, referred to as Ex equipment, requires special precautions for the construction, installation and use of equipment. When selecting equipment for use in hazardous (zoned) areas the equipment must have specific measures applied to equipment to avoid ignition of a surrounding explosive atmosphere.

Ex equipment is CE marked against the essential health and safety requirements (EHSR) of the ATEX Equipment Directive, which is implemented in the UK by the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (EPS Regulations). The required marking is shown below;

New equipment for use in hazardous areas is selected on a range of parameters;

- The type of explosive atmosphere e.g. gas, vapour
- The zone in which it is located or connected to
- The maximum surface temperature allowed in operation, which is specified based on the ignition temperature(s) of the materials that may be present
- Additional requirements are also applicable in some circumstances e.g.
    - Where the ambient temperature exceeds 40°C
    - Where there may be excessive dust layers > 5mm depth

B.1 Equipment Group

Electrical equipment for use in hazardous area zones is classified, into groups, relating to the type of explosive atmosphere for which it is to be used;

- Group I; electrical equipment for mines susceptible to firedamp
- Group II; electrical equipment for places with an explosive gas atmosphere, other than mines susceptible to firedamp
- Group III; electrical equipment for places with an explosive dust atmosphere

Groups II and III are sub-divided into the following location-based parameters;

Sub-group	Meaning
IIA	Gases and vapours such as propane
IIB	Gases and vapours such as ethylene
IIC	Gases and vapours such as acetylene and hydrogen
IIIA	Combustible flyings e.g. fibres
IIIB	Non-conductive dust
IIIC	Conductive Dust (electrical resistivity ≥10^3 Ωm)

The required equipment group for equipment is selected according to the table below;

Location based group and sub-division	Permitted equipment group
IIA	II, IIA, IIB or IIC
IIB	II, IIB or IIC
IIC	II or IIC
IIIA	IIIA, IIIB or IIIC
IIIB	IIIB or IIIC
IIIC	IIIC

For the types of dusts encountered in zoned areas in flour milling are non-conductive; therefore, Group IIIB applies in these areas.

Hazardous areas for gases and vapours are for gases, vapours or mists are not envisaged, but if they do exist, they are likely to be associated with ancillary areas. For illustrative purposes examples are given;

- Zoned areas for fuels such as natural gas or LPG would require Group IIA, but equipment marked Group IIB or IIC could also be used.
- Zoned areas for hydrogen e.g. large battery charging areas, would require Group IIC equipment.
- Equipment marked Group II e.g. without the sub-division A, B or C is suitable for use in all cases for gases and vapours.

B.2 Equipment Protection Level

Ex equipment is assigned an Equipment Protection Level (EPL), which is a measure of the integrity of ignition protection applied to the equipment. It is similar in concept to protection levels used in general machinery safety and has recently replaced Equipment Categories, which were the original method of measuring the integrity of ignition protection. Three levels of integrity for ignition protection are defined;

- **Very High;** equipment which is not a source of ignition in normal operation, during expected malfunctions or during rare malfunctions
- **High;** equipment which is not a source of ignition in normal operation, during expected malfunctions or during rare malfunctions
- **Enhanced;** equipment which is not a source of ignition in normal operation and which may have some additional protection to ensure that it remains inactive as an ignition source in the case of regular expected occurrences

EPLs are also divided based on the type of explosive atmosphere for which it is to be used e.g. they are aligned with the Equipment Groups in Section B.1;

EPL	Meaning
Ma	Group I equipment with a "very high" Level of Protection
Mb	Group I equipment with a "high" Level of Protection
Ga	Group II equipment with a "very high" Level of Protection
Gb	Group II equipment with a "high" Level of Protection
Gc	Group II equipment with an "enhanced" Level of Protection
Da	Group III equipment with a "very high" Level of Protection
Db	Group III equipment with a "high" Level of Protection
Dc	Group III equipment with an "enhanced" Level of Protection

The required EPL for equipment is selected based on the Zone in which the equipment is located or connected to;

Zone	Equipment Protection Level	ATEX Category for information
0	EPL Ga	1G
1	EPL Ga, Gb	1G or 2G
2	EPL Ga, Gb, Gc	1G, 2G, or 3G
20	EPL Da	1D
21	EPL Da, Db	1D or 2D
22	EPL Da, Db, Dc	1D, 2D or 3D
NB; It is important to recognise that explosion risk assessment may determine that a higher level of protection than the minimum specified above.		

B.3 Types of Protection

Ex electrical equipment has recognised types of protection according to IEC standards

Type of protection	Code	According to
Flameproof enclosure	“d”	IEC 60079-1
Pressurized enclosure	“p”	IEC 60079-2
Powder filled	“q”	IEC 60079-5
Oil immersion	“o”	IEC 60079-6
Increased safety	“e”	IEC 60079-7
Intrinsic safety	“i”	IEC 60079-11
Protection by pressurized room	“p”	IEC 60079-13
Protection by artificially ventilated room	“v”	
Non-sparking electrical equipment	“n”	IEC 60079-15
Encapsulation	“m”	IEC 60079-18
Enclosure	“t”	IEC 60079-31
Special protection	“s”	IEC 60079-33

A default relationship between EPLs and some types of protection is given in Table 2 of EN 60079-14. However, EPLs can differ from these defaults and where this occurs the EPL

marked on equipment takes precedence. Part of Table 2 relating to dusts is reproduced below for information / illustrative purposes.

EPL	Type of protection	Code	According to
Da	Encapsulation	“ma”	IEC 60079-18
	Protection by enclosure	“ta”	IEC 60079-31
	Intrinsically safe	“ia” or “iaD”	IEC 60079-11 or IEC 61241-11
	Special protection	“sa”	IEC 60079-33
Db	Encapsulation	“mb”	IEC 60079-18
	Protection by enclosure	“tb” or “tD”	IEC 60079-31 IEC 61241-1
	Pressurized enclosures	“pD”	IEC 61241-4
	Intrinsically safe	“ib” or “ibD”	IEC 60079-11 or IEC 61241-11
	Special protection	“sb”	IEC 60079-33
Dc	Encapsulation	“mc”	IEC 60079-18
	Protection by enclosure	“tc” or “tD”	IEC 60079-31 IEC 61241-1
	Pressurized enclosures	“pD”	IEC 61241-4
	Intrinsically safe	“ic”	IEC 61241-11
	Special protection	“sc”	IEC 60079-33

It is important to note that not all types of protection are applicable to gas and / or dust hazardous areas and that the preferred types of protection for each different type of equipment e.g. motors, instrumentation, should be standardised on a site wherever possible for ease of maintenance and inspection.

B.4 Maximum Surface Temperature

Ex equipment is selected so that its maximum surface temperature will not reach the ignition temperature of any gas, vapour or dust which may be present. For gases and vapours the maximum surface temperature must not exceed the auto ignition temperature (AIT) of the relevant gases / vapours. For dusts, a safety margin needs to be applied to auto-ignition temperatures and the maximum surface temperature of equipment should not exceed whichever is the lower value of;

- Minimum (dust cloud) ignition temperature (MIT_{cloud}) x ⅔
- 5mm Layer ignition temperature (LIT_{5mm}) - 75°C

The Temperature Class system is often used, it indicates the maximum surface temperature achieved in normal operation in an ambient temperature environment of no more than 40°C.

Class	Maximum surface temperature °C
T1	450
T2	300
T3	200

Class	Maximum surface temperature °C
T4	135
T5	100
T6	85

For the illustrative purposes in this appendix, it is assumed that the following values will cover the materials handled in a typical flour mill;

- Minimum (dust cloud) ignition temperature (MIT_{cloud}) ≥ 400ºC;
- 5mm layer ignition temperature (LIT_{5mm}) ≥ 275ºC

The maximum surface temperature of equipment should not exceed ⅔ x MIT= 260ºC or LIT - 75°C = 200ºC, whichever is lowest. This equates to a temperature class of T3 (maximum surface temperature 200ºC).

Additional requirements apply for cases where

- Ambient temperature is above 40ºC (see Section B.5 for details)
- Dust layers in excess of 5mm exist (see Section B.6 for details)

B.5 Ambient Temperature

The default ambient temperature range used for the design of ex equipment is -20ºC to 40ºC. If the ambient temperature is outside this temperature range, or if there is a temperature influence from other factors, e.g. the process temperature or exposure to solar radiation (sunlight).

These effect on equipment should be considered and where appropriate, equipment should be specified to have a wider design ambient temperature range than the default.

Ex equipment designed for use outside of this default temperature range will be clearly marked to indicate its design temperature range.

Cable glands normally do not have a temperature class or ambient operating temperature range marking. They do have a rated service temperature and unless marked, the service temperature is by default in a range of –20°C to 80°C. If different service temperatures are required, care should be taken, that the cable gland and the associated parts are suitable for such applications.

B.6 Excessive Dust Layers

Dust is generally a good insulator and prevents heat from dissipating from equipment. Where dust layers form on equipment, this insulating effect requires consideration. For dust layers up to 5mm in depth, the 75°C safety margin discussed in Section B.4 is applicable.

Where dust layers are greater than 5mm additional safety margins need to be applied, the effects of this are summarised below for a dust with 5mm layer ignition temperature of 275ºC.

Dust Layer Depth	Maximum permitted surface temperature °C	T Class
≤ 5mm	200	T4
10mm	170	T5
20mm	130	T6

For installations where the dust layer depth is greater than 50 mm, the maximum surface temperature of equipment must be specified, and the equipment used must be designed and marked with the maximum surface temperature T_L as reference to the permitted layer depth. The maximum surface temperature of the equipment T_L should be at least 75 °C lower than the ignition temperature of the dust, at layer depth L.

Where unavoidable dust layers form around the sides and bottom of equipment, or where equipment is totally submerged in dust, the insulation effect is much greater, and a much lower surface temperature may be necessary.

B.7 External Influences

In common with all electrical equipment, Ex electrical equipment should be selected and / or installed so that it is protected against external influences which could adversely affect the explosion protection. EN 60079-14 lists a wide range of these influences (see below). Only a limited number of these are likely to exist in a typical flour mill e.g. vibration associated with sifters and screens

- Extremely low or high temperatures
- Solar radiation
- Pressure conditions
- Corrosive atmosphere
- Vibrations
- Mechanical impacts
- Friction or abrasion
- Wind
- Painting processes
- Chemicals
- Water and moisture

- Dust
- Plants, animals, insects.

External influences should be identified as part of the installation design and selection of equipment for the installation and the measures applied for control should be documented and included in the verification dossier. It is also beneficial to justify why external influences have been ruled out as not credible.

Where equipment is subject to prolonged humidity and wide temperature variations that may lead to condensation affecting the type of protection; the equipment should have been designed to provide suitable measures to ensure satisfactory prevention of condensation or draining of any condensate.

B.8 Transportable, portable and personal equipment

Due to the demand of the application and enhanced flexibility for use, transportable, portable or personal equipment may be required to be used in a range of locations or areas. Equipment of a lower EPL should not be taken into an area requiring a higher EPL, unless it is otherwise protected.

In practice, such a limitation may be difficult to enforce and ideally all portable equipment should meet the requirements of the location to which the equipment will be exposed which requires the highest EPL. Similarly, the equipment group and temperature classification should be appropriate for all the gases, vapours and dusts in which the equipment may be used.

