



# GUIDELINE FOR PROCESS SAFETY MANAGEMENT

**Doc 186/21**

Revision of Doc 186/14

**EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL**

AVENUE DE L'ASTRONOMIE 30 • B-1210 BRUSSELS  
Tel: +32 2 217 70 98

E-mail: [info@eiga.eu](mailto:info@eiga.eu) • Internet: [www.eiga.eu](http://www.eiga.eu)



# GUIDELINE FOR PROCESS SAFETY MANAGEMENT

Prepared by AHG-S.2 of SAC

As part of a programme of harmonisation of industry standards, the European Industrial Gases Association, (EIGA) has published EIGA Doc 186, *Guideline for Process Safety Management*, jointly produced by members of the International Harmonisation Council and originally published by the Compressed Gas Association as CGA P.86, *Guideline for Process Safety Management*.

This publication is intended as an international harmonised standard for the worldwide use and application of all members of the Asia Industrial Gases Association (AIGA), Compressed Gas Association (CGA), European Industrial Gases Association, and Japan Industrial and Medical Gases Association (JIMGA). Each association's technical content is identical, except for regional regulatory requirements and minor changes in formatting and spelling.

## Disclaimer

All technical publications of EIGA or under EIGA's name, including Codes of practice, Safety procedures and any other technical information contained in such publications were obtained from sources believed to be reliable and are based on technical information and experience currently available from members of EIGA and others at the date of their issuance.

While EIGA recommends reference to or use of its publications by its members, such reference to or use of EIGA's publications by its members or third parties are purely voluntary and not binding.

Therefore, EIGA or its members make no guarantee of the results and assume no liability or responsibility in connection with the reference to or use of information or suggestions contained in EIGA's publications.

EIGA has no control whatsoever as regards, performance or non performance, misinterpretation, proper or improper use of any information or suggestions contained in EIGA's publications by any person or entity (including EIGA members) and EIGA expressly disclaims any liability in connection thereto.

EIGA's publications are subject to periodic review and users are cautioned to obtain the latest edition.



## Table of Contents

1	Introduction .....	1
2	Scope and purpose .....	1
2.1	Scope .....	1
2.2	Purpose .....	2
3	Definitions .....	3
3.1	Publication terminology .....	3
3.2	Technical definitions .....	3
4	Overview of process safety management elements .....	3
4.1	Process safety leadership .....	4
4.2	Risk identification and assessment .....	4
4.3	Risk management .....	4
4.4	Review and improvement .....	5
5	Process safety management elements .....	5
5.1	Element 1—Leadership commitment and responsibility .....	5
5.2	Element 2—Compliance with legislation and industry standards .....	6
5.3	Element 3—Employee selection, training, and competency .....	6
5.4	Element 4—Workforce involvement .....	7
5.5	Element 5—Communication with stakeholders .....	7
5.6	Element 6—Hazard identification and risk assessment .....	8
5.7	Element 7—Documentation, records, and knowledge management .....	9
5.8	Element 8—Process and operational status monitoring and handover .....	10
5.9	Element 9—Operating procedures .....	10
5.10	Element 10—Management of operational interfaces .....	11
5.11	Element 11—Standards and practices .....	11
5.12	Element 12—Management of change .....	13
5.13	Element 13—Operational readiness and process start-up .....	14
5.14	Element 14—Emergency and crisis management .....	15
5.15	Element 15—Inspection and maintenance .....	17
5.16	Element 16—Management of safety critical devices .....	17
5.17	Element 17—Work control, permit to work, and task risk management .....	18
5.18	Element 18—Contractors and suppliers — selection and management .....	19
5.19	Element 19—Incident investigation .....	19
5.20	Element 20—Audit, management review, and intervention .....	20
5.21	Element 21—Measures and metrics .....	21
6	References .....	22
Appendix 1 – Related publications .....		24
A1	General process safety management related documents and publications .....	24

### Amendments to 186/14

Section	Change
	<u>Editorial to align style with EIGA style manual</u>
	<u>Change of publication title</u>
1	<u>Revision of Introduction section for basis of guideline and references</u>
2.1	<u>Addition of some processes</u>
2.2	<u>Suggested phased introduction approach where appropriate</u>
5	<u>Change of section title from ‘requirements’ to ‘guidelines’ to match publication title, and change of ‘shall’ to ‘should’ to match publication purpose (guidance). Other minor changes to guidelines</u>

NOTE Technical changes from the previous edition are underlined

## 1 Introduction

Process safety management is of interest to many organisations looking to adopt a holistic and systematic approach to assuring the integrity of their operations.

This publication was adapted from the Energy Institute's document *High Level Framework for Process Safety Management* to be more specific to the industrial gases industry [1].<sup>1</sup>

The reader may choose to follow other process safety management systems such as the one developed by the American Institute of Chemical Engineers' (AIChE) Center for Chemical Process Safety (CCPS) [2]. For sites that are required to follow the requirements of the Seveso directives, those rules take precedence [3].

For the purpose of this publication, process safety management refers to providing guidance to improve process safety in industrial gas facilities. It is not meant to refer to the OSHA Process Safety Management regulations.

Appendix A lists other publications that are relevant to process safety management.

## 2 Scope and purpose

### 2.1 Scope

The process safety management framework may be applied to all processes within the industrial and medical gases industry. It is designed to address process safety hazards and be equally suitable for the processes that are found in the industry including:

- air separation units (ASU) and nitrogen generator facilities;
- hydrogen and carbon monoxide (HYCO) production facilities including electrolysis facilities;
- hydrogen purification units;
- acetylene production facilities;
- nitrous oxide production facilities;
- carbon dioxide production facilities;
- cylinder and container filling facilities;
- specialty gas production, package filling, and storage facilities;
- chemical handling and transport facilities;
- pipelines;
- transportation; and
- customer installations.

A facility may include not just the main production plant but all other ancillary equipment that has process hazards.

