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European Commission's Joint Research Centre

ASSESSMENT OF SAFETY MANAGEMENT SYSTEMS OF MAJOR HAZARD SITES

KEY POINTS AND CONCLUSIONS

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As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle. Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new methods, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners.

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Assessment of Safety Management Systems of Major Hazard Sites

European Commission

MAJOR ACCIDENT HAZARDS BUREAU

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Mutual Joint Visit on Seveso Inspections:
27-29 October 2010, Fulda, Germany

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Mark Hailwood, Maureen Heraty Wood and Dagmar Dräger

PREFACE

With the entering into force of the European Directive 96/82/EG (Seveso II Directive) the Member States are required to ensure that the operator of an establishment falling under the requirements of the Directive draws up a policy for the prevention of major accidents. This policy shall be designed to guarantee a high level of protection for man and the environment.

For so called “lower-tier” establishments this takes the form of the drawing up of a “Major Accident Prevention Policy – MAPP” according to the requirements of Article 7 of the directive. This document should take account of the principles contained in Annex III. For the so called “upper-tier” establishments the operator must draw up a major accident prevention policy and a safety management system (SMS) for implementing it. Within the Safety Report (Art. 9) it should be demonstrated that the MAPP and the SMS have been put into effect in accordance with Annex III.

However, there are still widespread questions as to when the assessment of the SMS by the competent authorities within the inspection process can determine that adequate steps have been taken, at what point can the demonstration by the operator be considered sufficient, and how can inspectors document their evidence of deficiencies in the SMS in such a way as to be able to derive effective enforcement measures from this? There is therefore a need to share experience and define the areas of common understanding with regard to the inspection and control of Safety Management Systems, as well as those areas where further work is needed. For this reason, this topic was selected as the focus of a workshop in the framework of the European Commission’s Mutual Joint Visit (MJV) Workshops for Seveso Inspections. The workshop results go some way towards showing that common understandings can be established amongst inspectors and that assessment criteria can be identified.

The MJV programme promotes technical exchange on common priority topics among Seveso inspectors to facilitate the sharing and adoption of good practices for enforcement and risk management. Results are disseminated as part of the Seveso Inspections Publication Series with the view that they may be of value to practitioners in both government and industry. The programme is one of a number of initiatives currently sponsored by the European Commission in place to support implementation of the Directive. It is co-ordinated with representatives of Member States inspectorates and the European Process Safety Centre.

The main purpose of publishing this document is to provide a collection of knowledge representing the state of practice in the EU in the expectation that it will aid Seveso inspectors and inspections programmes in reviewing and improving their performance as appropriate. It is understood that several approaches to controlling this type of major hazard may be equally effective and the document is not offered as a definitive assessment of all possible options in this regard. Moreover, the authors note that where information is provided on a practice applied in a particular country it has been provided with the view that this might be useful descriptive information. However, the document does not intend to represent a complete description of any one country's inspection practices since they often differ internally between regions and sometimes between competent authorities who share Seveso inspection responsibilities.

For more information on Seveso Directive implementation in the European Union, visit http://ec.europa.eu/environment/seveso/.

Contents

Executive Summary

The safety management system is now considered a central component of modern process safety management. It was first adopted into various European national laws in the early 1990s, most notably in the United Kingdom for offshore facilities following the 1988 *Piper Alpha* disaster in the North Sea. With the advent of the Seveso II Directive in 1996 (Directive 96/82/EC), the concept of the safety management system was enshrined as an essential element in control of sites with major chemical hazards across the European Union. The Cullen Report that was issued following the *Piper Alpha* disaster also introduced the operator obligation to "demonstrate" that it has a safety management system and recommended that regulators employ a systematic approach to inspections that was equally focused on compliance with safety management criteria as well as technical standards. [1]**Error! Reference source not found.**

With the entering into force of the Seveso II Directive[1], the Member States have ever since been required to ensure that the operator of an establishment falling under the requirements of the Directive draws up a policy for the prevention of major accidents. This policy shall be designed to guarantee a high level of protection for man and the environment. For lower-tier establishments this requirement is manifested in the obligation to establish a major accident prevention policy (MAPP) under Article 7 of the Directive. This document should take account of the principles contained in Annex III. For upper-tier establishments the operator must establish both a major accident prevention policy and a safety management system (SMS) for implementing it. According to Article 9 of the Directive, the operator must demonstrate that the MAPP and the SMS have been put into effect consistent with the principles articulated in Annex III. The

[1] Obligations associated with safety management systems are continued in Seveso III (2012/18/EU), but since the workshop took place prior to Seveso III coming into effect, the reference legislation of the document remains Seveso II.

Directive also clearly states that the level of complexity and detail of the safety management system should be in proportion to the level of risk present on the site.

Article 18 of the Directive requires conducting a systematic examination of the systems being employed at the establishment, whether of a technical, organizational or managerial nature, so as to ensure in particular:

- That the operator can demonstrate that he has taken appropriate measures, in connection with the various activities involved in the establishment, to prevent major-accidents,
- That the operator can demonstrate that he has provided appropriate means for limiting the consequences of major-accidents, on-site and off-site,
- That the data and information contained in the safety report, or any other report submitted, adequately reflects the conditions in the establishment
- That information has been supplied to the public pursuant to Article 13.

Public authorities are required to carry out inspections of the establishments which cover not only aspects of the technical but also organizational and managerial systems.

There are still widespread questions among many inspectors as to when the assessment of the SMS can determine that adequate steps have been taken, in particular:

- At what point, can the demonstration by the operator be considered sufficient?
- How can inspectors document their evidence of deficiencies in the SMS in such a way as to be able to derive effective enforcement measures from this?

The problem of evaluating the SMS has several dimensions. The safety report does not always create a narrative that is sufficiently transparent

in connecting major accident risks to the safety management system and relevant control measures. Large scale enterprises and corporations belonging to the upper-tier establishments of the Seveso II Directive may have a number of different certifications under quality, occupational health and safety, or environmental management standards. In this type of facility it is often difficult to assess how safety specifically with regard to major accident prevention is addressed. Small and medium-size enterprises often have limited resources and expertise for understanding what SMS processes they need so to establish and maintain an SMS appropriate to their risks. In some industries the operators have only a little knowledge of the regulations relating to major accidents making communication between authorities and operators about the SMS even more difficult.

It is clear that there is no simple formula for responding to these challenges that applies individually to each site. However, the systematic nature of an audit implies a common logic that should be applied systematically across sites. However, even when a logical audit system has been well-defined by authorities, substantial questions remain concerning how far to carry the logic, how to recognize where important gaps are present, how to be confident that implementation in practice with management claims, etc.

For this reason, it was recognized that sharing knowledge and experience among inspectors could be very useful for benchmarking good practice on inspection and control of SMS demonstrations. In addition, this exchange would be of value to identify common priorities for further development of knowledge and tools to aid inspectors in these efforts.

From 27-29 October 2010, the Regional Council of Darmstadt hosted a Mutual Joint Visit (MJV) workshop for Seveso Inspectors in Fulda, Germany on the topic of Safety Management Systems. Workshop participants consisted of 33 participants from inspection authorities from 17 EU Member States, 2 Candidate Countries and 2 countries of the European Economic Area. In addition a number of representatives from industry participated.