Transportable and portable equipment is generally only used in hazardous areas on a temporary basis and can include emergency generators, welding sets, fork lift trucks, air compressors, ventilation fans or blowers, portable electrically powered tools and testing / inspection equipment. Non-Ex transportable and/or portable equipment can be used if its use is controlled by appropriate safe work control system e.g. operating or maintenance procedures, risk assessment / method statements (RAMS) or permit to work (PTW) systems. If plugs and sockets are present in a hazardous area, they should be to the required EPL for the area. Alternately, they should only be energised, or connections made under a safe work control system.

Items of personal equipment which are battery or solar operated are sometimes carried by personnel and inadvertently taken into a hazardous area. Basic electronic wrist watches are an example of a low voltage, electronic devices which have been independently evaluated and found to be acceptable for use in a hazardous area under both historic and current EPL requirements.

All other personal battery or solar operated equipment, including modern electronic watches which incorporate other devices, should either

a) conform to a recognised type of protection appropriate to EPL, gas/dust group and temperature class requirements, or
b) be subjected to a risk assessment, or
c) be taken into the hazardous area under a safe work procedure

It should also be noted that there is an increased risk associated where lithium batteries are used to power personal electronic equipment.

For a typical flour mill, where the zoned areas are limited to dusts, workplaces zones are typically localised Zone 22 areas, with only a limited number of Zone 21 areas, and where the equipment group and temperature classification are standard throughout the mill; the recommended approach can often be simplified e.g.

- Items of transportable or portable electrical equipment which are routinely used for long periods of time in zoned areas of the workplace, should conform to a recognised type of protection appropriate to EPL, gas/dust group and temperature class requirements
- Items of transportable or portable electrical equipment which are occasionally used for short periods of time in zoned areas of the workplace should be controlled by appropriate work control systems, based on a risk assessment for their use
- Site policies should be put in place for personal battery or solar operated equipment such as watches, smart watches, fitness bands / trackers and mobile phones

B.9 Equipment Marking

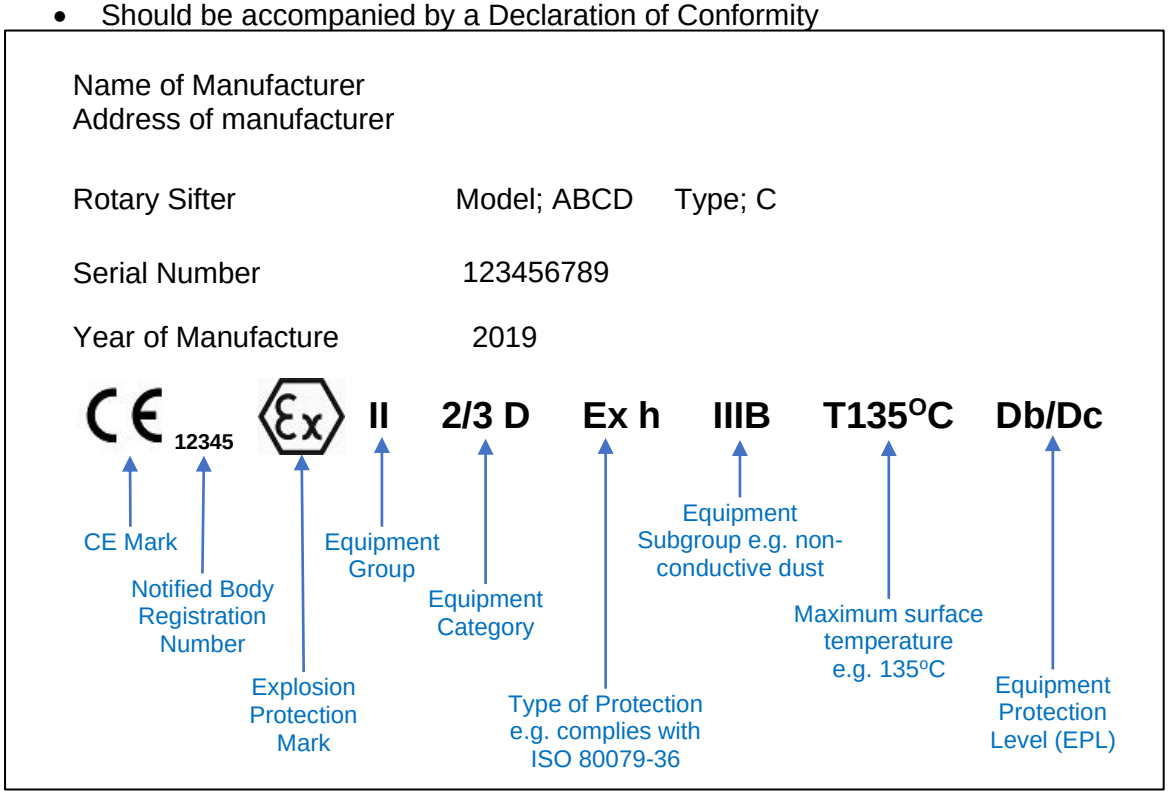
The manufacturer is required to fix the CE marking, including appropriate Ex marking, to Ex Equipment and explosion protection devices / systems. Markings must be legible and indelible and include the following minimum information;

- CE conformity assessment mark CE
- Explosion protection mark Ex followed by symbols for equipment group and category
- Markings to enable full identification, as a minimum
    - Name and address of the manufacturer
    - Designation of series or type
    - Batch or serial number, if any
    - Year of construction
    - Information essential to safe use, e.g. restricted conditions of use

Illustrative example nameplates are shown on the following pages;

Figure B.1 Illustrative Example Markings; non-electrical equipment

- Should be accompanied by a Declaration of Conformity

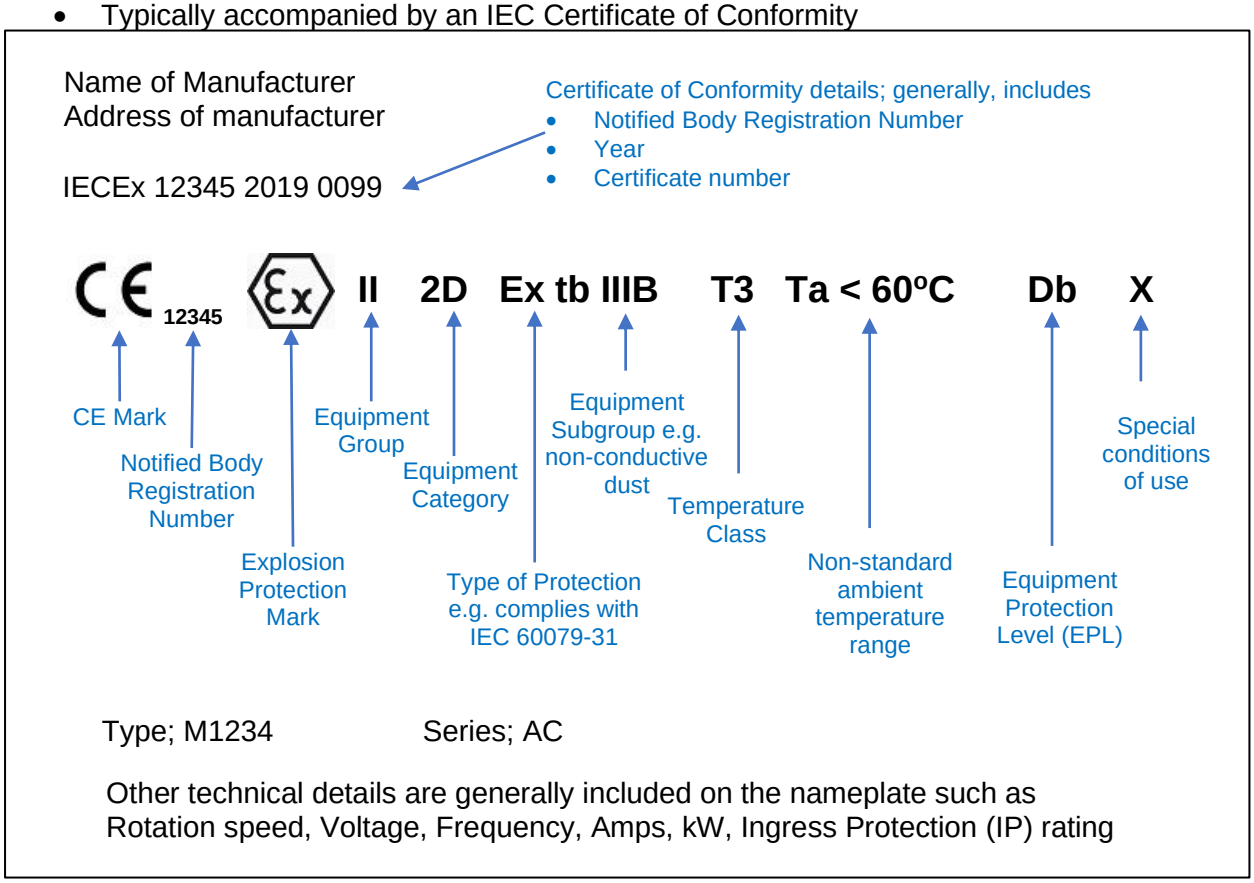


Key to Ex Marking;

- Equipment Group II; equipment is for use places other than mines which are liable to be endangered by explosive atmospheres
- Equipment Category 2/3D; indicates the suitability of equipment for the zone
  - D; indicates for use in dust zoned areas
  - 2/3; indicates the equipment has two different categories
    - Category 2; suitable for Zone 21 e.g. connected to pneumatic transfer system which is internally classified Zone 21
    - Category 3; suitable for Zone 22 e.g. located in a workplace which is classified Zone 22
  - The documentation accompanying the equipment should clearly define the part of the equipment which is Category 1 and the part that is Category 2.
- Type of Protection Ex h; indicates the equipment complies with ISO 80079-36
- Equipment Subgroup IIIB; indicates suitable for use with non-conductive dusts
- T135°C; indicates the maximum surface temperature of the equipment – in this case the ambient temperature is the standard / default of 40°C maximum ambient
- Equipment Protection Level Da/Db; indicates the suitability of equipment for the zone
  - Db/Dc; indicates the equipment has two different Equipment Protection Levels
    - Db; suitable for Zone 21 e.g. connected to pneumatic transfer system which is internally classified Zone 21
    - Dc; suitable for Zone 22 e.g. located in a workplace which is classified Zone 22

Figure B.2 Illustrative Example Markings; electrical motor

- Typically accompanied by an IEC Certificate of Conformity



Key to Ex Marking;

- Equipment Group II; equipment is for use places other than mines which are liable to be endangered by explosive atmospheres
- Equipment Category 23D; indicates the suitability of equipment for the zone
  - D; indicates for use in dust zoned areas
  - 2 indicates Category 2; suitable for Zone 21
- Type of Protection Ex tb; indicates the equipment complies with IEC 60079-31
- Equipment Subgroup IIIB; indicates suitable for use with non-conductive dusts
- Temperature Class T3; indicates maximum surface temperature 200ºC – but in this case note the non-standard maximum ambient temperature; 60ºC
- Equipment Protection Level Db; indicates suitable for Zone 21
- X; indicates special conditions of use - the documentation accompanying the motor should clearly define the special conditions of use, if these are not displayed on the nameplate.