The decision to apply various process safety management elements to a given process needs to be made by evaluating the tolerance of risk and agreeing on the management approach. For example,

---

<sup>1</sup> References are shown by bracketed numbers and are listed in order of appearance in the reference section.

transportation and pipeline risks may be managed by applying national and international codes and might not require all the elements of the process safety management framework to be applied.

In some countries, there can be existing regulatory requirements for process safety management systems. This framework is not intended to replace these requirements but may be used to supplement them for all industry regardless of regulatory requirements.

## 2.2 Purpose

The process safety management framework is intended to provide a design basis for the development of a process safety management system where an organisation does not have one. It also may be used as a common basis for benchmarking existing process safety management systems.

Where an organisation has a process safety management system or an integrated management system incorporating health, safety, and environmental and process safety management, they may carry out a gap assessment versus the requirements of each element in order to identify any aspects of the system that need to be enhanced.

When the initial assessment has been completed, the significance of the gaps should be determined, and a prioritised plan developed to address the identified issues. In some cases, there can be a significant programme of work needed to upgrade the management system to contain all of the elements of the process safety management framework. In these cases, it should be recognised that this upgrade work can take many years to complete effectively.

If an organisation does not have a process safety management system in place, a phased approach may be utilised. The following is a recommendation for a phased approach, but the needs of each organisation can vary:

### Phase 1:

- Leadership commitment and responsibility (Element 1);
- Compliance with legislation and industry standards (Element 2);
- Workforce involvement (Element 4);
- Operating procedures (Element 9);
- Management of change (Element 12);
- Emergency management (Element 14); and
- Work control, permit to work, and task risk management (Element 17).

### Phase 2:

- Employee selection, training, and competency (Element 3);
- Hazard identification and risk assessment (Element 6);
- Documentation, records, and knowledge management (Element 7);
- Operational readiness and process start-up (Element 13);
- Inspection and maintenance (Element 15); and
- Management of safety critical devices (Element 16).

### Phase 3:

- Communication with stakeholders (Element 5);
- Process and operational status monitoring and handover (Element 8);
- Management of operational interfaces (Element 10);
- Standards and practices (Element 11);
- Contractors and suppliers—selection and management (Element 18);
- Incident investigation (Element 19);
- Audit, management review, and intervention (Element 20); and
- Measures and metrics (Element 21).

### **3 Definitions**

For the purpose of this publication, the following definitions apply.

#### **3.1 Publication terminology**

##### **3.1.1 Shall**

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

##### **3.1.2 Should**

Indicates that a procedure is recommended.

##### **3.1.3 May**

Indicates that the procedure is optional.

##### **3.1.4 Will**

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

##### **3.1.5 Can**

Indicates a possibility or ability.

#### **3.2 Technical definitions**

##### **3.2.1 Work control**

Recognition of potential hazards prior to beginning work, including the limits of the permitted work and defined barriers.

### **4 Overview of process safety management elements**

The elements set out the key aspects to assure the integrity of operations. Each element contains an overview which states its intent and a number of guidelines which define what organisations should address. The elements can be grouped as in the following sections.

#### 4.1 Process safety leadership

There are five elements that set out how organisations should define and communicate the level of performance they are prepared to accept and how they should ensure that they put in place the necessary resources to achieve the required level of performance:

- Leadership commitment and responsibility ([Element 1](#));
- Compliance with legislation and industry standards ([Element 2](#));
- Employee selection, training, and competency ([Element 3](#));
- Workforce involvement ([Element 4](#)); and
- Communication with stakeholders ([Element 5](#)).

#### 4.2 Risk identification and assessment

There are two elements that set out what organisations should do to identify and assess the risks that they need to manage in order to assure the integrity of their operations. The two elements identify the necessary control measures and how organisations should record and maintain the process safety knowledge developed from the risk identification and assessment activities:

- Hazard identification and risk assessment ([Element 6](#)); and
- Documentation, records, and knowledge management ([Element 7](#)).

#### 4.3 Risk management

There are eleven elements that set out the control measures that organisations should use to manage key areas of risk:

- Process and operational status monitoring and handover ([Element 8](#));
- Operating procedures ([Element 9](#));
- Management of operational interfaces ([Element 10](#));
- Standards and practices ([Element 11](#));
- Management of change ([Element 12](#));
- Operational readiness and process start-up ([Element 13](#));
- Emergency management ([Element 14](#));
- Inspection and maintenance ([Element 15](#));
- Management of safety critical devices ([Element 16](#));
- Work control, permit to work, and task risk management ([Element 17](#)); and
- Contractors and suppliers—selection and management ([Element 18](#)).

#### 4.4 Review and improvement

There are three elements within the review and improvement area that set out how organisations should measure and review their compliance with the process safety management framework and how they should ensure that they learn from these measurements and the findings from investigations:

- Incident investigation (Element 19);
- Audit, management review, and intervention (Element 20); and
- Measures and metrics (Element 21).

### 5 Process safety management elements

This section lists all of the elements in detail. Each element commences with an overview and contains a number of guidelines which set out a more detailed definition of what organisations should ideally address.

#### 5.1 Element 1—Leadership commitment and responsibility

##### 5.1.1 Overview

Assurance of the integrity of an organisation's operations requires visible leadership commitment and accountability at all levels of the organisation. Management should establish a process safety policy, provide perspective, set process safety performance targets, and provide the structure and resources to achieve them.