The workshops each addressed a different SMS topic. For reasons of time, the third element (Operating Procedures) and fifth element (Planning for Emergencies) of the SMS, as defined in Annex III of the Seveso Directive, were not discussed. The remaining SMS elements were the focus of the workshops as indicated below:

- Workshop I: Organization and Personnel
- Workshop II: Identification and Evaluation of Major Hazards and Risks
- Workshop III: Management of Change
- Workshop IV: Monitoring Performance, Audit and Review

Participants were allocated to one of the 3 parallel break-out groups, focused on a different type of operator, as described above, but the same SMS inspection topic. Each workshop concluded with a plenary session in which the groups came together to share their results. For each plenary session rapporteurs noted the contents, recommendations and conclusions of the discussions and in the final session at the end of the workshop the compiled results were presented for a final discussion. The discussions, their results together with the introductory presentations generated the basis for this publication.

GENERAL OVERVIEW OF THE ASSESSMENT OF THE SMS

A large proportion of the inspection activities to-date have concentrated on determining whether or not procedures have been implemented and whether responsibilities have been adequately defined. A number of check-list and questionnaires exist to assist the inspectors in this task. When inspecting the SMS the authority inspectors need to be aware that each company will have its own individual design. Assessment of the SMS within the inspection requires a great deal of perception for the adequacy of the measures together with a technical understanding of the chemical processes involved.

In assessing the SMS, the inspector should keep in mind the following essential characteristics of an effective SMS:

1. Evidence of robust implementation, that is, the establishment of clear objectives and clear requirements that are consistently and rigorously followed.
2. Qualification of personnel involved in executing the safety management system, facilitating formation of a proper process hazard assessment (team), reliable execution of the management of change process, etc.
3. Performance monitoring, involving the objectives, reports and reviews for 1. and 2. The identification and dissemination and implementation of lessons learned.
4. Leadership from the top down that supports implementation and anticipates and resolves potential conflicts with other corporate objectives giving equal priority to safety.
5. Self-assessment and auditing processes conducted in a thorough manner with adequate frequency followed by appropriate and timely implementation of resulting recommendations.

Both the inspector and the operator are charged with auditing the SMS. By nature an audit requires a systematic and evidence-based approach. The evaluation generally starts with an overall assessment as to whether the SMS addresses all the necessary elements of Annex III. Then the evaluation should proceed to each element of the SMS and systematically seek to find evidence to determine the degree to which the SMS is known, understood, accepted, and followed in the organization. The following questions may go some way to addressing these aspects:

- Does the SMS contain the elements from Annex III of the Directive?
- Are responsibilities defined and assigned?
- Are procedures defined, implemented and adhered to?

- Does the operation on-site indicate that the SMS functions?
- Is safe operation a day-to-day and long term goal of the company?

Two further questions of particular importance within the inspection of the SMS are:

- How good is the SMS?
- How good does the operator believe the SMS to be?

ASSESSING ORGANIZATION AND PERSONNEL

Some key aspects of the safety management system are embedded in the organizational structure, including the assignment of roles and responsibilities to job functions, identifying competency and training needs of the persons assigned to the specific job functions, and establishing the communication mechanisms for providing important information across and up and down the organization. In effect, the safety management system provides the essential infrastructure to support the rest of the system.

Important considerations

When the SMS procedures have been outsourced. It is important to verify implementation of the SMS at the site. In all cases, it is never sufficient to rely on written procedures, but even more so when writing the SMS has been outsourced.

Employee training. The organization of personnel training is an important issue of the general topic of "organization and personnel". Both operator employees and contractor employees need to be aware of process safety issues and companies must monitor whether their procedures for organizing and training their employees and organizing contractors are functioning.

Contractor communication and training. Just as for employees, the operator should proactively provide contractor employees complete information on the hazards associated with their work and control measures to minimise the risk of accident.

What does success look like?

The following are examples volunteered by participants from their inspection experience:

- Safety is a management agenda item – it appears as a regular and important item at managerial meetings, not just safety meetings.
- Major hazards are addressed systematically in identifying competency, training, procedures and control measures.
- Safety critical tasks have been systematically identified and documented.
- There is sufficient evidence that employees and contractors are involved in the development and delivery of training and procedures.
- Training records reflect the implementation of training to address the identified needs and testing of competence is routinely conducted as follow-up to training or when replacing staff in a safety critical function.
- Interviews with employees confirm that procedures described in written documents are understood and followed.
- Selection and management of contractors and temporary workers reflects competency requirements identified for safety critical tasks (certification, qualifications and experience).
- Contractor supervision and follow-up is a routine part of company procedure and appropriately includes attention to risk management and safe work practices (the intelligent customer).

ASSESSING THE IDENTIFICATION AND EVALUATION OF MAJOR HAZARDS AND RISKS

Risk assessment is the cornerstone of the SMS. It is a continuous process in the global life-cycle of a company. The aim of the identification and evaluation of major hazards and risks is to ensure proper control of low-probability, high consequence events.

Important considerations

The role of management. Since management is responsible for managing resources, by necessity it plays a role in ensuring adequate resources are allocated to maintain the proper control measures to address the risks.

The relevance of accident lessons learned to the risk assessment. It is useful for the inspector to ask the company whether it has researched past accidents in conducting the risk assessment. Relevant findings from past accidents should be used as input since the lessons learned often influence and provide new information to improve standards and codes of practice.

What does success look like?

The following are examples volunteered by participants from their inspection experience:

- Risk assessment drives control processes for managing all of the following:
    - Operating procedures
    - Equipment
    - Training
    - Inspections and maintenance
    - Emergency planning

- Identification and evaluation of major hazards and risks are clearly proportionate in the site's risk management approach.
- Employees and contractors are aware of the risks associated with their work and their role in controlling them.
- The site risk assessment and individual process risk assessments are fully documented, including the process followed, results and information used to produce the outcome. Control measures and associated actions recommended by the risk assessment should be documented including follow-up (when and how they were implemented).
- There is a systematic selection and application of risk assessment methods and the consequence analysis was conducted by a competent expert.
- The off-site risk is communicated transparently to senior management and all stakeholders.

ASSESSING THE MANAGEMENT OF CHANGE (MOC) PROCESS

Seveso site operators often are not sufficiently aware that failure in the management of change is one of the most common causes of accidents. Every accident that occurs is proof that the safety management system is not 100% working to control the risks as it should. Sometimes the accident may be caused by latent errors, that is, from a change that was implemented many years ago but never communicated or documented or assessed in any way, and the associated risk only became evident when the accident occurred.

Important considerations

Management of change and aging of installations. Once a piece of equipment changes the operating process, this is an operational change. Replacement of parts is often simply not exchange of one

piece of one piece of equipment for another. It may be an upgrade that imposes changes on interfacing parts of the process or it may even require a process re-design. The material composition may have changed and may have an effect on downstream processes.

Organizational change. The process of managing organization of change should include identification of safety critical roles and the workload, competences and specialised training associated with each role. The risk analysis should serve as the basis for determining whether additional competency, training or a different workload distribution is required.

Involving human resources. The human resources department may be important in assessing the implications of the change, projecting it out over the short and medium-term and communicating it to management and other staff as might be appropriate.

What does success look like?

- Within the policy of the company a safety relevant change is clearly defined.
- The MoC process has a systematic hazard identification and evaluation process.
- MoC procedures are known by all personnel and applied systematically.
- Initiated changes are tracked all the way through to close-out and all changes are documented in procedures, piping and instrumentation diagrammes (P&ID), etc.
- Temporary changes are closed out and do not become permanent by default.
- Responsibilities are defined for initiating and authorising changes as well as approval on completion.
- The MoC process is led by management.