Notes;

- Care must be taken if motors are used with variable speed inverter drives as these can affect the maximum surface temperature. The documentation accompanying the motor should clearly define the requirements if variable speed drives are used.

APPENDIX C EQUIPMENT SUPPLY; KEY DOCUMENTATION

All equipment and explosion protection systems falling within the scope of the ATEX Equipment Directive must be accompanied two key types of documents, which should be transferred through the supply chain from the manufacturer to the end user;

- Instructions and safety information to allow safe installation, use, repair, maintenance and / or overhaul.
- A Declaration of Conformity, which declares the equipment as “safe” for its intended use. In a limited number of cases an attestation of conformity in conjunction with other required documents can be used.

These documents can often become lost in supply chains and it is imperative that they are available to the required groups of people at the appropriate stages e.g. installation, commissioning and operation / maintenance.

C.1 Instructions

Clear instructions and information must be provided in a language that is easily understood by the user. The form of the instructions e.g. paper or electronic, is not specified, however, since it cannot be assumed that the user has access to the means of reading instructions supplied in electronic form or made available on an internet site, paper copies are normally provided in addition to electronic copies.

Legally, the instructions must include the following as a minimum;

- The information that the equipment is marked with, except for the serial number
- Appropriate information to facilitate maintenance e.g. address of the importer, repairer
- Instructions, including necessary drawings and diagrams for safe use including
    - Installation
    - Putting into service, e.g. commissioning
    - Assembling and dismantling,
    - Adjustment
    - Maintenance (servicing and emergency repair),
- Drawings and diagrams necessary to make the instructions clear
- Electrical and pressure parameters, maximum surface temperatures and any other limit values
- Where necessary, the following additional information should be provided;
    - An indication of the danger areas in front of pressure-relief devices
    - Training instructions
    - Special conditions of use, including details of possible misuse which experience has shown might occur
    - Details of tools which may be fitted to the equipment or protective system

C.2 Declaration of Conformity

A Declaration of Conformity is a formal declaration by the manufacturer that equipment meets the essential health and safety requirements of all relevant European Directives, including the ATEX Equipment Directive e.g. declares the equipment is “safe” for its intended use.

In relation to the ATEX Equipment Directive, the contents of an EU Declaration of Conformity are legally defined and must contain the following statements and information;

Requirement	**Notes / Comments**
EU DECLARATION OF CONFORMITY (No XXXX)	The heading must clearly state that the document is an EU Declaration of Conformity. A reference number is not mandatory, but it can be useful for traceability purposes
1. Product model / product (product, type, batch or serial number)	This point should reflect the unique identification of the product.
2. Name and address of the manufacturer and, where applicable, his authorised representative	Straightforward, noting that the name (and/or the identification mark) on the product places the named organisation in the position of manufacturer (or his authorised representative in the European Union).
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.	Reaffirming the overall responsibility of the manufacturer on the product to be placed or put into service on the EU market.
4. Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image)	This includes the description of the concerned product: it could be a descriptive product designation e.g. Motor Control Unit Type ABC 123 and its intended use. For an assembly it should list the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed. Indication of all relevant provisions fulfilled by the equipment would include the markings affixed on the product, e.g. equipment group II, category 2 G (IIB T4).
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation	The references of the legislative acts (Regulations or Directives) to which conformity of the product is declared. If it is a multi-directive declaration, it should already be clear from the heading which directives the product conforms to. It is sufficient to indicate the codification or numbering of the legislative act (e.g. "Directive 2014/34/EU", "Directive 2006/42/EC", etc.) with no need to indicate the complete title and the publication references.

Continued on following page

Requirement	Notes / Comments
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared	The European harmonised standards quoted in the technical documentation file shall be indicated here. They should be indicated as listed in the relevant publication in the Official Journal of the European Union, being sufficient to indicate the number and the year of publication (e.g. "EN 1010-1:2004+A1:2010", "EN 60079-0:2012", etc.) and not by the national editions (BS, DIN, NF, UNI, UNE etc.), also taking into consideration that the year could be different. Where appropriate, other standards and/or technical specification used, as quoted in the technical documentation, should be indicated here, along with the justification for the use of a non-harmonised standard.
7. Where applicable, the notified body ... (name, number) performed … (description of intervention) and issued the certificate	Name and number of the notified body (or bodies) conducting the EU-type examination. Indication of the notified body's identification number, when applicable (where involved in the production phase) can be seen as a support to market surveillance actions. In the case of category 2 non-electrical equipment, it should refer to the notified body holding the copy of the technical documentation file. Where relevant, if the body responsible for oversight of the QA regime is not the same as the one issuing the original certificate, it should be named separately. However, the name and address of a notified body involved in the production phase is not a mandatory requirement. There shall be no reference to a notified body certificate unless it is one coming within the scope of the Directive. Voluntary certificates issued by bodies in their "private" capacity as certification bodies should be included in the technical documentation file as part of the evidence of conformity but should not be quoted on the declaration of conformity.
8. Additional information	Any other additional information that could be considered relevant for the declaration.
Signed for and on behalf of: (place and date of issue) (name, function) (signature)	Identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer. The signatory needs to be a responsible officer of the manufacturer or of the authorised representative.

C.3 Attestation of Conformity

The EU Declaration of Conformity must not be confused with the written attestation of conformity for components or an EU-Type examination certificate.

- An attestation of conformity for components. Components are products which have no autonomous function, but which are essential to the safe functioning of equipment and protective systems with respect to explosion protection. Examples include;
    - Terminals
    - Push button assemblies
    - Relays

    - Empty flameproof enclosures
    - Ballasts for fluorescent lamps
    - Encapsulated relays and contactors, with terminals and/or flying leads
    - Machinery brakes designed to be part of ATEX equipment
    - Pressurised containers including suppressant powder forming part of an explosion suppression system
    - Conveyor belting for a conveyor transporting combustible dusts
    - Suction hoses used on vacuum cleaners
    - Forks for forklift trucks
- An EU-Type Examination Certificate for a product is an attestation, issued by a registered Notified Body, that a product has undergone all the necessary conformity assessment procedures that result in the issuing of an EU-type examination certificate; it is not necessary for such products to undergo such conformity assessment procedures e.g. the Manufacturer does not have to issue a Declaration of Conformity for that particular product.

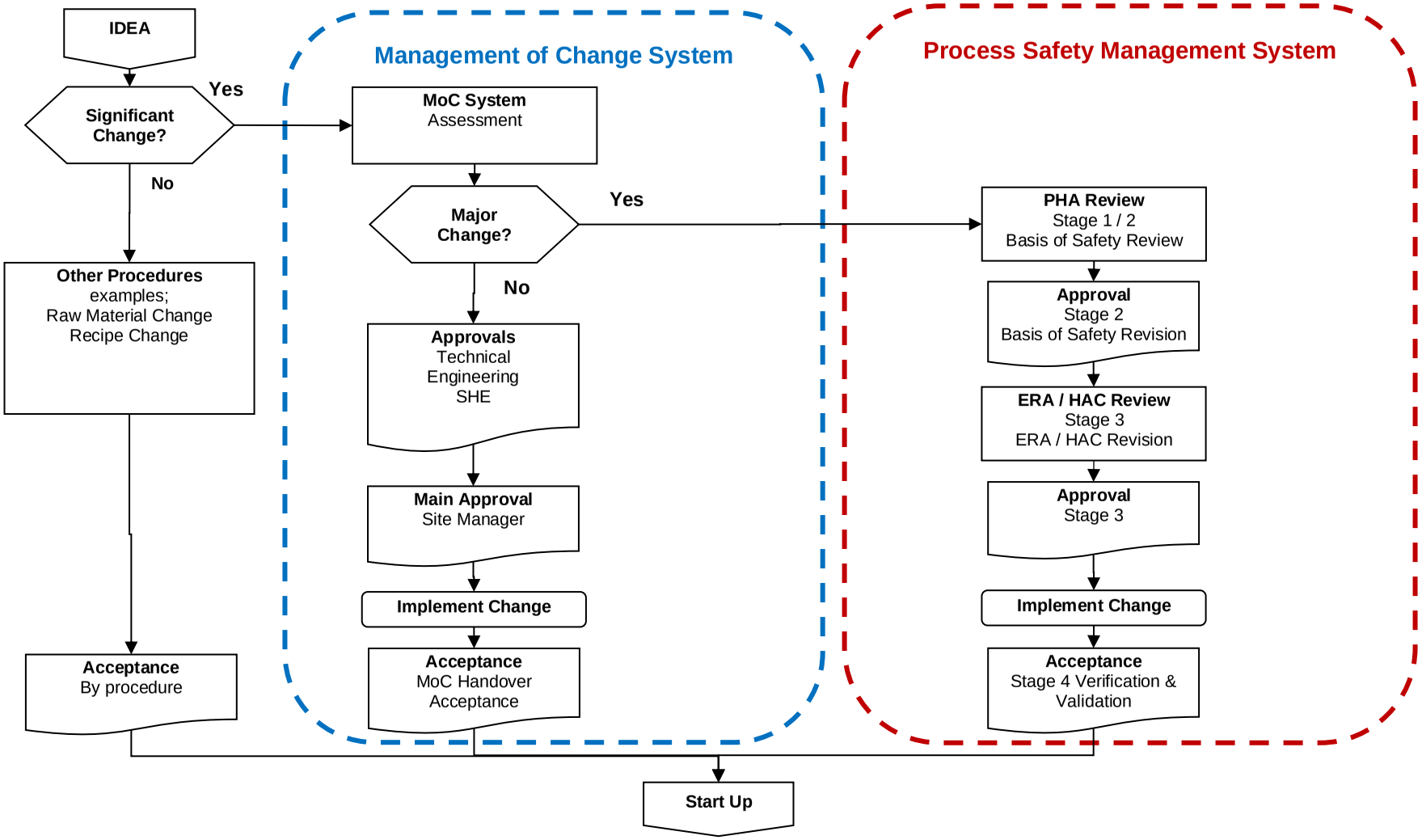
One example where an attestation of conformity for components is applicable, rather than a Declaration of Conformity, is a bucket elevator conveying belt, which is required to be manufactured from antistatic flame-retardant material for an ATEX Categorised bucket elevator.

C.4 Declaration of Incorporation

A Declaration of Incorporation is used when a manufacturer cannot issue a Declaration of Conformity because the product is incomplete and is designed to be incorporated into other apparatus which will then be CE marked before it is supplied to an end user.

It is important to note that the ATEX Equipment Directive, in line with other specialist equipment directives, does not contain provisions for the use of a Declaration of Incorporation. Declarations of Incorporation are only applicable the Machinery Directive.