##### 5.1.2 Guidelines

The following is a list of guidelines for Element 1:

- Documented process safety policy, which may be a part of a general safety policy, is in place and signed by a senior company executive such as the chief executive officer (CEO) or the responsible unit managing director (MD). These are living systems which are regularly reviewed and updated and communicated to all employees to reflect the needs of the organisation;
- Process safety risk management system is in place which meets applicable legislation, the process safety management framework guidelines, and any other guidelines to which the organisation subscribes with regard to its process safety activities;
- Management establishes the scope, priority, and schedule for the process safety risk management system implementation, considering the complexity and risks involved with their operations and products;
- Roles, responsibilities, authorities, and accountabilities for the management of process safety are known and exercised. Sufficient competencies and resources are made available to meet the desired process safety plan;
- Clear process safety objectives, performance targets, and action plans are established and performance is periodically evaluated;
- Directors and managers:
  - Visibly demonstrate personal commitment and accountability for process safety, leading by example and upholding core values and standards of the organisation; and
  - Recognise and reward positive process safety behaviours and performance and intervene to correct deviations from required performance at all levels in the organisation; and

- Leadership responsible for sites operated by others, (for example, joint venture companies), encourage the adoption of a process safety management framework.

For more information, see:

- Guidelines for Managing Process Safety Risks During Organizational Change, AIChE CCPS [4]; and
- EIGA Info HF 11, Organisation - “Safety Culture” [5].

## 5.2 Element 2—Compliance with legislation and industry standards

### 5.2.1 Overview

Compliance with legislation is a fundamental requirement for organisations. Management should ensure that the requirements of applicable legislation are identified, understood, and complied with.

### 5.2.2 Guidelines

The following is a list of guidelines for Element 2:

- Requirements of current and forthcoming applicable legislation, regulations, licenses, permits, codes, industry standards, and other governmental requirements are identified, documented, kept current, and communicated to those affected; and
- Compliance with legislation and mandatory or applicable industry standards is systematically verified.

For more information, see EIGA Doc 60, Seveso Documents - Guidance on Applicability, Assessment and Legal Documents for Demonstrating Compliance of Industrial Gases Facilities with Seveso Directive(s) [6].

## 5.3 Element 3—Employee selection, training, and competency

### 5.3.1 Overview

Control of processes depends upon having competent people in position. Management should ensure that existing and new personnel have the required competencies.

### 5.3.2 Guidelines

The following is a list of guidelines for Element 3:

- Required process safety competencies and requirements are defined for all roles in the organisation;
- Process is in place for evaluation, selection, and training of employees which confirms their competency with the specified requirements for the role;
- When organisational changes are made, ensure that knowledge transfer occurs to maintain continuity of critical activities;
- Roles and responsibilities should take into account human capabilities and limitations as well as human and organisational factors;
- Appropriate training is carried out for personnel taking up a new or revised position;
- Training plans are in place for all positions that impact process safety;

- The organisational structure and continuity of process safety management critical positions is reviewed periodically to ensure that it can meet the process safety management guidelines;
- Employee competency should be periodically assessed against requirements of their assigned role and responsibilities, or should be maintained via continuing professional development;
- Employee training and development needs are identified through a systematic process; and
- Training and development programmes are a combination of formal courses, coaching, and practical work.

For more information, see:

- Info HF 02, Individual - "Training and Competence" [7]; and
- EIGA Doc 23, Safety Training of Employees [8].

## **5.4 Element 4—Workforce involvement**

### **5.4.1 Overview**

Achieving process safety performance requires the commitment of the whole workforce. Management should align, involve, and empower the whole workforce in the identification and management of process safety hazards.

### **5.4.2 Guidelines**

The following is a list of guidelines for Element 4:

- Employees and full-time contractors are actively engaged in the improvement of process safety performance related to their work scope and have an understanding of process safety hazards, their identification, and management / control;
- Employees and full-time contractors are engaged with management in two-way communication regarding process safety policies, objectives, performance targets, action plans, and sharing of lessons learned related to their work scope; and
- Process safety promotion and engagement programmes are in place to continually increase the awareness, participation, and commitment of employees and full-time contractors.

## **5.5 Element 5—Communication with stakeholders**

### **5.5.1 Overview**

Establishing and maintaining stakeholders' confidence is a key factor in maintaining an organisation's license to operate.

In relation to major hazards, management shall identify key stakeholder groups and develop and maintain a good working relationship with them, understanding and addressing their issues and concerns.

External stakeholders may include industrial neighbours, local communities, customers, enforcement authorities and agencies, and local civil authorities.

Internal stakeholders may include business, operations, engineering and construction teams, and worker representatives (unions or workers councils, etc.).

### 5.5.2 Guidelines

The following is a list of guidelines for Element 5:

- Communications system is defined to develop and maintain a good working relationship with the identified stakeholders about its activities, including emergency response communications;
- Appropriate safety information is shared with stakeholders to demonstrate the organisation's commitment to process safety; and
- Effectiveness of programmes for communication with stakeholders is periodically reviewed by management.

## 5.6 Element 6—Hazard identification and risk assessment

### 5.6.1 Overview

A fundamental requirement of any process safety management system is the identification and assessment of risk. Management should ensure that a comprehensive risk assessment process systematically identifies, assesses, and provides mitigations for the risks arising from the organisation's operations.

### 5.6.2 Guidelines

The following is a list of guidelines for Element 6:

- A structured process is applied to identify the hazards and ensure that the risks arising from the organisation's assets and operations are systematically assessed;
- Appropriate risk assessments are conducted for:
  - Ongoing operations;
  - Handling and storage of hazardous materials;
  - Existing and new products and services;
  - New projects and new technologies; and
  - All changes requiring management of change.
- Risk prevention and mitigation measures are identified and implemented, using hierarchy of control principles (including inherently safer design), to manage the identified risks to a tolerable level;
- Tolerable level of risk is defined for all risks (impact to human health, safety, environment, and, where necessary, property);
- Risk assessments consider process safety risk as well as risk to environment, reputation, asset integrity, business interruption, security, third party assets, and customers;
- Risk assessments consider human (including organisational) factors, which could affect the likelihood or severity of outcomes;
- Risk assessments are led by competent personnel with no conflicts of interest with the affected process. Team members shall be selected considering the scope of the risk assessment and should include safety, operations or technology subject matter experts, and process safety professional;

- Risk assessments take into account learnings from incidents from both inside and outside the organisation;
- Completed risk assessments are reviewed, approved, and accepted by specific levels of management appropriate to the magnitude of the risk and any decisions are clearly documented;
- Identified stakeholders are kept informed about the risk assessment process and results;
- Risk assessment recommendations are reviewed periodically by the appropriate management and resolved in a timely manner; and
- Risk assessments are updated as changes occur or are reviewed and updated at a defined frequency.