ASSESSING MONITORING OF PERFORMANCE, AUDIT AND REVIEW

Whether the company has an audit team for process safety (at company or corporate level) is one of the key questions for the assessment of the SMS suitability for monitoring, auditing and reviewing performance. The team should have responsibility for planning and conducting audits, setting audit intervals, determining the content of the audit and ensuring that actions are tracked. Of importance is that the audit team is independent of the operations section which is being audited. Sometimes a company will not have a formal audit or monitoring system but other audits and routine offer feedback on safety performance.

Important considerations

Responsibility for the SMS. Responsibility for the SMS should be distributed over a number of positions within the organisation and involve the whole of the line management. There should be a process embedded in the SMS to check periodically that assigned personnel understand and are performing the tasks allocated in a competent and timely manner. It may be that a small site might have one person responsible for the SMS, but for most sites it is not recommended.

Safety performance indicator. There is a need for objective and consistent measures which address safety critical activities. One possible approach is the use of (Process) Safety Performance Indicators SPIs. If the SMS is effective then the operator should be able to demonstrate that the values within the SPIs are improving or at least constant, that the improvements are maintained over time and that spot-checks by authority inspectors validate the situation as described by the indicators.

Many inspectors have noted that the inspection should include a review of the quality of the safety performance indicators, if the company formally maintains such a feedback system. They offered a number of

suggestions to other inspectors on evaluating such systems as part of SMS inspection:

- The company must use indicators based on its own operations and experience with them. Inspectors should also question why the companies have chosen particular topics for indicators and how the management has determined that they are important.
- Inspection of the SMS should be based on more than just the output from the indicators. Qualitative feedback, e.g., from audits, occurrence of near misses and accidents, should also be regularly reported with lessons and recommendations extracted and incorporated into the safety management system.
- Companies should report on competency and training in their indicators. Several examples of measures of training are provided in various guidance documents that have been published by industry and government on safety performance indicators.
- Are the right questions being asked? When collecting data on near misses a high collection rate should make the operator proud, at least in the early stage of the programme. There is a need to compare smaller incidents (near misses) to the number of accidents.
- The quality of the analysis of feedback is important. To evaluate analytical quality, inspectors can inquire about the analytical process, e.g., who performs the analysis, the methods used, and how feedback is selected for analysis (for example, if a dataset is large or certain data are generated continuously). They may also ask to see an example of a report summarising results of an analysis and associated recommendations for follow-up.

What does success look like?

In identifying success the inspector needs to look for

- Evidence, via documentation, observation and interviews, that the appropriate behaviours and activities have taken place within the company.
- Senior management views the audit as an important activity contributing to continuous improvement rather than just a compliance activity.
- Management is involved in meetings to prepare for audits and discuss results and follow-up.
- The audit process completes the entire feedback loop of the so-called Deming-Cycle, i.e., Plan-Do-Check Act completed.
- All elements of the SMS are reviewed and results of the audit are fed back into the SMS system as a whole.

The following document provides a more detailed summary of the exchange of knowledge and experience among Seveso inspectors at the Mutual Joint Visit on Safety Management Systems.

1 SMS AND THE ROLE OF THE SEVESO INSPECTOR

1.1 BACKGROUND

The safety management system is now considered a central component of modern process safety management. It was first adopted into various European national laws in the early 1990s, most notably in the United Kingdom for offshore facilities following the 1988 *Piper Alpha* disaster in the North Sea. With the advent of the Seveso II Directive in 1996 (Directive 96/82/EC), the concept of the safety management system was enshrined as an essential element in control of sites with major chemical hazards across the European Union. The Cullen Report that was issued following the *Piper Alpha* disaster also introduced the operator obligation to "demonstrate" that it has a safety management system and recommended that regulators employ a systematic approach to inspections that was equally focused on compliance with safety management criteria as well as technical standards. **Error! Reference source not found.**

With the entering into force of the Seveso II Directive) the Member States were required to ensure that the operator of an establishment falling under the requirements of the Directive draws up a policy for the prevention of major accidents. This policy shall be designed to guarantee a high level of protection for man and the environment. For lower-tier establishments this requirement is manifested in the obligation to establish a major accident prevention policy (MAPP) under Article 7 of the Directive. This document should take account of the principles contained in Annex III. For upper-tier establishments the operator must establish both a major accident prevention policy and a safety management system (SMS) for implementing it. According to Article 9 of the Directive, the operator must demonstrate that the MAPP and the SMS have been put into effect consistent with the

principles articulated in Annex III. The Directive also clearly states that the level of complexity and detail of the safety management system should be in proportion to the level of risk present on the site.

The SMS as described in Annex III consists of the organizational structure, responsibilities, practices, procedures, processes and resources for the implementation of the MAPP. According to the Annex, the SMS must address the following issues:

- Organization and personnel
- Identification and evaluation of major hazards
- Operational control
- Management of change
- Planning for emergencies
- Monitoring performance
- Audit and review

The Annex III principles are also well-aligned with the structures of ISO 9001 and ISO 14000 standards for quality management and environmental management.

Article 18 of the Directive requires that the competent authority conducts a systematic examination of the systems being employed at an establishment, whether of a technical, organizational or managerial nature, so as to ensure in particular:

- That the operator can demonstrate that he has taken appropriate measures, in connection with the various activities involved in the establishment, to prevent major-accidents,
- That the operator can demonstrate that he has provided appropriate means for limiting the consequences of major-accidents, on-site and off-site,

- That the data and information contained in the safety report, or any other report submitted, adequately reflects the conditions in the establishment
- That information has been supplied to the public pursuant to Article 13.

1.2 CHALLENGES IN INSPECTING SAFETY MANAGEMENT SYSTEMS

In 1998 the European Commission published a guidance document explaining how the fundamental elements outlined in Annex III should be broadly interpreted in the context of the control of major chemical hazard sites. [2] Many Member States also produced more detailed guidance for operators and some Member States also produced tools (e.g., questions and strategies) for their inspectors on auditing a site's SMS.

The majority of those tasked with the role of an inspector within the competent authorities have a qualification in a technical, engineering or natural science discipline. The assessment of the establishment's compliance with technical requirements and its process for determining necessary corrective measures is well within the competency of such qualified staff. However, addressing issues which are difficult to formulate within well-defined parameters is a very different type of assessment. Over the past few years, methods, tools and approaches have been developed by inspectors and their organizations to cope with some of these problems. However, there are still widespread questions among many inspectors as to when the assessment of the SMS can determine that adequate steps have been taken, in particular:

- At what point, can the demonstration by the operator be considered sufficient?
- How can inspectors document their evidence of deficiencies in the SMS in such a way as to be able to derive effective enforcement measures from this?

The difficulty of inspecting safety management systems in chemical process establishments is not a new topic. Notably, a number of challenges were already foreseen in an initiative to test the validity of the EU guidance on implementation of MAPP and SMS requirements in 1997. Results from exercises conducted by France on various industrial sites concluded that "very company-specific SMS can be very difficult to assess." In addition, the findings also highlighted that the safety culture of the operator can make a great deal of difference to the inspector's task, making it more, or less, easy. [1]

The problem of evaluating the SMS is often rooted in the construction of the safety report. Operators vary considerably in their skill at arguing on behalf of the robustness of their safety management systems. The safety report does not always create a narrative that is sufficiently transparent in connecting major accident risks to the safety management system and relevant control measures. The inspector may struggle to find both an adequate narrative on paper and also in the inspection itself if the site itself cannot put all the pieces together (even if they might exist). [3]

Inspector audits of SMS on large scale vs. smaller scale industrial sites also may face different challenges. Large scale enterprises and corporations belonging to the upper-tier establishments of the Seveso II Directive are often already in a situation that a management system is in place. Sometimes this is an operative necessity. Sometimes it is the result of the certification under quality, occupational health and safety, or environmental management standards. In this type of facility it is often difficult to assess how safety specifically with regard to major accident prevention is addressed (i.e., process safety). This situation is particularly the case if an integrated management system has been developed which covers the whole range of management activities. This complexity can make it difficult for inspectors to identify whether the necessary systems and structures for major accident prevention are in place.