APPENDIX D; CATEGORIES OF CHANGE



APPENDIX E. EXAMPLE PLANT / EQUIPMENT MODIFICATION CONTROL FORM

Site;		Dept;		Ref;	*Example Only*
Originator;				Date;	
Title;				Permanent or Temporary delete	

PART 1; DESCRIPTION OF THE MODIFICATION / CHANGE	
Description (attach drawings / sketches and other documents if applicable): • Details can be attached as separate documents and referenced	
For temporary changes; define the expiry time period for the change	
Justification / Reason for Change:	

Type of Plant / Equipment involved;			
1. Milling • **** • **** • **** • ****	2. Heat Treatment • **** • **** • **** • ****	3. Other • Packaging • Co-Product Handling • **** • ****	4. Utilities • Natural Gas • Boilers • Fuels (e.g. diesel) • Drainage systems

ASSESSMENT TEAM – Minimum involvement; Production/Operations and Engineering

- SHE Department to review the assessment, can be involved at SHE Manager's discretion
- Other functions can be involved if required

Department	**Name**	**Job Title**
Production / Operations		
Engineering		
Technical		

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Process Safety; Fire / Explosion Hazards - Does the change;	**Yes/No**	**Comments**
Introduce or alter the location of releases of flammable materials?		
Alter the containment of a flammable material or increase the likelihood of release?		
Introduce or alter likelihood of a flammable (explosive) atmosphere?		
Introduce a source of ignition or increase the likelihood of an ignition source?		
Affect stability or controllability of any part of the process?		
Alter a fire or explosion protection or prevention system?		
Process Safety; Decomposition / Reaction Hazards - Does the change;	**Yes/No**	**Comments**
Alter the chemical composition or physical properties of materials?		
Alter the stability of materials? (e.g. during a heating or drying stage)?		
Affect stability or controllability of any part of the process?		
Alter a safety instrumented system? e.g. high temperature interlock		
Process Safety; Pressure / Temperature Hazards - Does the change;	**Yes/No**	**Comments**
Introduce potential causes of over-pressurising any part of the system?		
Alter potential causes of over-pressurising any part of the system?		
Introduce potential causes of under-pressurising any part of the system?		
Alter potential causes of under-pressurising any part of the system?		
Introduce potential causes of raising the temperature in any part of the system?		
Alter potential causes of raising the temperature in any part of the system?		
Introduce potential causes of lowering the temperature in any part of the system?		
Alter potential causes of lowering the temperature in any part of the system?		
Alter a pressure system?		
Affect equipment installed for preventing or minimising over / under pressurisation?		
Process Safety; Acute Toxic Hazards; not applicable to flour milling		
Occupational Health Hazards - Does the change;	**Yes/No**	**Comments**
Alter how any hazardous substances are handled?		
Increase exposure to hazardous substances or dusts?		
Alter or increase exposure to Biological agents? e.g. Legionella, sewerage		
Alter any exposure control systems (e.g. LEV)		
Alter or require additional PPE / RPE?		
Require any special decontamination?		
Alter a safety instrumented system?		
Alter a pressure or vacuum relief system?		
Alter the primary containment system for a health hazardous substance?		
Alter the secondary containment system (e.g. bund) for a health hazardous substance?		
Environmental Impact - Does the change;	**Yes/No**	**Comments**
Introduce or alter the location of releases of environmentally dangerous materials?		
Introduce or alter the location of releases of environmentally hazardous materials?		
Introduce or alter the location of any discharge points?		
Introduce any new effluent streams, waste streams?		
Alter the quantities of existing effluent streams or waste(s)?		
Alter the composition or physical properties of existing effluent streams or waste(s)?		
Alter any secondary containment? (e.g. bunds)		
Alter the environmental risk assessment for any part of the process?		
Affect any treatment or abatement systems?		
Require removal or decontamination of plant or equipment?		
Alter the primary containment system for an environmentally dangerous material?		
Alter the secondary containment system for an environmentally dangerous material?		

Continued on following page

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Machinery / Equipment Hazards - Does the change;	**Yes/No**	**Comments**
Introduce new or alter existing machinery or work equipment? e.g. covered by PUWER		
Affect equipment requiring inspection under legislation such as COSHH, PSSR, LOLER		
Affect guarding or interlocks designed to prevent access to dangerous parts/zones?		
Introduce or alter potential causes of high or very low temperature?		
Affect controls for starting, or restarting after stoppage?		
Affect controls for changing speed, pressure or other operating conditions?		
Affect controls for stopping the work equipment in a safe manner?		
Affect controls to bring equipment to a complete stop for health and safety?		
Affect controls which switch off all sources of energy after stopping?		
Affect emergency stop controls?		
Affect audible, visible or other warnings to alert people equipment is about to start?		
Affect means to isolate the work equipment from all its sources of energy?		
Affect the stability, fixing or clamping of work equipment?		

Machinery / Equipment Hazard Prompts List

Mechanical
- *Moving parts*
- *Moving transmission parts*
- *Moving parts involves in the process*
- *Break-up during operation*
- *Falling or ejected parts*
- *Uncontrolled movements*
- *Sharp edges, angles, rough surfaces*

Electrical
Static electricity (harm to people)
Energy Supply
- *Hydraulic*
- *Pneumatic*
- *Mechanical (kinetic)*
- *Thermal*

Extreme temperature
- *High*
- *Low*

Fire
Explosion
Noise
Vibration (harm to people)
Ionising radiation
Non-ionising radiation
Laser radiation
Emission; hazardous materials/substances
Trapping / entanglement
Slips, trips, falls

Workplace Hazards - Does the change;	***Yes/No***	***Comments***
Affect the stability and solidity of a building or structure? e.g. structural loadings		
Affect the maintenance of the workplace, and of equipment, devices and systems?		
Affect the effectiveness or suitability of workplace ventilation?		
Affect the temperature of an indoor workplace?		
Introduce harmful or offensive fumes from heating systems?		
Affect the effectiveness or suitability of workplace lighting?		
Affect the cleanliness of the workplace or build-up of waste materials in the workplace?		
Affect the free space allowing safe movement and access within the workplace?		
Affect the suitability of workstations or seating?		
Affect the suitability or condition of floors and traffic routes?		
Introduce new or alter existing causes of falls or falling objects?		
Introduce new transparent or translucent surfaces that require breakage protection?		
Affect existing transparent or translucent surfaces that require breakage protection?		
Affect safety for opening and/or cleaning windows, skylights and ventilators?		
Affect the organisation, suitability or safety of traffic (vehicle) and pedestrian routes?		
Affect the safety or suitability of doors, gates, escalators or moving walkways?		
Affect the suitability or sufficiency of sanitary conveniences or washing facilities?		
Affect the adequacy or accessibility of drinking water supplies?		
Affect the suitability for accommodation (storage) or changing of clothing?		
Affect the suitability or sufficiency or accessibility of facilities for rest and to eat meals?		

SHE Critical Equipment - Does the change;	**Yes/No**	**Comments**
Affect Safety Instrumented Systems? e.g. SIL rated interlocks		
Affect Machinery Safety Systems? e.g. PL rated interlocks		
Affect electrical equipment in hazardous Ex zoned areas?		
Affect non-electrical equipment in hazardous Ex zoned areas?		
Affect explosion prevention or protection systems or devices?		
Affect pressure systems, pressure / vacuum relief systems or flame arresters?		
Affect gas or fire detection, alarm or fire protection systems?		
Affect any other SHE Critical equipment (add detail)		

Continued on following page

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS
Regulatory Impact
Operational Impact;
Engineering Impact;
Start Up / Commissioning Impacts;
Comments or Notes;

PART 3; CHANGE CONTROL				
SHE ASSESSMENT		ACTION MANAGEMENT		
Process Safety; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
PHA / Basis of Safety revision				
Explosion risk assessment revision				
Area classification (Ex zoning) revision				
Other Process Safety risk assessment revision				
Occupational Health; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Following of procedures for introducing new substances				
Hazardous substance risk assessment revision				
Biological health hazard risk assessment revision				
Other occupational health risk assessment revision				
Environmental Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Aspects & Impacts Register revision				
Environmental risk assessment revision				
Release limit revision or sampling frequency revision				
Waste disposal hazardous waste producers licence revision				
Changes to effluent or waste treatment				
Other Environmental controls				
Machinery / Equipment Safety; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Machinery / Equipment risk assessment revision				
Lifting equipment risk assessment revision				
Other machinery / equipment risk assessment revision				
Workplace Safety; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Workstation risk assessment revision				
Traffic (vehicle) risk assessment revision				
Other workplace risk assessment revision				
Regulatory Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
REACH registration revision				
IPPC permit revision				
Any other regulatory license or permit revision				
SHE Critical Equipment; Does the change require revision of criticality assessment / documentation for:	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Safety Instrumented Systems				
Machinery Safety Systems				
Ex electrical equipment				
Ex mechanical equipment				
Non ATEX rated mechanical equipment ignition hazards				
Pressure / vacuum relief systems or flame arresters				
Gas or fire detection, alarm or fire protection systems?				
Pressure Systems or Primary Containment Systems				
Secondary Containment Systems				
Any other SHE Critical equipment (add detail)				
Operational Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation / training of ops. staff				
Revision of operating procedures or log sheets				
Revision of emergency procedures or response plans				
Further SHE Assessment e.g. Operability Studies				

PART 3; CHANGE CONTROL				
SHE ASSESSMENT		**ACTION MANAGEMENT**		
Engineering Impact; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation or training of Eng. Staff				
Revision of Engineering Standards				
Revision of block diagrams, flow diagrams or P&IDS				
Revision of site or building plans				
Revision of equipment or machinery documentation				
Revision of electrical supplies or equipment documentation				
Revision of inspection / preventive maintenance				
Start-up / Commissioning; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Pre-start up safety review (PSUSR)				
Commissioning Plan				
Other actions (list details)		**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Comments or Notes;				

Example form for illustration only – approval and later sections not included

APPENDIX F. EXAMPLE PROCESS CHANGE CONTROL FORM

Two example forms are presented;

- An Initial Assessment Form; which can be used as part of an operating or quality management procedure to screen out minor changes which do not need to be managed by the process change management system. It is particularly useful where the safe operating limits of a process are not formally and clearly defined
- A Process Change Control Form; which can be used for significant changes that require management using the process change management system

F.1 Process Change Initial Assessment Form

Site;		Process;		Ref;	
Originator;				Date;	
Title;				Permanent or Temporary delete	

PART 1; DESCRIPTION OF THE CHANGE					
Date;		Revision No;			
Grade / Recipe;		Batch / Run Nos;			
Equipment;		Batch / Run Size;			
Technical Supervision Level required delete as required		1 (Full)	2 (Medium)	3 (Low)	4 (None)
Trial Description and Special Instructions:					
Justification / Reason for Change:					
Print Name;	Sign;		Date;		
Person with overall accountability for change					
Person(s) assigned to assist supervising or monitoring the change;					

PART 2; PRE-ASSESSMENT		
Question / Factor	**Yes/No**	**Comments / Action**
Does the change introduce a process operation or rework procedure which has not been carried been out for 2 years?		**If YES; review Plant Modifications to ensure there have been no significant changes**
Are manual handling or ergonomic aspects affected?		**If YES; revise Manual Handling Assessment**
Is a new or alternative raw material introduced to the process?		**If YES; complete remainder of Part 2**
Is the use of an existing raw material significantly changed?		**If NO; continue to Part 3; Risk Assessment**
If a new raw material is involved; has it been approved for use on site?		**If NO; contact SHE Manager**
Is there a significant change to the COSHH assessment? e.g. method of handling or amount handled, PPE or LEV standards		**If YES; revise COSHH Assessment**
Is there regulatory impact? e.g. • *Product Registration or Product Compliance?* • *Add other significant regulatory impacts as needed*		**If YES; contact SHE Manager** ***If in doubt; contact SHE Manager***