For more information, see:

- Hazard Identification Procedures, AIChE CCPS [9]; and
- EIGA Doc 75, Determination of Safety Distances [10].

## **5.7 Element 7—Documentation, records, and knowledge management**

### **5.7.1 Overview**

Accurate records and information are essential to identify, assess, and manage process safety risk. Management should ensure that the information required to support safe operation is identified, available, and up to date.

### **5.7.2 Guidelines**

The following is a list of guidelines for Element 7:

- Measures or practices are in place to define, develop, and maintain the required documentation and records necessary to support robust operation and maintenance of facilities;
- Documentation and records are available to those who need to use them;
- Documentation and records including those kept electronically are appropriately safeguarded from unauthorised revision or deletion;
- Measures or practices are in place to ensure that documentation is periodically reviewed and kept up to date;
- Procedure defining retention period for all documentation and records; and
- Documentation and records include those generated to meet the requirements of all other process safety management elements such as but not limited to:
  - Process safety information including process design considerations and basis for safe operating limits, design drawings (for example, P&IDs, PFD, Single line electrical diagrams, hazardous area drawings, relief system data, ventilations system data for hazardous occupied enclosures, etc.);
  - Equipment records (inspection, testing, maintenance, and modification);
  - Work and operating logs;
  - Training and competency records;

- Incident investigation reports;
- Operating and maintenance procedures;
- Permits and licenses;
- Risk assessments;
- Management of change documents; and
- Hazard review information.

## **5.8 Element 8—Process and operational status monitoring and handover**

### **5.8.1 Overview**

Comprehensive process and operational status monitoring and effective handover between work groups is essential to assure the continued integrity of the organisation's operations. Management should ensure that the process and operational status monitoring and handover requirements are defined, understood, and carried out.

### **5.8.2 Guidelines**

The following is a list of guidelines for Element 8:

- Safe operating limits (SOLs) are defined for equipment and processes and are kept up to date;
- Operating parameters are systematically monitored;
- Excursions beyond SOLs are identified and followed up; and
- Handover arrangements for the following are defined, understood, and implemented:
  - Operational and maintenance shift handover;
  - Successive work groups; and
  - Job positions (one to another).

For more information, see:

- EIGA Info HF 07, Organisation - “Communications on Safety” [11]; and
- EIGA Doc 132, *Unmanned Air Gas Plants: Design and Operation* [12].

## **5.9 Element 9—Operating procedures**

### **5.9.1 Overview**

Facilities shall be operated within established parameters and according to legislation. In order to achieve this, management should ensure that process safety information is available and utilised.

### **5.9.2 Guidelines**

The following is a list of guidelines for Element 9:

- Approved operating manuals and procedures are identified, available, accurate, up to date, understood and used, and include human factors considerations;

- Operating manuals are designed to maximise usability by providing clear step by step directions and minimise the likelihood of error and non-compliance;
- Operating manuals and procedures should state clear SOLs, the steps required to prevent an excursion outside the SOL, and clear instructions on actions to be taken if an excursion outside the SOL occurs;
- Operating manuals should cover normal start up and shutdown and steady state operation as well as temporary operations and emergency shutdowns; and
- Operating manuals and procedures are periodically reviewed and updated. These reviews involve supervisors and personnel who are required to use them.

For more information, see:

- Guidelines for Risk Based Process Safety, AIChE CCPS [13]; and  
NOTE Section 4.3.1 of this AIChE guideline focuses on operational procedures.
- EIGA Info HF 04, Task - “Design and Effectiveness of Procedures” [14].

## 5.10 Element 10—Management of operational interfaces

### 5.10.1 Overview

Operational interfaces with customers, suppliers, contractors, as well as interfaces between internal groups, who provide or receive services, utilities, or products, can impact the organisation’s operations. Management shall ensure that operational interfaces are identified, assessed, and managed.

### 5.10.2 Guidelines

The following is a list of guidelines for Element 10:

- Operational interfaces are identified, documented, and risks from failures of the interface are assessed. Both parties of the interface should be included in the assessment; and
- Based on the risk assessed, measures should be in place to ensure process safety is maintained.

The Project Management Institute (PMI) has extensive information on this element [16].

## 5.11 Element 11—Standards and practices

### 5.11.1 Overview

Process safety performance is enhanced by using applicable standards and safe working practices. Management should ensure that the standards and safe working practices to support project, maintenance, and operational activities are identified, developed, and consistently applied.

### 5.11.2 Guidelines

The following is a list of guidelines for Element 11:

- Design, inspection, and maintenance standards are defined, which bring together legislative requirements, industry and the organisation’s standards, and good practices;
- Safe working practices are defined, which bring together legislative requirements and industry standards and guidelines and the organisation’s good practices into a set of guidelines;

- Standards and practices:
  - Meet or exceed applicable legislative requirements;
  - Ensure process safety risks are accounted for; and
  - Take into account possible human failures and other factors that could influence the likelihood of those failures;
- Approved standards and practices are periodically reviewed to take into account changes to legislation, industry standards and guidelines, and the organisation's best practices and findings from incidents;
- Approved standards and practices are available to those who need them, including contractors;
- Authority to approve standards and practices is formally assigned to nominated competent individuals;
- Deviation from design standards is permitted only after assessment, review, and approval by nominated competent individuals and after the rationale for the decision is documented;
- When a new or updated standard or practice is issued, the new standard or practice is communicated to existing facilities for risk evaluation; and
- Project management work processes ensure that key stages in the project development lifecycle are reviewed and approved by specified levels of management with due consideration of process safety management practices. Work process requirements include:
  - Project management procedures are documented, well understood, readily available to those who need to use them (including contractors) and executed by qualified personnel;
  - Criteria are established and procedures are in place for conducting and documenting risk assessment at specific project stages to confirm the integrity of new assets and existing assets which have been substantially modified (see Element 6);
  - Any changes in the process safety impact of a facility on the local community are assessed and, if required, communicated to relevant authorities;
  - Design and construction of new or modified facilities use approved standards and practices that:
    - Meet or exceed applicable regulatory requirements;
    - Embody responsible requirements where legislation does not exist;
    - Encompass robust process safety management practices; and
    - Address vulnerability and security.
  - Pre-commissioning review is performed (see Element 13) and documented;
  - Procedures are in place to identify and manage the process safety risks arising from the mothballing and decommissioning or disposal of assets including dismantling, demolition, and site remediation; and
  - Performance measures are established to monitor the success or failure of a change to meet its intended purpose and whether it has any unintended effect on safety.