On the other hand, large scale enterprises and corporations belonging to the lower-tier establishments may already have a management system in place. Nonetheless, the system may not explicitly cover the

issues of chemical process safety as described in Annex III of the Seveso II Directive. In addition, small and medium-size enterprises often have limited resources and expertise for understanding what SMS processes they need so to establish and maintain an SMS appropriate to their risks. As noted in a study of Article 7 implementation in lower-tier sites, "… In these cases the owner/manager is alone responsible for everything and these enterprises are above all else ruled by economic constraints. As an inevitable consequence, the operators have only a little knowledge of the regulations relating to major accidents which make communication between authorities and operators even more difficult." [4] This imbalance between resources and requirements creates a particular dilemma in terms of how the inspector obtains the necessary evidence to assess the SMS on such sites. There may also be a question in regard to the role of the inspector, whether he/she can be advising and educating the operator using the audit process. Moreover, in some industries, it may not be unusual to find small and medium enterprises counted among upper-tier sites, e.g., storage and production of fireworks, explosives, agricultural chemicals and fuel, which only exacerbates the concerns and predicament of the inspector.

It is clear that there is no simple formula for responding to these challenges that applies individually to each site. However, the systematic nature of an audit implies a common logic that should be applied systematically across sites. For example, the Belgian guidance for inspectors on auditing SMS proposes evaluating the demonstration evaluation on the basis of the presence of one or more defined measures that the company may be taking. (The company may also offer other measures or justification for not establishing some measures based on the logic embedded in the guidance.) However, even when the authorities have established a systematic approach to auditing, the inspector may still find it difficult it to recognize where important gaps are present and how to be relatively confident that implementation in practice is consistent with the written company procedure.

For this reason, it was recognized that sharing knowledge and experience among inspectors could be very useful for benchmarking good practice on inspection and control of SMS demonstrations. In

CASE STUDY: NOX ACCIDENT

During the start-up of a nitric acid production facility a huge (> 22 tonnes) of nitrous oxide (NOx) was released at a height of 80 metres via the chimney.

The nitric acid process involves the combustion of ammonia in oxygen to form NO, followed by the further oxidation of the NO to NO_2 under heating. The NO_2 is then absorbed in water to produced nitric acid ad NO.

The NOx emission occurred in the early morning of 9 April 2010 because the DeNOx plant had become unstable during start-up. The emission at the height of 80 metres was considered a "safe location" for the establishment and no onsite workers were affected. There was, however, a cross-border emission to a neighbouring country which led to irritation by inhalation in exposed members of the public. The UNECE Helsinki Treaty on the transboundary effects of industrial accidents was applicable.

The findings of the authorities' investigation into the accident were:

There was insufficient water supplied to the DeNOx installation which had not been detected.

- A manual valve was open to the wastewater system.
- The flow meter before the manual valve indicated sufficient flow.
- The NOx monitoring was not appropriate for the start-up process.

The enforcement measures adopted in conclusion were:

- The NOx monitoring should be carried out using two different ranges, one for start-up and one for normal operations.
- The flow meter and manual value in the water line should be redesigned so that information regarding the flow of water to the tower of the DeNOx system is obtained.

- The manual valve should be locked in position.
- The operating procedures should be modified based on the learnings from the incident.

In considering the role of the SMS in this accident deficiencies could be identified in many of the elements.

- SMS-2: Identification of Major Hazards + Assessment of Risks
  - Low flow on Absorption Column identified: risk rating too low
  - HAZOP: no identification of wrong position of flow meter vs. manual valve
- SMS-3: Operational Control
  - Compilation, verification and validation of operating procedures for shutdown and start-up of the installation were insufficient. (There were several types of procedures: safety critical, frequent and non-frequent).
  - The format and language of operating procedures interfered with precise communication of procedures and when they should be used.
- SMS-4: Management of Change
  - Change of operating procedures did not follow existing management of procedures.
  - In any case the management of change procedures themselves did not provide sufficient criteria as to when operating procedures should be revised.
- SMS-5: Emergency Preparedness
  - There was no way to know how much of the NOx was released. (There was no monitoring.)
- SMS-6+7: Monitoring Performance and Audits + Review
  - No action was taken following an earlier similar accident

addition, this exchange would be of value to identify common priorities for further development of knowledge and tools to aid inspectors in these efforts.

1.3 THE MUTUAL JOINT VISIT WORKSHOP ON SAFETY MANAGEMENT SYSTEMS

From 27-29 October 2010, the Regional Council of Darmstadt hosted a Mutual Joint Visit (MJV) workshop for Seveso Inspectors in Fulda, Germany on the topic of Safety Management Systems. The Regional Council of Darmstadt is one of the three regional competent authorities for the implementation of the Seveso II Directive in the German State of Hessen. The region includes the cities of Darmstadt, Frankfurt am Main and Wiesbaden and the metropolitan Rhine-Main region. A large number of chemical manufacturing and storage facilities are to be found in a region which is also home to circa 5 million people.

Workshop participants consisted of 33 participants from inspection authorities from 17 EU Member States, 2 Candidate Countries and 2 countries of the European Economic Area. In addition a number of representatives from industry participated.

The workshop was based on the concept of small group discussions focused on various topics and subtopics within the theme of safety management systems. Each work group was asked to focus on a different type of operator as follows:

- Small and medium-sized enterprises (SMEs),
- Large scale enterprises and corporations (upper-tier)
- Large scale enterprises and corporations (lower-tier)

The MJV was structured into a series of seven sessions. The first two sessions were plenary sessions covering general introductory topics as well as, a series of presentations of chemical accidents in which failures in the Safety Management System were a significant contribution to the occurrence or severity of the accident. In this second session six short presentations were made by various participants to assist in focusing

discussions on the consequences of deficiencies in the SMS. The next four sessions were workshop sessions with participants divided into break-out groups for discussion. The final session was a plenary session in which conclusions from all the break-out sessions were discussed together.

The workshops each addressed a different SMS topic. For reasons of time, the third element (Operating Procedures) and fifth element (Planning for Emergencies) of the SMS, as defined in Annex III of the Seveso Directive, were not discussed. The remaining SMS elements were the focus of the workshops as indicated below:

- Workshop I: Organization and Personnel
- Workshop II: Identification and Evaluation of Major Hazards and Risks
- Workshop III: Management of Change
- Workshop IV: Monitoring Performance, Audit and Review

Participants were allocated to one of the 3 parallel break-out groups, focused on a different type of operator, as described above, but the same SMS inspection topic. Each workshop concluded with a plenary session in which the groups came together to share their results. For each plenary session rapporteurs noted the contents, recommendations and conclusions of the discussions and in the final session at the end of the workshop the compiled results were presented for a final discussion. The discussions, their results together with the introductory presentations generated the basis for this publication.

2 OVERVIEW OF SMS CONCEPTS AND DEFINITIONS

The workshop included an introductory session to establish a common basis for discussion about inspecting the SMS, including its definition, obligations of Seveso establishments, and general principles for evaluating effectiveness. This chapter summarizes the main points resulting from the session.