PART 3; RISK ASSESSMENT					
Ref No.	**Description of risk and estimation of the effect of change**		**L**	**C**	**R**
1		Before			
		After			
2		Before			
		After			
3		Before			
		After			

Key; L = Likelihood C = Consequence R = Risk Risk = L x C Max. Risk R =

POTENTIAL SHE IMPACT OF THE CHANGE Max. Risk _____ x Complexity _____ =

Likelihood of Incident		Consequence of Incident		Complexity of Change	
1	Very Unlikely, 1 in 10,000	1	No noticeable impact Minor quality issue only	1	Minor change to a single parameter
2	Possibly, 1 in 1,000	2	Process remains within normal operating limits. Significant quality issue only	2	Changes to multiple parameters with known effects
3	Likely, 1 in 100	3	Process exceeds normal operating limits, but well within Basis of Safety	3	Significant change to a single key parameter with known effects
4	Very Likely, 1 in 10	4	Process exceeds normal operating limits, and could exceed Basis of Safety	4	Significant changes to a several key parameters or repeated changes over a period of time
5	Expected	5	Process exceeds normal operating limits, and expected to exceed Basis of Safety	5	Complex change to a wide range of key parameters or change(s) with unknown effects

Sign (Assessor)	Name	Job Title

TECHNICAL MANAGER APPROVAL (required if Potential SHE Impact > 6)		Approved		Denied	
Comments;					
Print Name;	Sign;		Date;		

PLANT MANAGER APPROVAL (required if Potential SHE Impact > 6)		Approved		Denied	
Comments;					
Print Name;	Sign;		Date;		

If the Potential SHE Impact is > 10 or if the change is denied; the change MUST follow the full approval procedure for Process Change – Raise a Process Change Control Form

F.2 Process Change Control Forms

Site;		Process;		Ref;	
Originator;				Date;	
Title;				Permanent or Temporary delete	

PART 1; DESCRIPTION OF THE CHANGE					
Date;		Revision No;			
Grade / Recipe;		Batch / Run Nos;			
Equipment;		Batch / Run Size;			
Technical Supervision Level required delete as required		1 (Full)	2 (Medium)	3 (Low)	4 (None)
Trial Description and Special Instructions:					
Justification / Reason for Change:					
Print Name;	Sign;			Date;	

ASSESSMENT TEAM – Minimum involvement; Technical and Production/Operations SHE Department to review the assessment, can be involved at SHE Manager's discretion

- Other functions can be involved if required

Department	**Name**	**Job Title**
Technical		
Production / Operations		

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Process Safety Hazards; Does the change;	**Yes/No**	**Comments**
Affect how acute toxic materials are handled or processed? not applicable to flour milling		
Affect how flammable materials are handled or processed?		
Affect how reactive or unstable materials are handled or processed?		
Affect how environmentally dangerous materials are handled or processed?		
Alter the chemical composition or physical properties of materials?		
Alter the stability of materials? (e.g. during a heating or drying stage)?		
Affect stability or controllability of any part of the process?		
Affect compatibility with materials of construction of process equipment?		
Occupational Health & Safety Hazards - Does the change;	**Yes/No**	**Comments**
Affect how any hazardous substances or biological agents are handled or processed?		
Increase exposure to hazardous substances, dusts or biological agents?		
Require additional use of an exposure control systems (e.g. LEV, PPE / RPE)		
Environmental Impact - Does the change;	**Yes/No**	**Comments**
Affect how environmentally hazardous materials are handled or processed?		
Affect quantity or composition of authorised discharges or effluent / waste streams?		
Affect any treatment or abatement systems? or require special treatment?		
Regulatory Impact		
Operational Impact;		
Technical Impact;		
Comments or Notes;		

PART 3; CHANGE CONTROL

SHE ASSESSMENT		ACTION MANAGEMENT		
Process Safety; including major environmental impact **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
PHA / Basis of Safety revision				
Explosion risk assessment revision				
Area classification (Ex zoning) revision				
Other Process Safety risk assessment revision				
Occupational Health & Safety; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Following of procedures for introducing new substances				
Hazardous substance risk assessment revision				
Biological health hazard risk assessment revision				
Ergonomic e.g. manual handling risk assessment revision				
Other occupational health risk assessment revision				
Environmental Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Aspects & Impacts Register revision				
Environmental risk assessment revision				
Release limit revision or sampling frequency revision				
Waste disposal hazardous waste producers licence revision				
Changes to effluent treatment or waste handling				
Other Environmental controls				
Regulatory Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
REACH registration revision				
IPPC permit revision				
Any other regulatory license or permit revision				
SHE Critical Equipment; Does the change require revision of criticality assessment / documentation for:	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Safety Instrumented Systems				
Hazardous area electrical or mechanical equipment				
Pressure / vacuum relief systems or flame arresters				
Gas or fire detection, alarm or fire protection systems?				
Pressure Systems or Primary Containment Systems				
Any other SHE Critical equipment (add detail)				
Operational Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation / training of ops. staff				
Revision of operating procedures or log sheets				
Revision of emergency procedures or response plans				
Further SHE Assessment e.g. Operability Studies				
Technical Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation or training of tech. staff				
Revision of Formulation Boundaries				
Revision any other Technical Documentation (add detail)				
Start-up / Commissioning; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Pre-start up safety review (PSUSR)				
Commissioning Plan				

PART 3; CHANGE CONTROL			
SHE ASSESSMENT	**ACTION MANAGEMENT**		
Other actions (list details)	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Comments or Notes;			

Example form for illustration only – approval and later sections not included

APPENDIX G. EXAMPLE ORGANISATIONAL CHANGE CONTROL FORM

Site;		Ref;	
Originator;		Date;	
Title;		Permanent or Temporary delete	

PART 1; DESCRIPTION OF THE PROPOSED CHANGE
Background;
Explain the background leading to the proposed change
Description of the change;
Describe the proposed change, include organograms *Explain if the change is permanent or temporary – if temporary explain timing etc.*
Justification / Reason for Change:
Explain the justification for the change

Print Name;	Sign;	Date;

INITIAL ASSESSMENT TEAM;
Minimum involvement; Responsible Line Manager(s) for the department(s) affected

- SHE Department to review the assessment, can be involved at SHE Manager's discretion
- Other functions can be involved if required

Department	Name	Job Title

PART 2; INITIAL ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Does the change involve a role with potentially significant SHE impacts?	**Yes/No**	**Comments**
Corporate Management		*If the change involves these types of roles; focus on them in the questions below as they could significantly increase the category of the change*
Site Management		
First Line Manager *Process or Plant with major fire / explosion hazards or other major accident hazard area*		
Plant Operator *Process or Plant with major fire / explosion hazards or other major accident hazard area*		
Engineer *Plant with major fire / explosion hazards or other major accident hazard area*		
Maintenance Technician *Plant with major fire / explosion hazards or other major accident hazard area*		
Technical Support		
SHE Department		
Emergency Response Persons		
Does the change involve any of the following?	**Yes/No**	**Comments**
Reduction in number of positions		*Focus on the roles identified above – but if the changes do not involve the key roles above, record the impacts on other roles*
Reduction in number of personnel		
Minor increase in duties/workload		
Major increase in duties/workload		
Minor change in responsibilities		
Major change in responsibilities		
Minor change in competencies or experience		
Major change in competencies or experience		
Could the change affect SHE performance in the following areas?	**Yes/No**	**Comments**
Process Safety (Major Accident) Management		*Focus on major accident hazard management, but also consider how other elements of SHE performance could be impacted*
Occupational Health and Safety Management		
Environmental Management		
Management of Change		
Substance Control		
Risk Assessment		
Communications		
Permit Systems and Rules (including contractor management)		
Accident and Incident Reporting and Investigation		
Emergency Management and Response, including first aid		
Audits, Monitoring and Inspections		
Management Review		
Procedures and Instructions (including safe operation of the process and plant)		
Asset Integrity Management (maintaining plant in a safe condition)		
Regulatory Compliance or Product Stewardship		
Recruitment, training and competency		

PART 3; CHANGE CATEORISATION		
Based on the assessment above define the category	**CHANGE CATEGORY**	
Category	**Definition Note;** **major accident hazard e.g. fire / explosion hazards or violent release of energy**	
Insignificant	Change with negligible impact on major accident hazard risk	
Minor	Change with minor impact on major accident hazard risk	
Significant	Change with potential significant impact on major accident hazard risk	
Major	Change with potential major impact on major accident hazard risk	
Sign (Assessor)	**Name**	**Job Title**
Sign (Authoriser)	**Name**	**Job Title**
Changes categorised as Significant or Major require further detailed assessment and approval – continue assessment using Parts 4 – 8 of this form.		

PART 4; DETAILED ASSESSMENT Follows on from Parts 1 – 3 for changes categorised as Significant or Major
Chosen methods of assessment and attachments
Justify the methods used for carrying out the full assessment, particularly if they deviate from the recommended methods. *Record the attachments to this form and record the persons involved in carrying out the assessments (if they are not recorded on attachments)*

GUIDE QUESTIONS / PROMPTS Complete based on the results of the assessments	
Question / Prompt	**Assessment / Comments**
Have all the roles with major accident responsibilities and all key tasks been identified and successfully transferred to the new organisational structure?	
Have the new organisational arrangements been assessed as adequate for all scenarios including, normal operation, start-up, shutdown, process upsets and emergencies?	
Has potential impact on human reliability from other factors been considered e.g. • Excessive workload • Poor communications • Deficiencies in teamwork • Conflicting priorities • Low morale	
Has the assessment been fully participative, ensuring that the knowledge (including informally held knowledge) and views of people involved has been gathered and given dispassionate consideration?	
Have appropriate training needs analyses been carried out to identify any competence gaps? (including potential loss of skills and knowledge)	
Where needed, is competence assurance process in place (or planned) to ensure adequate transition arrangements?	
Have increased major accident hazard risks from using contractors/ 3rd parties been considered e.g.: • Sufficient resources to effectively manage outsourced major accident risks • Loss of technical competence, but sufficient remaining to be an 'intelligent customer' • Contingency plans if 3rd party is no longer able or willing to deliver to requirements?	
Have any other risks been identified as a result of the changes and what is to be done to managed them?	