There are numerous CGA and EIGA practices that are documented and published. They are too numerous to reference in this publication. The relevant publications are best searched for using CGA and EIGA's websites.

## 5.12 Element 12—Management of change

### 5.12.1 Overview

The introduction of any form of change into an organisation, if not appropriately managed, can significantly increase the levels of process safety risk. Management should ensure that risks arising from any form of change are systematically identified, assessed, and managed.

### 5.12.2 Guidelines

The following is a list of guidelines for Element 12:

- Process is in place to systematically identify, assess, and manage the risks arising from both temporary and permanent changes;
- The process for managing change addresses:
  - Authority for approval of changes;
  - Compliance with legislation and approved standards;
  - Acquisition of needed permits;
  - Documentation including reason and technical basis for change;
  - When process hazard analysis is required due to the complexity or scope of the change being proposed; and
  - Communication of risks and their mitigations associated with the change.
- Management of change addresses changes to:
  - Equipment not being replaced in kind;
  - Interconnections between a new process and any existing processes;
  - Operations or operating procedures;
  - Organisation, reporting structures, or working patterns that affect the operating process;
  - Feedstocks, products, materials, or substances outside of the design parameters;
  - Software or control configuration;
  - Design or specifications;
  - Standards or practices; and
  - Inspections, maintenance, or testing programmes.
- Management of change considers impacts to:
  - Health and safety (including process safety);

- Environment;
  - Reputation;
  - Quality of final product;
  - Security;
  - Third-party assets; and
  - Business interruption.
- Management of change considers human and organisational factors and ensures that responsibilities for critical tasks remain clearly assigned throughout the change;
  - Temporary changes do not exceed initial authorisation for scope or time without review and approval;
  - Risks of the change are assessed by nominated competent individuals;
  - Changes are approved by nominated competent individuals commensurate with the risk associated with the proposed change; and
  - Pertinent records covering all changes are maintained.

For more information, see:

- EIGA HF 10, *Organisation - “Managing Organisational Change”* [17];
- ISO 45001, *Occupational health and safety management systems* [18]; and

NOTE ISO 45001 provides requirements with guidance for use. Clause 8.1.3 covers management of change.

- EIGA Doc 51, *Management of Change* [19].

## **5.13 Element 13—Operational readiness and process start-up**

### **5.13.1 Overview**

The commissioning and start-up of new, modified, or existing plant and equipment is a high-risk operation. Management should ensure that there is a systematic process to verify that plant and equipment is in a safe condition and that personnel are prepared before start-up or return to normal operation.

### **5.13.2 Guidelines**

The following is a list of guidelines for Element 13:

- There is a systematic process for checking operational readiness and the integrity of systems before they are brought into service;
- Checking process addresses:
  - New or modified plant, processes and equipment;
  - Major equipment returned from maintenance; and
  - Restart after a trip or a planned shutdown of the full plant or a part of the plant.

- There are defined criteria for operational readiness. The criteria should cover, but are not limited to:
  - Equipment;
  - Control system and software;
  - Operating procedures and documentation; and
  - Human and organisational factors.
- Selected criteria should address the following items:
  - Construction is in accordance with specifications;
  - Risk management recommendations have been addressed and required actions taken;
  - Regulatory and permit requirements are met; and
  - Emergency and operations procedures are in place and adequate.
- Maintenance procedures are assigned for development:
  - Required training of personnel and communication related to process safety management aspects has been accomplished; and
  - Necessary process safety documentation is readily available to those who need to use it.
- System checks are carried out and documented by competent personnel;
- There are defined criteria for categorising and handling identified issues and outstanding work items;
- Completed system checks are reviewed, approved, and accepted by specific levels of management appropriate to the magnitude of the risk; and
- Commissioning and start-up procedures have defined stages, hold / check points, and progression criteria and review authorities.

## 5.14 Element 14—Emergency and crisis management

### 5.14.1 Overview

The consequences of an incident can be significantly reduced if the organisation is prepared to handle potential emergency situations. Management should ensure that, in the event of an incident, the organisation is prepared for all necessary actions which might be required for the protection of the public, all personnel on site, the environment, plant, equipment, and the organisation's reputation.

### 5.14.2 Guidelines

The following is a list of guidelines for Element 14:

- Emergency procedures are prepared for all identified credible emergency scenarios including those created by neighbouring facilities. Emergency response plans (ERPs) are documented, accessible, and clearly communicated. The ERPs should cover but may not be limited to:
  - Response organisation structure;

- Defined roles and responsibilities;
  - Internal and external communication procedures;
  - Procedures for accessing and mobilising personnel and equipment for emergency response;
  - Locations for assembly or muster for evacuation scenarios;
  - Procedures for interfacing with other organisations, including the general public and external emergency response organisations;
  - Public relations; and
  - Recovery and remediation.
- Regular programme of training and physical performance drills involving internal and external resources is used to exercise, develop, and improve capabilities for a range of emergencies;
  - There are arrangements to ensure that specified levels of management periodically review ERPs, using findings from drills and incidents to identify and address issues and opportunities for improvement;
  - Equipment and facilities needed for emergency response are readily available and maintained and information (for example, site layout drawings and hazardous inventory data) that might be needed in an emergency is kept up to date;
  - Adequate numbers of competent personnel are available to fulfill the defined roles in the emergency plans; and
  - Mutual aid schemes involving relevant third parties and external services are established and agreed.