The Seveso II Directive establishes a clear obligation for operators of upper-tier establishments to establish a major accident prevention policy (MAPP) and a safety management system as laid out in Annex III. Whilst it has been widely acknowledged that the Seveso II Directive is not well worded in regard to similar lower-tier site obligations, lower-tier establishments are in fact required to establish the MAPP and ensure that it is properly implemented. It is to be designed to guarantee a high level of protection by appropriate means including management systems.[2] Similarly the safety report, defined in Article 9 of the Directive, has amongst others, the purpose of demonstrating that a major accident prevention policy and a safety management system for implementing it have been put into effect. Thus it is safe to say that similar requirements exist for all establishments

[2] Article 8 of the Seveso III Directive (2012/18/EU), effective 1 June 2015, clarifies this obligation: "The MAPP shall be implemented by appropriate means, structures and by a safety management system …"

2.1 GENERAL REQUIREMENTS

A Safety Management System (SMS) includes the organization, the processes and procedures of an establishment together with their documentation. According to the Annex, the elements of the safety management system are divided into seven specific categories:

- Organization and personnel
- Identification and evaluation of major hazards
- Operational control
- Management of change
- Planning for emergencies
- Monitoring perform
- Audit and review

All operations which are of a safety relevant character are included in the SMS. Suitable and sufficient control and correction processes must be defined so that the performance of the SMS can be assessed.

The Directive requires that the performance of the SMS should be assessed as an ongoing process and that a periodic review of the MAPP and the effectiveness and suitability of the SMS is carried out by senior management. Public authorities are required to carry out inspections of the establishments which cover not only aspects of the technical but also organizational and managerial systems.

Whilst the SMS is constituted from managerial structures and organizational procedures in written form, it is not only documentation and the assigning of responsibilities. The SMS must be clearly lived out in the day-to-day operation of the establishment. It must address the technical safety of the establishment and must contain “control-loops” to ensure that the necessary measures are carried out. The SMS can be compared to the continual improvement cycle of the ISO 14001 and other international standards. The hierarchy of the structure of the documents including the written processes and procedures is the

means by which the operators written safety policy is transported to the employees, that is all employees at all levels.

Figure 1: Hierarchy of an SMS

Both operators and authority inspectors need to be aware that the Safety Management System (SMS) may be one of many individual management systems operating within a company; e.g. financial management, occupational health and safety management (OHSAS 18001), quality management (ISO 9001, TQM), environmental management (ISO 14001, EMAS). Management systems are implemented to ensure that a variety of goals are achieved. Some operators have set up an integrated management system (IMS). However, when assessing an IMS it is important to identify whether an appropriate balance between the various goals has been achieved and in the case of the Seveso II Directive, whether the goals of a SMS are adequately addressed.

A SMS regulates various aspects of the operation of the establishment and the processes of the SMS can be considered as organizational barriers between the hazard and the undesired event (major accident) as in Reason's Swiss Cheese Model. However, no barrier is perfect. Only a combination of barriers is suitable for the reliable prevention of major accidents. Understanding the weaknesses and maintaining the processes are important aspects of the "control loop".

2.2 ASSESSMENT OF SMS EFFECTIVENESS

A large proportion of the inspection activities to-date have concentrated on determining whether or not procedures have been implemented and whether responsibilities have been adequately defined. A number of check-list and questionnaires exist to assist the inspectors in this task. When inspecting the SMS the authority inspectors need to be aware that each company will have its own individual design. Assessment of the SMS within the inspection requires a great deal of perception for the adequacy of the measures together with a technical understanding of the chemical processes involved.

The difference between approving the SMS and verifying that the SMS has been implemented was also raised by some participants. In general all inspectors are charged with verifying that a MAPP and SMS are applied to an appropriate degree (i.e., in consideration of proportionality of the risk) on Seveso sites such that they can be considered compliant with the Directive. For all participants but one the authority's responsibility to oversee SMS was limited to compliance verification. One participant indicated that its government authority also was required to formally approve the MAPP.

Assessing the SMS should keep in mind the following essential characteristics of an effective SMS:

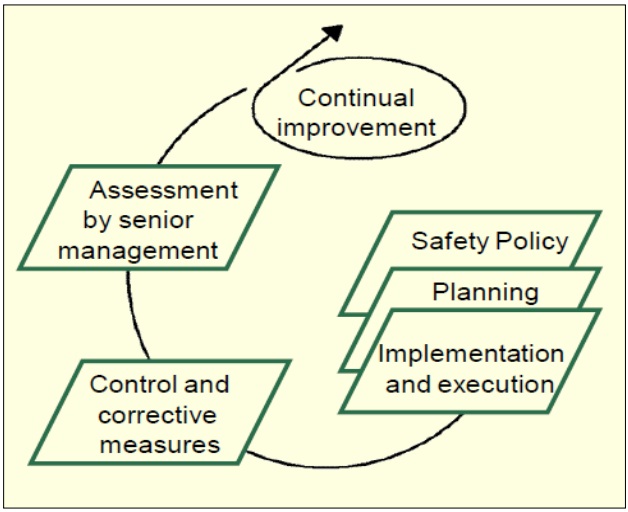
- Robust implementation, that is the establishment of clear objectives and clear requirements, that are consistently and rigorously followed.
- Qualification of personnel involved in executing the safety management system, facilitating formation of a proper process hazard assessment (team), reliable execution of the management of change process, etc.
- Performance monitoring, involving the objectives, reports and reviews for the previous two points. The identification and dissemination and implementation of lessons learned.

- Leadership from the top down that supports implementation and anticipates and resolves potential conflicts with other corporate objectives giving equal priority to safety.
- Self-assessment/auditing processes that are conducted in a thorough manner with adequate frequency followed by appropriate and timely implementation of resulting recommendations.

Both the inspector and the operator are charged with auditing the SMS. By nature an audit requires a systematic and evidence-based approach. The evaluation generally starts with an overall assessment as to whether the SMS addresses all the necessary elements of Annex III. Then the evaluation should proceed to each element of the SMS and systematically seek to find evidence to determine the degree to which the SMS is known, understood, accepted, and followed in the organization. The following questions may go some way to addressing these aspects:

- Does the SMS contain the elements from Annex III of the Directive?
- Are responsibilities defined and assigned?
- Are procedures defined, implemented and adhered to?
- Does the operation on-site indicate that the SMS functions?
- Is safe operation a day-to-day and long term goal of the company?

Figure 2: Model of SMS based on ISO 14001



Two further questions of particular importance within the inspection of the SMS are:

- How good is the SMS?
- How good does the operator believe the SMS to be?

In answering these questions it is necessary in the first instance for the operator to have an effective measure. [1] The time between (major) accidents is not suitable as the only measure of process safety, and neither are Lost Time Injury Rates (LTIR) nor Fatal Accident Rates (FAR) from occupational safety appropriate. There is a need for objective and consistent measures which address safety critical activities. One possible approach is the use of (Process) Safety Performance Indicators (P)SPIs. If the SMS is effective then the operator should be able to demonstrate that the values within the SPIs are improving or at least constant, that the improvements are maintained over time and that spot-checks by authority inspectors validate the situation as described by the indicators.