PART 4; DETAILED ASSESSMENT Follows on from Parts 1 – 3 for changes categorised as Significant or Major
Implementation Plan *Record the implementation plan or summarise the plan and attach a copy of it to the form* *The level of detail should be proportionate to the complexity and category (potential effect) of the change.* *The implementation plan should include identification of pre-change (activities that must be achieved prior to implementation, transition phase and post-change actions (activities that can be conducted following implementation).* *Actions should use the SMART principle with the proposed actions agreed with the persons responsible for the action* *The timescale for implementation should be realistic and not rushed.* *Implementation plan should include mitigation to address risks for example:* • *Conducting handovers where individuals change post/role* • *Review and completion of training* • *Completion of communication plans* • *Detail how the change implementation will be monitored to prevent deviation from the plan* • *Contingency plans* *Timing and requirements for post-implementation review, feedback and close-out.*

Example form for illustration only – approval and later sections not included

APPENDIX H. ILLUSTRATIVE FORMS; SECTION 4.5 EXAMPLE CHANGES

Three illustrative forms are presented for the example changes discussed in Section 4.5

- Section 4.5.3 Example Plant Modification; Replacement of wheat cleaning sieve
- Section 4.5.4 Example Process Change; Change in gluten supply
- Section 4.5.5 Example Organisational Change; Replacement of an engineer

H.1 Example Plant Modification; Replacement of wheat cleaning sieve

Site;	*Example 4.5.3*	Dept;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Replace wheat cleaning sieve XXXX*			Permanent or ~~Temporary~~ delete	

PART 1; DESCRIPTION OF THE MODIFICATION / CHANGE	
Description (attach drawings / sketches and other documents if applicable): • Details can be attached as separate documents and referenced *Replace the existing wheat cleaning sieve with a <make>, <model>, <size>*	
For temporary changes; define the expiry time period for the change	*N/A - permanent*
Justification / Reason for Change: *The current sieve has reached the end of its working life and regularly breaks down. The new sieve will be more reliable and be more efficient at wheat cleaning*	

Type of Plant / Equipment involved;			
1. Milling • *Wheat Cleaning* • **** • **** • ****	2. Heat Treatment • **** • **** • **** • ****	3. Other • Packaging • Co-Product Handling • **** • ****	4. Utilities • Natural Gas • Boilers • Fuels (e.g. diesel) • Drainage systems

ASSESSMENT TEAM – Minimum involvement; Production/Operations and Engineering

- SHE Department to review the assessment, can be involved at SHE Manager's discretion
- Other functions can be involved if required

Department	**Name**	**Job Title**
Production / Operations	*J. Bloggs*	
Engineering	*A.N. Engineer*	
Technical	*N/A*	

Site;	*Example 4.5.3*	Dept;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Replace wheat cleaning sieve XXXX*			Permanent or ~~Temporary~~ delete	

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Process Safety; Fire / Explosion Hazards - Does the change;	**Yes/No**	**Comments**
Introduce or alter the location of releases of flammable materials?	*Yes*	*The new sieve will provide improved dust containment and / or dust aspiration and will be ATEX Ex equipment suitable for use in the required zone(s).*
Alter the containment of a flammable material or increase the likelihood of release?	*Yes*	
Introduce or alter likelihood of a flammable (explosive) atmosphere?	*No*	
Introduce a source of ignition or increase the likelihood of an ignition source?	*Yes*	
Affect stability or controllability of any part of the process?	*No*	
Alter a fire or explosion protection or prevention system?	*No*	
Process Safety; Decomposition / Reaction Hazards - Does the change;	**Yes/No**	**Comments**
Alter the chemical composition or physical properties of materials?	*No*	*No significant sources of heat and no thermal stability issues with wheat cleaning*
Alter the stability of materials? (e.g. during a heating or drying stage)?	*No*	
Affect stability or controllability of any part of the process?	*No*	
Alter a safety instrumented system? e.g. high temperature interlock	*No*	
Process Safety; Pressure / Temperature Hazards - Does the change;	**Yes/No**	**Comments**
Introduce potential causes of over-pressurising any part of the system?	*No*	*No significant sources of pressure*
Alter potential causes of over-pressurising any part of the system?	*No*	
Introduce potential causes of under-pressurising any part of the system?	*No*	
Alter potential causes of under-pressurising any part of the system?	*No*	
Introduce potential causes of raising the temperature in any part of the system?	*No*	
Alter potential causes of raising the temperature in any part of the system?	*No*	
Introduce potential causes of lowering the temperature in any part of the system?	*No*	
Alter potential causes of lowering the temperature in any part of the system?	*No*	
Alter a pressure system?	*No*	
Affect equipment installed for preventing or minimising over / under pressurisation?	*No*	
Process Safety; Acute Toxic Hazards; not applicable to flour milling		
Occupational Health Hazards - Does the change;	**Yes/No**	**Comments**
Alter how any hazardous substances are handled?	*Yes*	*The new sieve will provide improved dust containment and / or dust aspiration. The existing dust aspiration system has enough capacity to provide the correct level of aspiration on the new sieve*
Increase exposure to hazardous substances or dusts?	*No*	
Alter or increase exposure to Biological agents? e.g. Legionella, sewerage	*No*	
Alter any exposure control systems (e.g. LEV)	*Yes*	
Alter or require additional PPE / RPE?	*No*	
Require any special decontamination?	*No*	
Alter a safety instrumented system?	*No*	
Alter a pressure or vacuum relief system?	*No*	
Alter the primary containment system for a health hazardous substance?	*No*	
Alter the secondary containment system (e.g. bund) for a health hazardous substance?	*No*	
Environmental Impact - Does the change;	**Yes/No**	**Comments**
Introduce or alter the location of releases of environmentally dangerous materials?	*No*	*Minor increase in co-products e.g. screenings and dust which will enter the existing co-product handling streams*
Introduce or alter the location of releases of environmentally hazardous materials?	*No*	
Introduce or alter the location of any discharge points?	*No*	
Introduce any new effluent streams, waste streams?	*No*	
Alter the quantities of existing effluent streams or waste(s)?	*Yes*	
Alter the composition or physical properties of existing effluent streams or waste(s)?	*Yes*	
Alter any secondary containment? (e.g. bunds)	*No*	
Alter the environmental risk assessment for any part of the process?	*No*	
Affect any treatment or abatement systems?	*No*	
Require removal or decontamination of plant or equipment?	*No*	
Alter the primary containment system for an environmentally dangerous material?	*No*	
Alter the secondary containment system for an environmentally dangerous material?	*No*	

Continued on following page

Site;	Example 4.5.3	Dept;	Milling	Ref;	Example Only
Originator;	A. N. Other			Date;	
Title;	Replace wheat cleaning sieve XXXX			Permanent or ~~Temporary~~ delete	

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS

Machinery / Equipment Hazards - Does the change;	Yes/No	Comments
Introduce new or alter existing machinery or work equipment? e.g. covered by PUWER	Yes	The new sieve will be CE marked machinery complying with relevant EN standards and will be installed, commissioned, maintained and operated / controlled according to the OEM instructions
Affect equipment requiring inspection under legislation such as COSHH, PSSR, LOLER	Yes	
Affect guarding or interlocks designed to prevent access to dangerous parts/zones?	Yes	
Introduce or alter potential causes of high or very low temperature?	No	
Affect controls for starting, or restarting after stoppage?	Yes	
Affect controls for changing speed, pressure or other operating conditions?	Yes	
Affect controls for stopping the work equipment in a safe manner?	Yes	
Affect controls to bring equipment to a complete stop for health and safety?	Yes	
Affect controls which switch off all sources of energy after stopping?	Yes	
Affect emergency stop controls?	Yes	
Affect audible, visible or other warnings to alert people equipment is about to start?	No	
Affect means to isolate the work equipment from all its sources of energy?	Yes	
Affect the stability, fixing or clamping of work equipment?	Yes	

Machinery / Equipment Hazard Prompts List

Mechanical
- *Moving parts*
- *Moving transmission parts*
- *Moving parts involves in the process*
- *Break-up during operation*
- *Falling or ejected parts*
- *Uncontrolled movements*
- *Sharp edges, angles, rough surfaces*

Electrical
Static electricity (harm to people)
Energy Supply
- *Hydraulic*
- *Pneumatic*
- *Mechanical (kinetic)*
- *Thermal*

Extreme temperature
- *High*
- *Low*

Fire
Explosion
Noise
Vibration (harm to people)
Ionising radiation
Non-ionising radiation
Laser radiation
Emission; hazardous materials/substances
Trapping / entanglement
Slips, trips, falls

Workplace Hazards - Does the change;	Yes/No	Comments
Affect the stability and solidity of a building or structure? e.g. structural loadings	No	The new sieve footprint within the building may be different to the old sieve. Carry out detailed assessment to ensure that it has suitable access for maintenance and inspection
Affect the maintenance of the workplace, and of equipment, devices and systems?	Yes	
Affect the effectiveness or suitability of workplace ventilation?	No	
Affect the temperature of an indoor workplace?	No	
Introduce harmful or offensive fumes from heating systems?	No	
Affect the effectiveness or suitability of workplace lighting?	No	
Affect the cleanliness of the workplace or build-up of waste materials in the workplace?	No	
Affect the free space allowing safe movement and access within the workplace?	Yes	
Affect the suitability of workstations or seating?	No	
Affect the suitability or condition of floors and traffic routes?	No	
Introduce new or alter existing causes of falls or falling objects?	No	
Introduce new transparent or translucent surfaces that require breakage protection?	No	
Affect existing transparent or translucent surfaces that require breakage protection?	No	
Affect safety for opening and/or cleaning windows, skylights and ventilators?	No	
Affect the organisation, suitability or safety of traffic (vehicle) and pedestrian routes?	No	
Affect the safety or suitability of doors, gates, escalators or moving walkways?	No	
Affect the suitability or sufficiency of sanitary conveniences or washing facilities?	No	
Affect the adequacy or accessibility of drinking water supplies?	No	
Affect the suitability for accommodation (storage) or changing of clothing?	No	
Affect the suitability or sufficiency or accessibility of facilities for rest and to eat meals?	No	

SHE Critical Equipment - Does the change;	Yes/No	Comments
Affect Safety Instrumented Systems? e.g. SIL rated interlocks	No	CE marked machinery; manufacturer will specify machinery safety systems. Sieve is located in and connected to zoned areas; specify Ex equipment with suitable EPL and T Class. Sieve may require special earthing; see OEM manual for details !
Affect Machinery Safety Systems? e.g. PL rated interlocks	Yes	
Affect electrical equipment in hazardous Ex zoned areas?	Yes	
Affect non-electrical equipment in hazardous Ex zoned areas?	Yes	
Affect explosion prevention or protection systems or devices?	Yes	
Affect pressure systems, pressure / vacuum relief systems or flame arresters?	No	
Affect gas or fire detection, alarm or fire protection systems?	No	
Affect any other SHE Critical equipment (add detail)	No	

Continued on following page

Site;	*Example 4.5.3*	Dept;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Replace wheat cleaning sieve XXXX*			Permanent or ~~Temporary~~ delete	

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS
Regulatory Impact
No significant regulatory impact. Impact is limited to minor changes to explosion risk assessment and hazardous area classification only
Operational Impact;
Minimal change to operations. Impact is limited to training and familiarisation with the operation of the new sieve
Engineering Impact;
Minor changes to maintenance and inspection e.g. *Revised preventive maintenance and inspection regime for the sieve* *Training and familiarisation with maintenance and inspection of the new sieve*
Start Up / Commissioning Impacts;
Commissioning and initial operation to be carried out according to OEM instructions.
Comments or Notes;

Site;	Example 4.5.3	Dept;	Milling	Ref;	Example Only
Originator;	A. N. Other			Date;	
Title;	Replace wheat cleaning sieve XXXX			Permanent or ~~Temporary~~ delete	