For more information, see:

- NFPA 1600®, *Standard on Continuity, Emergency, and Crisis Management* [20];  
NOTE The National Commission on Terrorist Attacks Upon the United States (the 9/11 Commission), recognised NFPA 1600® as the US National Preparedness Standard. Widely used by public, not-for-profit, nongovernmental, and private entities on a local, regional, national, international, and global basis, NFPA 1600® has been adopted by the U.S. Department of Homeland Security as a voluntary consensus standard for emergency preparedness.
- NFPA 704, *Standard System for the Identification of the Hazards of Materials for Emergency Response* [20];
- ISO 45001 [17];  
NOTE ISO 45001 provides requirements with guidance for use. Clause 8.2 covers emergency management.
- EIGA Info HF 06, *Organisation - "Site Emergency Response"* [21]; and
- EIGA Doc 80, *Handling Gas Container Emergencies* [22].

## 5.15 Element 15—Inspection and maintenance

### 5.15.1 Overview

Maintaining the integrity of plant and equipment is an essential component of process safety. Management should ensure that the necessary inspection and maintenance requirements are identified and carried out to reduce the likelihood of a significant incident as a result of failure of plant or equipment.

### 5.15.2 Guidelines

The following is a list of guidelines for Element 15:

- Equipment is uniquely identified and a file is kept of all design information and maintenance activity on the equipment;
- Equipment inspection and maintenance programmes are risk-based and / or time-based. Inspection and maintenance programmes should address and integrate long term equipment integrity and process safety compliance assurance;
- There are systems in place to ensure that equipment inspection and maintenance programmes are reviewed periodically, using findings from the programmes, industry experience, and incidents to identify and address issues and opportunities for improvement;
- Competent personnel are available to establish and perform the inspection and maintenance programmes;
- There are systems in place to ensure that findings and recommendations from the equipment inspection and maintenance programmes are prioritised and addressed; and
- Deviations from established inspection and maintenance programmes are approved by management.

There are numerous CGA and EIGA practices that are documented and published. EIGA Info HF 05, Task - "Maintenance" is a specific example [23]. The relevant publications are best searched for using CGA and EIGA's website.

## 5.16 Element 16—Management of safety critical devices

### 5.16.1 Overview

An essential requirement for process safety is that safety critical equipment and devices (SCDs) are in service and functioning correctly. Management should ensure that safety critical equipment and devices are identified and appropriately managed, so that they are in service and functioning correctly.

### 5.16.2 Guidelines

The following is a list of guidelines for Element 16:

- SCDs are uniquely identified and a file is kept of all design information and maintenance activity on the equipment;
- SCD testing, inspection and maintenance programmes are in place and approved by competent individuals;
- There are systems in place to ensure that SCD testing, inspection, and maintenance programmes are reviewed periodically using findings from the programme, industry experience, and incidents to identify and address issues and opportunities for improvement;

- Plans and schedules are developed for execution of testing, inspection, and maintenance programmes based upon the risk associated with failure of the SCDs;
- Competent personnel are available to establish and perform the testing, inspection, and maintenance programmes;
- There are systems in place to ensure that findings and recommendations from the SCD testing, inspection, and maintenance programmes are prioritised and addressed; and
- Procedures for disarming, deactivation, or bypassing of SCDs are reviewed and approved by management.

Safety critical devices are referred to and discussed in several CGA and EIGA publications. CGA P-36, *The Safe Preparation of Gas Mixtures*, and EIGA Doc 147, *Safe Practices Guide for Cryogenic Air Separation Plants*, are specific examples [24, 25]. CGA and EIGA publications related to this element are often specific to generic equipment such as storage vessels or specific to products such acetylene, nitrous oxide, oxygen, and other compressed gases and liquids.

## **5.17 Element 17—Work control, permit to work, and task risk management**

### **5.17.1 Overview**

The execution of maintenance and other work activities, if not appropriately managed, can significantly increase the levels of process safety risk. Management should ensure that effective work control, permit to work, and task risk management arrangements are in place and followed to control the risks arising from work activities.

### **5.17.2 Guidelines**

The following is a list of guidelines for Element 17:

- Appropriate work control and permit to work arrangements are employed to assure the safety of personnel, plant, processes, and the integrity of the equipment during work and maintenance activities;
- There are systems in place that ensure that process safety risks arising from work tasks are systematically identified and assessed before work starts, as circumstances change, and where new risks arise during execution of work;
- Risk control measures are identified and implemented to mitigate and manage the identified risks;
- Task risk assessments consider risk to:
  - Health and safety of employees, contractors, customers, and members of the public;
  - Environment; and
  - Equipment.
- Completed task risk assessments are reviewed and approved by nominated competent individuals and any decisions are clearly documented;
- All of the workgroup is made aware of task risk assessments and required control processes; and
- Competent personnel are available to perform the required work control, permit to work, and task risk management arrangements.

For more information, see EIGA Doc 40, *Work Permit Systems* [26].

## 5.18 Element 18—Contractors and suppliers — selection and management

### 5.18.1 Overview

Contractors and suppliers doing work on the organisation's behalf can impact its operations and its reputation. Management should ensure that contractors and suppliers perform in a manner that is consistent and compatible with the organisation's process safety requirements.

### 5.18.2 Guidelines

The following is a list of guidelines for Element 18:

- There is a process to ensure that services from contractors and suppliers are evaluated and selected against criteria that include an assessment of capabilities to perform work safely and in compliance with all applicable legislation;
- All contractors are informed and trained on relevant organisation procedures and practices for the work that they undertake;
- Effective organisational, communication, and control arrangements are in place between organisation personnel and contractor personnel to manage the risks effectively;
- Contractor and supplier performance is routinely monitored and assessed, feedback is provided, and non-conformities are corrected. Poor performance results in removal from approved contractor / supplier list; and
- Competent personnel are available to carry out the required contractor and supplier selection and management arrangements.