A number of publications exist which provide guidance on developing safety indicators[3]:

- HSE (UK) Developing process safety indicators: A step-by-step guide for chemical and major hazard industries (2006) http://www.hse.gov.uk/pubns/books/hsg254.htm
- HSE (UK) Key process safety performance indicators: A short guide for Directors and CEOs (2008) www.hse.gov.uk/leadership/keyindicators.pdf
- RIVM (The Netherlands): A literature review on safety performance indicators supporting the control of major hazards (2012) http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2012/juli/A_literature_review_on_safety_performance_indicators_supporting_the_control_of_major_hazards
- RIVM (The Netherlands): Safety performance indicators for the safety management of Seveso companies (2012 - in Dutch) http://www.gevaarlijkelading.nl/sites/default/files/default/veiligheidsindicatoren_brzo.pdf
- CEFIC (EU). Guidance on process safety performance indicators (2011) http://www.cefic.org/Policy-Centre/Environment--health/Seveso/Documents/
- CCPS (USA) Process Safety Leading and Lagging Metrics – You Don't Improve What You Don't Measure (2006) www.aiche.org/sites/.../CCPS_Process Safety_Lagging_2011_2-24.pdf

[3] Several publications have been issued on process safety performance indicators since this workshop took place and they have also been added here to the list presented in the workshop.

- The Energy Institute. Research report: Human factors performance indicators for the energy and related process industries (2010). http://www.energyinst.org/technical/human-and-organizational-factors/human-factors-performance-indicators
- OECD Guidance on developing safety performance indicators (2nd Ed., 2008) http://www.oecd-ilibrary.org/environment/oecd-guidance-on-safety-performance-indicators_9789264019119-en

Assessment of individual SMS elements

The audit of the SMS should include an individual assessment of the effectiveness of each of the seven SMS elements. This assessment should also be systematic and evidence-based. Specific questions can be used to guide an audit for each element and a range of options in this regard are presented in the following paragraphs.

With regard to **organization and personnel**, three aspects: roles and responsibilities, identification of training needs, and involvement of employees. In assessing this element, questions that should be asked are:

- Are roles and responsibilities defined, and communicated to the relevant people with clear accountabilities also assigned?
- Is there a systematic approach to organizing training and to following up on it?
- Do employees who are "end users" participate in the design of the training programme, the development of standard operating procedures, the execution of process hazard analyses (where appropriate), etc.?
- Is there a clear ownership of the safety management system?
- Is there adequate top-down management commitment to process and plant safety with recognizable leadership?

- Is this not only in writing, but also lived out? – Walking the talk!
- Does a "management loop" exist which involves agreeing objectives? Is the objective setting formal and individualised and follow-up using defined review milestones?

The **identification and evaluation of major hazards** should be carried out systematically and consider both normal and abnormal operation and include an assessment of their likelihood and severity. In assessing this element the following questions are relevant:

- Are the hazard identification processes adequate (see literature on HAZID, HAZOP)?
- Are appropriate criteria defined for the assessment of the identified hazards and the risk reduction measures?
- Are requirements defined regarding the qualification of the individuals who are to lead and carry out this process?

The primary goal of plant process safety considerations should be to handle inevitable hazard potentials professionally, so that the likelihood of their activation and adverse effects to environment, people and assets is as low as practicable. Simply put: keep the hazard potentials contained.

Operational control covers the procedures and instructions for the operation (including maintenance) of plant, processes, equipment and temporary stoppages. For the assessment of this element questions should be asked with regard to:

- How is knowledge of the safety critical processes and design/plant elements transferred into SOPs and the like?
- In what way are relevant elements of the safety review (Process Hazard Analysis) part of SOPs or similar procedures and part of the training of operators, craftsmen (and others)?
- How are operating staff ("end users") involved in writing and/or reviewing procedures?

Management of change (MoC) involves procedures for planning modifications to, or the design of new installations, processes or storage facilities. Question for the assessment of this element should cover:

- Are criteria defined as to what a change is and what makes it critical (refer to HAZID)?
- Which process and criteria are defined for the evaluation of a modification as being safety critical and how can safe operation be ensured? – HAZOP, PHA or similar.
- Is an MoC-process for permanent and temporary changes established and are temporary changes tracked?
- Are those individuals requesting modifications and those responsible for processes and installations which are to be modified appropriately qualified in HAZID and the MoC-process?

In **planning for emergencies**, procedures to identify foreseeable emergencies by systematic analysis and to prepare, test and review emergency plans to respond to such emergencies are to be defined. The question to be asked in assessing this element is

- Provided that all of the requirements for the definition of procedures are fulfilled, do training and drills take place?

For **monitoring performance** a range of information is used including performance indicators. For example, in one well-known multinational company various data are tracked in addition to major incidents, such as loss of primary containment and status of process hazard assessments. For the diverse business units, as appropriate, information such as findings from internal inspections, and failures or faults in safety instrumentation, etc., are also considered. Investigations and the taking of corrective action as a result of reports on major accidents, near misses, failure of protective measures, and their follow-up on the basis of lessons learnt, are also an important part of performance measurement. In assessing the function of this element of the SMS the following questions should be asked:

- Is a set of relevant performance indicators identified with a leading function relative to major incidents?
- Is a systematic approach to find the root cause of incidents implemented?
- Are the lessons learned identified and communicated effectively?

In **audit and review**, a periodic systematic assessment of the major accident prevention policy and the effectiveness and suitability of the safety management system should be established and executed. This exercise involves a documented review of performance of the policy and safety management system and its updating by senior management. To assess this element the following should be considered:

- Regular self-assessments and localised internal audits on specific topics prioritised due to history, near-misses, and other feedback
- Independent internal audit function and/or third party inspections or audits
- External validations, e.g., ISO certificates
- Reports to top management who also require periodic reports to monitor the implementation of recommendations

2.3 SAFETY LEADERSHIP, CULTURE AND PERFORMANCE INDICATORS

On 17-19 March 2010 the European Commission's Joint Research Centre held a workshop on "Safety Leadership, Safety Culture and Safety Performance Indicators: Applying the Lessons of Safety Leadership, Culture and Performance Measurement After BP Texas City". The workshop was targeted specifically to identify knowledge, tools and actions for achieving and sustaining effective leadership in major accident prevention across the process industries. In particular, the workshop emphasized the importance of two mechanisms, safety culture and safety performance measurement, with the view that top management can influence and utilize them to promote continuous and targeted safety improvement. Some common principles on the importance of and linkage between these three concepts were summarized at the MJV workshop.

Safety leadership and the role of safety culture and performance indicators gained considerable prominence in the risk management community based on investigation findings from the Baker Panel report ensuing from the 17 March 2005 accident in the Texas City, Texas (USA) BP refinery. The concepts themselves were not new to industrial risk management but prior discussion was largely confined to safety experts in industry (led by the top performing multinationals in this regard), government and academia. In fact, similar themes were stressed in the findings and lessons learned from major European accidents, notably BP Grangemouth (2000) and Piper Alpha (1989).

The Baker Report established safety performance indicators and safety culture as mainstream elements of process safety management as both tools and evidence of effective safety leadership. The main thrust of the report's conclusions was that a strong safety culture coupled with a rigorous safety management system is a root level defence against

major accidents at hazardous installations. Moreover, corporate management cannot practice its oversight function without a precisely calibrated feedback on the performance of the safety management system. The investigation report of the U.S. Chemical Safety Board of the same accident also cited numerous leadership failures associated with safety management systems in its investigation report, noting in particular gross oversights in terms of supervision and training of operators, communication of critical risk management tasks, and evidence of a culture that ignored the importance of standard procedures.

The JRC workshop sought to explore current efforts in the European Union to promote stronger safety performance through the integration of leadership, indicators and measurement. It focused on three important linked concepts within this message and promoted within the Baker Report as follows:

- A positive safety culture is important for good process safety performance.
- Leadership sets the process safety tone at the top of the organization. It also includes owning and implementing effective policies and arrangements to manage risks, allocating resources and making effective decisions about the day to day management of business risks.
- Leaders need appropriate information on the performance of the process safety management system in order to make effective decisions that support and maintain effective control of major hazard risks and, where appropriate, take corrective action.