PART 3; CHANGE CONTROL

SHE ASSESSMENT		ACTION MANAGEMENT		
Process Safety; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
PHA / Basis of Safety revision	No			
Explosion risk assessment revision	Yes		Before start-up	
Area classification (Ex zoning) revision	Yes		Before start-up	
Other Process Safety risk assessment revision	No			
Occupational Health; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Following of procedures for introducing new substances	No			
Hazardous substance risk assessment revision	No			
Biological health hazard risk assessment revision	No			
Other occupational health risk assessment revision	No			
Environmental Impact; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Aspects & Impacts Register revision	No			
Environmental risk assessment revision	No			
Release limit revision or sampling frequency revision	No			
Waste disposal hazardous waste producers licence revision	No			
Changes to effluent or waste treatment	No			
Other Environmental controls	No			
Machinery / Equipment Safety; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Machinery / Equipment risk assessment revision	Yes		Before start-up	
Lifting equipment risk assessment revision	No			
Other machinery / equipment risk assessment revision	No			
Workplace Safety; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Workstation risk assessment revision	No			
Traffic (vehicle) risk assessment revision	No			
Other workplace risk assessment revision	No			
Regulatory Impact; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
REACH registration revision	No			
IPPC permit revision	No			
Any other regulatory license or permit revision	No			
SHE Critical Equipment; Does the change require revision of criticality assessment / documentation for:	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Safety Instrumented Systems	No			
Machinery Safety Systems	Yes		Before start-up	
Ex electrical equipment	Yes		Before start-up	
Ex mechanical equipment	Yes		Before start-up	
Non ATEX rated mechanical equipment ignition hazards	No			
Pressure / vacuum relief systems or flame arresters	No			
Gas or fire detection, alarm or fire protection systems?	No			
Pressure Systems or Primary Containment Systems	No			
Secondary Containment Systems	No			
Any other SHE Critical equipment (add detail)	No			
Operational Impact; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation / training of ops. staff	Yes		Before start-up	
Revision of operating procedures or log sheets	Yes		Before start-up	
Revision of emergency procedures or response plans	No			
Further SHE Assessment e.g. Operability Studies	No			

Site;	*Example 4.5.3*	Dept;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Replace wheat cleaning sieve XXXX*			Permanent or ~~Temporary~~ delete	

PART 3; CHANGE CONTROL

SHE ASSESSMENT		ACTION MANAGEMENT		
Engineering Impact; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation or training of Eng. Staff	*Yes*		*Before start-up*	
Revision of Engineering Standards	*No*		*Before start-up*	
Revision of block diagrams, flow diagrams or P&IDS	*Yes*		*Before start-up*	
Revision of site or building plans	*Yes*		*Before start-up*	
Revision of equipment or machinery documentation	*Yes*		*Before start-up*	
Revision of electrical supplies or equipment documentation	*Yes*		*Before start-up*	
Revision of inspection / preventive maintenance	*Yes*		*Before start-up*	
Start-up / Commissioning; Does the change require;	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Pre-start up safety review (PSUSR)	*No*			
Commissioning Plan	*No*			
Other actions (list details)		**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Carry out thorough LEV testing of modified dust aspiration	*Yes*		*Before start-up*	

Comments or Notes;

Example form for illustration only – approval and later sections not included

H.2 Example Process Change; Change in gluten supply

Site;	*Example 4.5.4*	Process;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Change in gluten supply*			~~Permanent or~~ Temporary delete	

PART 1; DESCRIPTION OF THE CHANGE					
Date;	*dd-mmm-yyyy*	Revision No;			
Grade / Recipe;	*All grades of flour*	Batch / Run Nos;			
Equipment;	*Gluten silo and feed systems*	Batch / Run Size;			
Technical Supervision Level required delete as required		~~1 (Full)~~	~~2 (Medium)~~	3 (Low)	~~4 (None)~~

Trial Description and Special Instructions:

Carry out a production trial using a new grade of gluten <name> and <supplier>

Justification / Reason for Change:

Potential reduction in cost and potential improved quality finished product

Print Name; *A. N. Other*	Sign;	Date; *dd-mmm-yyyy*

Person with overall accountability for change	*A. N. Other*

Person(s) assigned to assist supervising or monitoring the change;

List the key people involved

PART 2; PRE-ASSESSMENT

Question / Factor	**Yes/No**	**Comments / Action**
Does the change introduce a process operation or rework procedure which has not been carried been out for 2 years?	*No*	**If YES; review Plant Modifications to ensure there have been no significant changes**
Are manual handling or ergonomic aspects affected?	*No*	**If YES; revise Manual Handling Assessment**
Is a new or alternative raw material introduced to the process?	*Yes*	**If YES; complete remainder of Part 2**
Is the use of an existing raw material significantly changed?	*Yes*	**If NO; continue to Part 3; Risk Assessment**
If a new raw material is involved; has it been approved for use on site?	*Yes*	**If NO; contact SHE Manager**
Is there a significant change to the COSHH assessment? e.g. method of handling or amount handled, PPE or LEV standards	*No*	**If YES; revise COSHH Assessment**
Is there regulatory impact? e.g. • *Product Registration or Product Compliance?* • *Add other significant regulatory impacts as needed*	*Yes*	**If YES; contact SHE Manager** ***If in doubt; contact SHE Manager***

Site;	*Example 4.5.4*	Process;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Change in gluten supply*			~~Permanent or~~ Temporary delete	

PART 3; RISK ASSESSMENT ***(Explosion Indices within design basis for explosion relief)***

Ref No.	Description of risk and estimation of the effect of change		L	C	R
1	*New gluten supply has explosion indices which are well within the values used for the design of the explosion relief system on the gluten silo. No significant impact on the basis of safety*	Before	*1*	*3*	*2*
		After	*1*	*3*	*2*
2	*Potential for change to product registration or product compliance Note; this is managed by separate QC Controls / HACCP*	Before			
		After			
3		Before			
		After			

Key;	**L = Likelihood**	**C = Consequence**	**R = Risk**	**Risk = L x C**	**Max. Risk R =** *2*

POTENTIAL SHE IMPACT OF THE CHANGE **Max. Risk** ____*3*____ **x Complexity** ____*3*____ **=** ***9***

Likelihood of Incident		Consequence of Incident		Complexity of Change	
1	Very Unlikely, 1 in 10,000	1	No noticeable impact Minor quality issue only	1	Minor change to a single parameter
2	Possibly, 1 in 1,000	2	Process remains within normal operating limits. Significant quality issue only	2	Changes to multiple parameters with known effects
3	Likely, 1 in 100	3	Process exceeds normal operating limits, but well within Basis of Safety	3	Significant change to a single key parameter with known effects
4	Very Likely, 1 in 10	4	Process exceeds normal operating limits, and could exceed Basis of Safety	4	Significant changes to a several key parameters or repeated changes over a period of time
5	Expected	5	Process exceeds normal operating limits, and expected to exceed Basis of Safety	5	Complex change to a wide range of key parameters or change(s) with unknown effects

Sign (Assessor)	Name	Job Title
A. N. Other	*A. N. Other*	

TECHNICAL MANAGER APPROVAL (required if Potential SHE Impact > 6) **Approved** *X* **Denied**

Comments;
Confirmed that explosion indices are below those used
Low SHE impacts – follow quality management procedures

Print Name; *T. Manager* Sign; *T. Manager* Date;

PLANT MANAGER APPROVAL (required if Potential SHE Impact > 6) **Approved** *X* **Denied**

Comments;
Low SHE impacts - follow quality management procedures

Print Name; *P. Manager* Sign; *P.. Manager* Date;

If the Potential SHE Impact is > 10 or if the change is denied; the change MUST follow the full approval procedure for Process Change – Raise a Process Change Control Form

Site;	*Example 4.5.4*	Process;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Change in gluten supply*			~~Permanent or~~ Temporary delete	

PART 3; RISK ASSESSMENT ***(Uncertainty in explosion indices)***

Ref No.	Description of risk and estimation of the effect of change		L	C	R
1	*New gluten supply has unknown explosion indices which may be greater than the current gluten supply. May exceed the design of the explosion relief system on the gluten silo*	Before	*1*	*3*	*3*
		After	*1*	*4*	*4*
2	*Potential for change to product registration or product compliance* *Note; this is managed by separate QC Controls / HACCP*	Before			
		After			
3		Before			
		After			

Key; L = Likelihood C = Consequence R = Risk Risk = L x C Max. Risk R = *4*

POTENTIAL SHE IMPACT OF THE CHANGE Max. Risk ____*4*____ x Complexity ____*3*____ = *12*

Likelihood of Incident		Consequence of Incident		Complexity of Change	
1	Very Unlikely, 1 in 10,000	1	No noticeable impact Minor quality issue only	1	Minor change to a single parameter
2	Possibly, 1 in 1,000	2	Process remains within normal operating limits. Significant quality issue only	2	Changes to multiple parameters with known effects
3	Likely, 1 in 100	3	Process exceeds normal operating limits, but well within Basis of Safety	3	Significant change to a single key parameter with known effects
4	Very Likely, 1 in 10	4	Process exceeds normal operating limits, and could exceed Basis of Safety	4	Significant changes to a several key parameters or repeated changes over a period of time
5	Expected	5	Process exceeds normal operating limits, and expected to exceed Basis of Safety	5	Complex change to a wide range of key parameters or change(s) with unknown effects

Sign (Assessor)	Name	Job Title

TECHNICAL MANAGER APPROVAL (required if Potential SHE Impact > 6) **Approved** *X* **Denied**

Comments;
Potential High SHE impacts – follow full scope of process change management procedure

Print Name; *T. Manager* Sign; *T. Manager* Date;

PLANT MANAGER APPROVAL (required if Potential SHE Impact > 6) **Approved** *X* **Denied**

Comments;
Potential High SHE impacts – follow full scope of process change management procedure

Print Name; *P. Manager* Sign; *P.. Manager* Date;

If the Potential SHE Impact is > 10 or if the change is denied; the change MUST follow the full approval procedure for Process Change – Raise a Process Change Control Form

Site;	*Example 4.5.4*	Process;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Change in gluten supply*			~~Permanent or~~ Temporary delete	

PART 2; SHE ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Process Safety Hazards; Does the change;	**Yes/No**	**Comments**
Affect how acute toxic materials are handled or processed? not applicable to flour milling	*No*	*New gluten supply may have different fire / explosion properties. Potential to exceed the basis of safety for the gluten silo*
Affect how flammable materials are handled or processed?	*Yes*	
Affect how reactive or unstable materials are handled or processed?	*No*	
Affect how environmentally dangerous materials are handled or processed?	*No*	
Alter the chemical composition or physical properties of materials?	*No*	
Alter the stability of materials? (e.g. during a heating or drying stage)?	*No*	
Affect stability or controllability of any part of the process?	*No*	
Affect compatibility with materials of construction of process equipment?	*No*	
Occupational Health & Safety Hazards - Does the change;	**Yes/No**	**Comments**
Affect how any hazardous substances or biological agents are handled or processed?	*No*	
Increase exposure to hazardous substances, dusts or biological agents?	*No*	
Require additional use of an exposure control systems (e.g. LEV, PPE / RPE)	*No*	
Environmental Impact - Does the change;	**Yes/No**	**Comments**
Affect how environmentally hazardous materials are handled or processed?	*No*	
Affect quantity or composition of authorised discharges or effluent / waste streams?	*No*	
Affect any treatment or abatement systems? or require special treatment?	*No*	

Regulatory Impact

No significant regulatory impact, but there is potential for exceeding the basis of safety for the gluten silo, which could significantly increase explosion risks

Operational Impact;

Minimal change to operations e.g. quality issues only

Technical Impact;

Product quality issues are possible. Potential for change to product registration or product compliance - this will be managed by separate QC Controls / HACCP systems.