For more information, see EIGA Doc 118, *Safe Management of Contractors* [27].

## 5.19 Element 19—Incident investigation

### 5.19.1 Overview

An essential aspect of process safety performance improvement is learning from incidents and near misses and taking action to prevent their recurrence. Management should ensure that incidents and near misses are consistently reported and investigated and that identified actions and learnings are implemented on a timely basis.

### 5.19.2 Guidelines

The following is a list of guidelines for Element 19:

- System is in place for incident reporting, investigation, follow-up and capturing lessons learned from incidents and near misses including but not limited to:
  - Injury to people;
  - Environment incidents;
  - Damage to assets or reliability events;
  - Loss of process containment;
  - Energy release; and

- Deactivation of safety critical devices.
- Reporting of incidents and near misses by all personnel including contractors and suppliers is mandatory;
- Incidents and near misses are classified and investigated on the basis of actual and potential outcome;
- Incidents and near misses are investigated according to a documented procedure on a timely basis;
- Investigations identify root causes and management system failures, including technical, human, and organisational factors;
- Effective arrangements are in place to ensure that incidents or near misses are investigated when they involve customers, contractors, or supplier personnel;
- There are processes in place to learn from relevant incidents, near misses, and good practices;
- Competent personnel are available to perform the required investigations;
- Completed investigations are reviewed and approved by specific levels of management appropriate to the classification of the incident;
- Where appropriate and recognising legal and security constraints, identified stakeholders who could be impacted by hazards are kept informed about the findings and recommendations from investigations;
- Recommendations are monitored and tracked to completion; and
- Process safety incident statistics and performance trends are reviewed by specified levels of management.

For more information, see:

- EIGA Doc 90, *Incident/Accident Investigation and Analysis* [28];
- EIGA Info HF 03, *Organisation - “Human Factors in Incident Investigation”* [29]; and
- EIGA Info HF 01, *Human Factors - “An Overview”* [30].

## **5.20 Element 20—Audit, management review, and intervention**

### **5.20.1 Overview**

Regular review and audit of effective application of the process safety management framework is vital to ensure that process safety performance continues to meet the defined targets. Management should ensure that there is both routine review and independent audit of each element of the process safety management guidelines.

### **5.20.2 Guidelines**

The following is a list of guidelines for Element 20:

- Performance measures are established to monitor the degree to which the process safety management guidelines are being met for each implemented element;

- Organisation's operations are routinely monitored, incorporating process safety management performance measures, and are periodically reviewed by specified levels of management;
- Process safety management guidelines implemented within the organisation are periodically reviewed and updated as necessary to ensure that they continue to meet the needs of the organisation;
- Audit criteria are defined to provide a consistent basis for audit and a consistent basis for development of the audit analysis;
- Defined internal (second party) and / or external (third party) audit programme is in place. The audit assesses application of process safety management guidelines and the effectiveness of the management review;
- Audits are conducted by trained and competent persons. Whenever possible, multidisciplinary teams, including process safety professionals and personnel with operational and technical expertise should be used;
- Frequency and scope of the audits should reflect the complexity of the operation, the level of risk, and previous compliance history;
- Audit findings are documented and reviewed with the auditee. Audit summary is communicated with management;
- Necessary actions to correct and prevent identified issues and deviations in performance below defined tolerance levels are identified, appropriately prioritised, scheduled, and tracked to completion;
- Effectiveness of the audit programme is periodically reviewed and the findings are used to make improvements;
- Understanding of the requirements of all elements and effective application of the process safety management guidelines are periodically tested within the organisation; and
- Audit performance trends for all elements are periodically reviewed by management.

For more information, see:

- EIGA Doc 102, Safety Audit Guidelines [31]; and
- EIGA Doc 135, Environmental Auditing Guide [32].

## **5.21 Element 21—Measures and metrics**

### **5.21.1 Overview**

Process safety performance indicators, measures, and metrics are important for improvement of process safety. Two types of indicators are required; leading and lagging. Leading indicators show if controls are working as intended while lagging indicators show whether or not an outcome is being achieved. Management should ensure that performance indicators, measures, and metrics are appropriate and effective in improving process safety performance.

### **5.21.2 Guidelines**

The following is a list of guidelines for Element 21:

- Correct selection of indicators is important since inappropriately selected indicators can result in knowledge gaps or can result in unwarranted confidence. Indicators should provide a means to measure activity, status, or performance against requirements and goals:

- Lagging indicators should identify and classify incidents; and
- Leading indicators should identify and classify conditions that could ultimately lead to more severe consequences. and
- Indicators should be tracked and periodically reviewed by management to identify actions to drive improvement.

## 6 References

Unless otherwise specified, the latest edition shall apply.