Two developments in particular seemed to demand a systematic review of these concepts by competent authorities: 1) The increasing use of the leadership-culture-measurement paradigm by industry in risk

management and 2) the more focused academic attention on development of effective approaches based on this paradigm as a result. Seveso competent authority obligations most notably affected by these developments are inspections, safety management systems, safety reports, and accident investigation.

In a very practical way, how to recognize weaknesses and strengths in the leadership-culture-performance measure chain in a specific context was thought to be useful in both active and reactive enforcement situations:

- *Active situations* are situations in which the authority actively seeks to encourage and foster use of these concepts to improve major hazard control on the site.
- *Reactive situations* are defined as situations in which the operator presents such activities as evidence of compliance and the competent authority must perforce evaluate their adequacy in a compliance context.

Moreover, over the long-term, knowledge and experience gained by working with these concepts in practice may deliver an even more important advantage to competent authorities. In particular, patterns may emerge that sharpen their ability to recognize good performers and also understand what makes them so. Thus, it is thought that competent authorities may generally be concerned about how the

CASE STUDY: CHANGING A HOSE COUPLING LED TO AN EXPLOSION

A tank containing Hydrogen Peroxide (HP) was wrongly filled with a substance called "XYZ" (DTPA and Sodium Hydroxide), exploded and flew over the factory roof, but thankfully no one was injured!

So wrong, step by step

- One delivery of HP was received in the morning, the next delivery was expected in the afternoon.
- When the truck with DTPA, arrives, the gate keeper phones the operator and tells him that HP has arrived.
- The plant operator tells the driver that "XYZ" is called HP in this plant, but the tanker pipe coupling does not fit the site tank coupling. (This is the last barrier in preventing filling the wrong tank).
- The plant operator calls the maintenance group which switches the coupling from the DTPA tank and mounts it on the HP tank.
- The filling starts into the wrong tank, temperature rises, an alarm sounds, filling is stopped, and cooling with water is not successful. The operators can see smoke and pulsations and so they run from the place. The tank explodes…

All barriers are broken …

Except for the high temperature alarm, that eventually stopped the filling.

- Barrier 1: Check by the gate keeper fails. The operator is given the understanding that HP is on the way because everybody expects it!

*To ensure anonymity of the site, the real product name is not used.

- Barrier2: The unique coupling is changed and cannot prevent the filling of the wrong substance.
- Barrier3: Work permission for the change is not granted. It is solved ”the non-bureaucratic way”, between former colleagues?

Reflections:

- You never know what can happen! Or…
- The barriers are important but cannot always prevent an accident.
- ”It is very likely that the unlikely event will happen”
- Focus on accident consequences, not on accident probability.

Take away the barrier, break down the wall

- Break down the walls between the people that do the practical work, maintenance and the plant operators on one side, and the people who create the instructions and the routines on the other side.
- A good safety management system can only be created with mutual respect and confidence between these two groups.
- A SMS routine is only working if it is understood, accepted, implemented and regularly followed up.
- SMS routines must be improved by a good system for the reporting of deviations, near-misses and accidents.
- The very important process knowledge of the operator can never be replaced by good routines.

implementation of industrial risk management policy should be adapting to, and even benefitting, from these trends.

The workshop consisted of presentations from over 20 speakers from government, industry and academia. In general the government experts presented from the point of view of how to encourage industry to take leadership to promote effective safety management systems, both from the standpoint of overall policy direction (top down) and the standpoint of enforcement measures (bottom up). Speakers included interventions from the United Kingdom, Norway, Czech Republic, France and Germany. Notably, a number of tools have been developed by government authorities to guide industry in the establishment of each of the components (safety leadership, safety culture and safety performance indicators).

Industry presentations were both conceptual and practical. Some industry presenters discussed the philosophical approach underpinning the linkage between safety leadership, safety culture and safety performance indicators. BP Corporation provided insight on their ongoing efforts following the BP Texas City accident to drive towards more effective safety management through focused leadership, guide corporate culture towards safer behaviour, and to measure performance to provide timely feedback on the strength of safety management systems at all levels.

The representatives from the research community offered quite diverse perspectives from research findings as both a reflection of lessons learned from past failures and as possible clues to targeting improvements. The presentations included findings on the linkage between behaviours of actors at the different corporate levels and safety culture. Two presentations highlighted elements associated with establishment of safety performance indicators, with one noting the importance of establishing manageable measurement systems and the

other looking at indicators that could be established as also risk communication tools. Another presentation viewed organizational behaviour and specifically potentially failures through the prism of 10 past catastrophic events.

From these varied presentations a number of common themes emerged:

- **The importance of safety performance indicators to safety management systems**

A safety management system consistently implemented by qualified personnel ensures a high level of safety performance. However, process safety management needs monitoring and regular input from dedicated leading and lagging indicators to measure how safety management efforts are performing. Performance indicators are important communication tools to track the system properly. Internal regular checks provide necessary input for continuous improvement. However, to be effective and credible, the monitoring system needs to be developed with full involvement of line staff.

It is clear that structured performance indicators are being developed within the chemical industry. These are initially being concentrated towards the "lagging indicators" or "outcome indicators" and that "leading" or "activity" indicators will come later. From a preventative point of view, the activities which are carried out to prevent process safety incidents would appear to be more relevant.

Amongst the major chemical and petroleum companies the question of "safety leadership" has, over the years, increased in acceptance and is now an aspect which is widespread. But the concept of safety

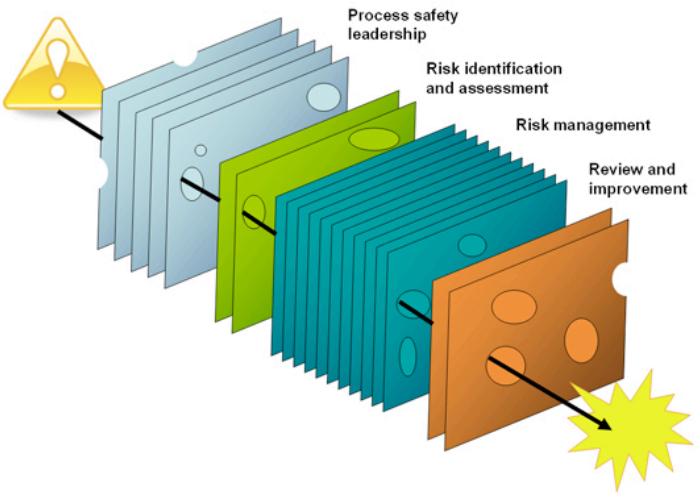


Figure 3: High level framework for process safety management [5]

leadership is a fragile one. When competition with other company interests manifests itself, then all too often safety loses out. In many cases recognition of the importance of safety leadership has only come about as a consequence of an accident.

- **The link between safety management systems and safety leadership**

Leaders have a major impact on safety and staff perceptions. It is their responsibility to communicate that process safety is a core value and that the organization's safety management systems are a dynamic element of the overall operation. Leaders should foster learning organizations that seek and examine feedback at all levels. This implies a particular rigour in analysing and addressing risks identified through an honest and consistent application of the safety management system. It also requires applying recommendations resulting from risk analyses,

the management of change process, accidents and near misses, analyses of safety performance indicators, and inspections and audits, with a follow-up process that checks that recommendations have been carried out as directed.