Comments or Notes;

Site;	*Example 4.5.4*	Process;	*Milling*	Ref;	*Example Only*
Originator;	*A. N. Other*			Date;	
Title;	*Change in gluten supply*			~~Permanent or~~ Temporary delete	

PART 3; CHANGE CONTROL

SHE ASSESSMENT		ACTION MANAGEMENT		
Process Safety; Including major environmental impact **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
PHA / Basis of Safety revision	*Yes*		*Before approval*	
Explosion risk assessment revision	*Yes*		*Before approval*	
Area classification (Ex zoning) revision	*No*			
Other Process Safety risk assessment revision *SHE Critical Equipment, Operational Impact, Technical Impact of changes to risk assessment or bases of safety to be assessed*	*Yes*		*Before approval*	
Occupational Health & Safety; *Section omitted from this example*				
Environmental Impact; *Section omitted from this example*				
Regulatory Impact; *Section omitted from this example*				
SHE Critical Equipment; Does the change require revision of criticality assessment / documentation for:	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Safety Instrumented Systems				
Hazardous area electrical or mechanical equipment				
Pressure / vacuum relief systems or flame arresters				
Gas or fire detection, alarm or fire protection systems?				
Pressure Systems or Primary Containment Systems				
Any other SHE Critical equipment (add detail)				
Operational Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation / training of ops. staff				
Revision of operating procedures or log sheets				
Revision of emergency procedures or response plans				
Further SHE Assessment e.g. Operability Studies				
Technical Impact; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Revision of training documentation or training of tech. staff				
Revision of Formulation Boundaries				
Revision any other Technical Documentation (add detail)				
Start-up / Commissioning; **Does the change require;**	**Yes/ No**	**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Pre-start up safety review (PSUSR)				
Commissioning Plan				
Other actions (list details)		**Responsible Person**	**Before Handover/Start up or Before Final Closure**	**Complete (Date)**
Comments or Notes;				

Example form for illustration only – approval and later sections not included

H.3 Example Organisational Change; Replacement of an engineer

Site;	*Example 4.5.5*	Ref;	*Example Only*
Originator;	*A. N. Other*	Date;	
Title;	*Replacement of site Electrical Engineer*	Permanent or ~~Temporary~~ delete	

PART 1; DESCRIPTION OF THE PROPOSED CHANGE		
Background;		
The current site electrical engineer is retiring in 6 months' time and a replacement is required.		
Description of the change;		
Describe the proposed change, include organograms *Explain if the change is permanent or temporary – if temporary explain timing etc.*		
Justification / Reason for Change:		
For electrical safety, the site requires a competent electrical engineer.		
Print Name; *A.N. Other*	Sign; *A.N. Other*	Date;

INITIAL ASSESSMENT TEAM;
Minimum involvement; Responsible Line Manager(s) for the department(s) affected

- SHE Department to review the assessment, can be involved at SHE Manager's discretion
- Other functions can be involved if required

Department	Name	Job Title
		Line Manager
		Site SHE Manager

Site;	*Example 4.5.5*	Ref;	*Example Only*
Originator;	*A. N. Other*	Date;	
Title;	*Replacement of site Electrical Engineer*	Permanent or ~~Temporary~~ delete	

PART 2; INITIAL ASSESSMENT – GUIDE QUESTIONS / PROMPTS		
Does the change involve a role with potentially significant SHE impacts?	**Yes/No**	**Comments**
Corporate Management	*No*	*Replacement of a technical (discipline) engineer, however new engineer may not have relevant flour milling experience*
Site Management	*No*	
First Line Manager Process or Plant with major fire / explosion hazards or other major accident hazard area	*No*	
Plant Operator Process or Plant with major fire / explosion hazards or other major accident hazard area	*No*	
Engineer Plant with major fire / explosion hazards or other major accident hazard area	*Yes*	
Maintenance Technician Plant with major fire / explosion hazards or other major accident hazard area	*No*	
Technical Support	*No*	
SHE Department	*No*	
Emergency Response Persons	*No*	
Does the change involve any of the following?	**Yes/No**	**Comments**
Reduction in number of positions	*No*	*New engineer may not have relevant flour milling experience, particularly relating to management of electrical equipment in hazardous dust areas*
Reduction in number of personnel	*No*	
Minor increase in duties/workload	*No*	
Major increase in duties/workload	*No*	
Minor change in responsibilities	*No*	
Major change in responsibilities	*No*	
Minor change in competencies or experience	*Yes*	
Major change in competencies or experience	*Yes*	
Could the change affect SHE performance in the following areas?	**Yes/No**	**Comments**
Process Safety (Major Accident) Management	*Yes*	*Loss of flour milling specific experience in management of electrical equipment in hazardous dust areas could impact explosion risk management*
Occupational Health and Safety Management	*Yes*	
Environmental Management	*No*	
Management of Change	*Yes*	
Substance Control	*No*	
Risk Assessment	*No*	
Communications	*No*	
Permit Systems and Rules (including contractor management)	*Yes*	
Accident and Incident Reporting and Investigation	*No*	
Emergency Management and Response, including first aid	*No*	
Audits, Monitoring and Inspections	*No*	
Management Review	*No*	
Procedures and Instructions (including safe operation of the process and plant)	*No*	
Asset Integrity Management (maintaining plant in a safe condition)	*Yes*	
Regulatory Compliance or Product Stewardship	*No*	
Recruitment, training and competency	*No*	

PART 3; CHANGE CATEORISATION		
Based on the assessment above define the category	**CHANGE CATEGORY**	*Significant*

Category	**Definition Note;** major accident hazard e.g. fire / explosion hazards or violent release of energy
Insignificant	Change with negligible impact on major accident hazard risk
Minor	Change with minor impact on major accident hazard risk
Significant	Change with potential significant impact on major accident hazard risk
Major	Change with potential major impact on major accident hazard risk

Sign (Assessor)	**Name**	**Job Title**
Sign (Authoriser)	**Name**	**Job Title**

Changes categorised as Significant or Major require further detailed assessment and approval – continue assessment using Parts 4 – 8 of this form.

Site;	*Example 4.5.5*	Ref;	*Example Only*
Originator;	*A. N. Other*	Date;	
Title;	*Replacement of site Electrical Engineer*	Permanent or ~~Temporary~~ delete	

PART 4; DETAILED ASSESSMENT Follows on from Parts 1 – 3 for changes categorised as Significant or Major

Chosen methods of assessment and attachments

The change only just falls into the Significant category – it is a change to a single role on site, which has a limited number of specific responsibilities relating to explosion risk management.

A simple task map identifying roles and responsibilities carried out by the current Electrical Engineer and those to be carried out by the new Electrical Engineer, combined with a competency assessment / training needs analysis for each of those roles and responsibilities is sufficient to develop a simple implementation plan. Identifying training needs, supervision / support needs and transfer of any roles or responsibilities to other people.

GUIDE QUESTIONS / PROMPTS Complete based on the results of the assessments

Question / Prompt	Assessment / Comments
Have all the roles with major accident responsibilities and all key tasks been identified and successfully transferred to the new organisational structure?	*Change is limited to a single role on site, which has a limited number of specific responsibilities relating to explosion risk management.* • *Management of electrical equipment in hazardous areas* • *Management of ECI aspects of other explosion risk controls such as safety interlocks, explosion protection systems, earthing and bonding, lightning protection and primary electrical safety*
Have the new organisational arrangements been assessed as adequate for all scenarios including, normal operation, start-up, shutdown, process upsets and emergencies?	*See separate task map and see implementation plan below.*
Has potential impact on human reliability from other factors been considered e.g. • Excessive workload • Poor communications • Deficiencies in teamwork • Conflicting priorities • Low morale	*Behavioural skills (e.g. managerial skills, communication or interpersonal skills and professional commitment) are not covered by the technical training*
Has the assessment been fully participative, ensuring that the knowledge (including informally held knowledge) and views of people involved has been gathered and given dispassionate consideration?	*The current electrical engineer has been involved in developing the task map and competence requirements. The implementation plan includes review and discussion with the replacement electrical engineer*
Have appropriate training needs analyses been carried out to identify any competence gaps? (including potential loss of skills and knowledge)	*The replacement engineer may not have the underpinning knowledge and understanding of explosion hazards and risk controls and how they apply in flour milling. See competence assessment / training needs analysis*
Where needed, is competence assurance process in place (or planned) to ensure adequate transition arrangements?	*Yes, a separate competence assessment / training needs analysis for each of the roles and responsibilities identified in the task mapping is included in the implementation plan.*
Have increased major accident hazard risks from using contractors/ 3rd parties been considered e.g.: • Sufficient resources to effectively manage outsourced major accident risks • Loss of technical competence, but sufficient remaining to be an 'intelligent customer' • Contingency plans if 3rd party is no longer able or willing to deliver to requirements?	*Due to the potential lack of underpinning knowledge and understanding of explosion hazards and risk controls and how they apply in flour milling; the implementation plan includes transitionary arrangements such as supervision / support needs and transfer of any roles or responsibilities to other people*
Have any other risks been identified as a result of the changes and what is to be done to managed them?	*No other risks identified*

Site;	*Example 4.5.5*	Ref;	*Example Only*
Originator;	*A. N. Other*	Date;	
Title;	*Replacement of site Electrical Engineer*	Permanent or ~~Temporary~~ delete	

PART 4; DETAILED ASSESSMENT Follows on from Parts 1 – 3 for changes categorised as Significant or Major

Implementation Plan

1. *Map the key roles and responsibilities carried out by the current Electrical Engineer*

2. *Map the key roles and responsibilities that are to be carried out by the new Electrical Engineer*
   a. *Confirm that they will be the same as the current Electrical Engineer or*
   b. *Develop a transition plan to transfer any specific roles and responsibilities to another job role*

3. *Review the job description and competence requirements before advertising the vacancy, focus on*
   a. *Minimum (mandatory) competence requirements*
   b. *Preferable competence requirements e.g. flour milling, or similar industry, experience*
   c. *Technical and Behavioural competencies*

4. *Develop a detailed competence requirement for each of the key roles and responsibilities that are to be carried out by the new Electrical Engineer – for example see Section 2.0 of the nabim guidance document for the management of electrical equipment in hazardous (Ex zoned) areas (Ref. HSD 181157-B). Example key roles / responsibilities that could be included in the task map;*
   a. *Management of primary electrical safety (electrical responsible person)*
   b. *Management of electrical equipment in hazardous areas*
   c. *Management of explosion protection systems*
   d. *Management of earthing and bonding (ignition protection)*
   e. *Management of lightning protection systems*
   f. *Management of safety interlocks*
   g. *Management of 3rd party contractors*

5. *Once a replacement has been selected – carry out an initial competence assessment / training needs analysis against each of the key roles and responsibilities to identify*
   a. *Training needs (technical and behavioural)*
   b. *Supervision / support needs during transition period*

6. *Once the new engineer starts – review the initial competency assessment / training needs analysis with them and finalise it as a time-based transition plan.*

Example form for illustration only – approval and later sections not included