- [1] *High Level Framework for Process Safety Management, First Edition*, Energy Institute. [www.publishing.energyinst.org](http://www.publishing.energyinst.org).
- [2] *Center for Chemical Process Safety*, American Institute for Chemical Engineers. [www.aiche.org](http://www.aiche.org).
- [3] Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances, [www.europa.eu](http://www.europa.eu).
- [4] *Guidelines for Managing Process Safety Risks During Organizational Change*, Center for Chemical Process Safety, American Institute for Chemical Engineers. [www.aiche.org](http://www.aiche.org).
- [5] EIGA Info HF 11, *Organisation - "Safety Culture"*, [www.eiga.eu](http://www.eiga.eu).
- [6] EIGA Doc 60, *Seveso Documents - Guidance on Applicability, Assessment and Legal Documents for Demonstrating Compliance of Industrial Gases Facilities with Seveso Directive(s)*, [www.eiga.eu](http://www.eiga.eu).
- [7] EIGA Info HF 02, *Individual - "Training and Competence"*, [www.eiga.eu](http://www.eiga.eu).
- [8] EIGA Doc 23, *Safety Training of Employees*, [www.eiga.eu](http://www.eiga.eu).
- [9] *Hazard Identification Procedures*, Center for Chemical Process Safety, American Institute for Chemical Engineers, [www.aiche.org](http://www.aiche.org).
- [10] EIGA Doc 75, *Determination of Safety Distances*, [www.eiga.eu](http://www.eiga.eu).
- [11] EIGA Info HF 07, *Organisation – "Communications on Safety"*, [www.eiga.eu](http://www.eiga.eu).
- [12] EIGA Doc 132, *Unmanned Air Gas Plants: Design and Operation*, [www.eiga.eu](http://www.eiga.eu).
- [13] *Guidelines for Risk Based Process Safety*, Center for Chemical Process Safety, American Institute for Chemical Engineers, [www.aiche.org](http://www.aiche.org).
- [14] EIGA Info HF 04, *Task - "Design and Effectiveness of Procedures"*, [www.eiga.eu](http://www.eiga.eu).
- [15] Project Management Institute, [www.pmi.org](http://www.pmi.org).
- [16] EIGA Info HF 10, *Organisation - "Managing Organisational Change"*, [www.eiga.eu](http://www.eiga.eu).
- [17] ISO 45001, *Occupational health and safety management systems*, [www.iso.org](http://www.iso.org).
- [18] EIGA Doc 51, *Management of Change*, [www.eiga.eu](http://www.eiga.eu).
- [19] NFPA 1600®, *Standard on Continuity, Emergency, and Crisis Management*, National Fire Protection Association, [www.nfpa.org](http://www.nfpa.org).

- [20] NFPA 704, *Standard System for the Identification of the Hazards of Materials for Emergency Response*, National Fire Protection Association, [www.nfpa.org](http://www.nfpa.org).
- [21] EIGA Info HF 06, *Organisation - "Site Emergency Response"*, [www.eiga.eu](http://www.eiga.eu).
- [22] EIGA Doc 80, *Handling Gas Container Emergencies*, [www.eiga.eu](http://www.eiga.eu).
- [23] EIGA Info HF 05, *Task - "Maintenance Error"*, [www.eiga.eu](http://www.eiga.eu).
- [24] CGA P-36, *The Safe Preparation of Gas Mixtures*, [www.cganet.com](http://www.cganet.com).
- [25] EIGA Doc 147, *Safe Practices Guide for Cryogenic Air Separation Plants*, [www.eiga.eu](http://www.eiga.eu).
- [26] EIGA Doc 40, *Work Permit Systems*, [www.eiga.eu](http://www.eiga.eu).
- [27] EIGA Doc 118, *Safe Management of Contractors*, [www.eiga.eu](http://www.eiga.eu).
- [29] EIGA Doc 90/13, *Incident/Accident Investigation and Analysis*, European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [30] EIGA Info HF 03/17, *Organisation - "Human Factors in Incident Investigation,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [31] EIGA Info HF 01/17, *Human Factors - "An Overview,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [32] EIGA Doc 102/03, *Safety Audit Guidelines*, European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [33] EIGA Doc 135/12, *Environmental Auditing Guide*, European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [34] Sutton, Ian. *Process Risk and Reliability Management*, Gulf Professional Publishing, 2014. <https://www.elsevier.com/books-and-journals/gulf-professional-publishing>
- [35] Spellman, Frank. *A Guide to Compliance for Process Safety Management/Risk Management Planning (PSM/RMP)*, CRC Press, 1998. [www.crcpress.com](http://www.crcpress.com)
- [36] OSHA 3132, *Process Safety Management*, U.S. Department of Labor. [www.osha.gov](http://www.osha.gov)
- [37] OSHA 3133, *Process Safety Management Guidelines for Compliance*, U.S. Department of Labor. [www.osha.gov](http://www.osha.gov)
- [38] OSHA 3909, *Process Safety Management for Storage Facilities*, U.S. Department of Labor. [www.osha.gov](http://www.osha.gov)
- [39] EIGA Info HF 08/18, *Task - "Alarm Handling,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [40] EIGA Info HF 09/09, *Task - "Fatigue from Working Patterns - Shiftwork and Overtime,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [41] EIGA Info HF 12/12, *Task - "Human Factors in Design,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)
- [42] EIGA Info HF 13/12, *Organisation - "Human Reliability,"* European Industrial Gases Association. [www.eiga.eu](http://www.eiga.eu)

## Appendix 1 – Related publications

### (Informative)

This appendix lists other publications that are relevant to process safety management and align with the specific process safety management elements listed in this document. Some publications listed in this appendix are in need of review, (in some cases specifically to integrate process safety related items) and will be updated in due course. Resources specific to each element are referenced in each element's section.

#### A1 General process safety management related documents and publications

- *Guidelines for Risk Based Process Safety*, Center for Chemical Process Safety, American Institute for Chemical Engineers [13];

NOTE In addition to this publication, CCPS has an extensive library of process safety guidelines for each element of a process safety programme.

- *Sutton, Ian. Process Risk and Reliability Management* [33];
- *Spellman, Frank. A Guide to Compliance for Process Safety Management/Risk Management Planning (PSM/RMP)* [34];
- *OSHA 3132, Process Safety Management* [35];
- *OSHA 3133, Process Safety Management Guidelines for Compliance* [36]; and
- *OSHA 3909, Process Safety Management for Storage Facilities* [37].

There are numerous EIGA publications that are related to process safety management, examples include:

- EIGA Info HF 08, *Task - "Alarm Handling"* [38];
- EIGA Info HF 09, *Task - "Fatigue from Working Patterns - Shiftwork and Overtime"* [39];
- EIGA Info HF 12, *Task - "Human Factors in Design"* [40]; and
- EIGA Info HF 13, *Organisation - "Human Reliability"* [41].