Process safety leadership has been proved to make good business sense, but this message is often lost by artificial lines that are drawn to separate business and safety standards. Those establishments with a robust safety leadership make an effort to ensure that employees are not confronted with conflicting goals and objectives.

- **The link between safety leadership, safety management systems and safety culture**

It is important that leaders cultivate and maintain a working culture that motivates ongoing vigilance and further safety improvement. While development of modern technical and organizational means continue to be relevant for safe manufacturing processes, optimal functionality of these elements can only be achieved if they are supported by a high level safety culture. On the other hand, reasonable achievement in the area of safety culture cannot be expected unless a minimum level of performance of the safety management system is in place.

Safety culture is the whole of activities and attitudes, shared by management and by employees, that influences control of safety and health risks within the organization. Part of organizational culture includes shared beliefs and values as well as shared language and symbols for communicating them in relevant situations. The elements of a common culture are manifested daily in both the formalized and unformalized activities, habits, and behaviours of all layers of an organization.

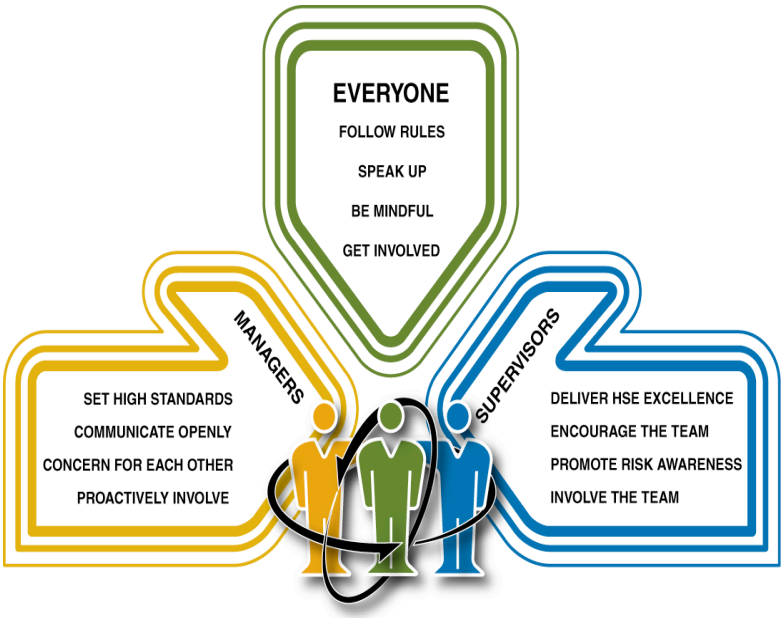


Figure 4: Overview of Health and Safety Behaviour Standard [6]

A “good” safety culture fosters safety awareness such that risks are not normalized and there is an emphasis on using only procedures that are proved to work and fit-for-purpose with the associated risks understood. This kind of culture requires a level of trust between management and staff and across different teams so that there can be open communication about potential risk associated with change and situation abnormalities. As such, there should be a clear understanding in the organization that culture is not an individual property but something that develops in the interaction between people and certain framework conditions.

A strong learning culture is always present when the safety culture is positive. A learning culture encourages reporting of events and near-misses relevant to process safety. All events are investigated to the

extent warranted by their significance and potential for learning. Reporting abnormalities and unintended events is encouraged and the system for reporting and analysing an occurrence is viewed as objective and simple to use.

- **The role of authorities in influencing safety leadership and culture**

Safety leadership and safety indicators do not make safety but they are strongly influenced by the commitment of both and industry and government regulators to high safety performance. It is important that government holds industry accountable for safety in in its business decisions. Progress in safety performance can only be achieved when both policymakers and management dare to take a risk based on knowledge and acceptance of no compliance. For this reason, regulators should establish clear expectations at the top level endorsing enforcement approaches that engage and challenge an organization's senior leadership.

The regulator's influence is largely rooted in its ability to establish and monitor standards of safety performance. Safety leadership and safety culture are linked responsibilities whose inspection and enforcement belongs solely to the operator. On the other hand, regulatory inspectors cannot enforce a particular culture or leadership style; however, they can observe the consequences in safety performance. The performance of the safety management system in particular holds clues to the overall leadership and cultural attitudes of the organization. Hence, it is particularly important that inspectors give attention to evidence of the functional effectiveness of the various elements of the safety management system. In turn policymakers should make observations from which company management can obtain insights on needed improvements in safety leadership and safety culture.

3 ASSESSMENT OF SMS BY THE AUTHORITY INSPECTORS

A session on SMS by authorities was carried out for each of the following four elements in a workshop format with the participants divided into three groups:

- *Organization and personnel*
- *Identification and evaluation of major hazards and risks*
- *Management of change*
- *Monitoring performance, audit and review*

Experience suggests that a majority of the causes of accidents have their roots in at least one of these components of the SMS.

The break-out sessions were also divided into three different groups that looked at each topic with the perspective of a particular type of site, as follows:

- *Lower-tier establishments*
- *Upper-tier establishments which are small or medium-size enterprises (SMEs)*
- *Upper-tier establishments which are large enterprises or part of corporations.*

Each break-out session was followed by a plenary discussion in which each group's key points and observations were discussed. Furthermore, in the concluding session, the four workshop topics were reviewed again under the headings: "Issues", "Challenges", and "What does success look like?" to provide a focus which allows an inspector to develop a strategy to address the topic within their own inspection activities. This chapter synthesizes the results of the discussions for each topic.

The authority's strategy for assessing the SMS should assume that the structure of the SMS will vary depending on the type of hazard inherent in the facility along with other facility characteristics but most notably, the size and complexity of the company. The following section describes various approaches to four of the seven elements of the SMS.

The assessment of SMS requires more detective work than other types of inspection. There is the requirement for the inspector to identify the evidence which satisfies them that the system is appropriate and functions correctly and where necessary to show the deficiencies so as to convince the operator that there are issues to be addressed.

3.1 ORGANIZATION AND PERSONNEL

Some key aspects of the safety management system are embedded in the organizational structure, including the assignment of roles and responsibilities to job functions, identifying competency and training needs of the persons assigned to the specific job functions, and establishing the communication mechanisms for providing important information across and up and down the organization. In effect, the safety management system provides the essential infrastructure to support the rest of the system.

The following elements form the core of the safety management system:

- An informed leadership that monitors overall process safety performance and supports decision making that takes account of risk management needs.
- Linkage of accountability and ownership of specific risk management outcomes to specific job functions
- A systematic process to communicate safety critical information clearly and as necessary to involved staff, management and contract workers, e.g., when a change or action may affect hazard

control in a certain area, an abnormal situation, near miss occurrence, or other potential accident precursor, etc.

- A systematic approach to training, including the identification of necessary competencies (those which exist and those which are needed) and delivery of training as appropriate.
- Employee involvement such that personnel are consulted in the planning of training, and the development and writing of procedures, hazard identification, and related activities. Employee involvement drives ownership and at the same time allows experienced staff to serve as a reality check for various procedures and analyses under development.
- Mechanisms to foster awareness among all personnel of hazard identification and control measures associated with their work, such as actively providing information on the hazards involved with carrying out activities with hazardous substances and suitable measures to minimize the risk and impact of an accident.

Special considerations for different types of sites

Large enterprises

In large enterprises there is an expectation that the prevention of major accidents should be a key aspect of the organization. Inspectors stated that they would expect to see evidence that prevention of major accidents would be formally included in the agenda of management meetings at the site. If the inspector was not allowed to see the documents (e.g., due to business confidentiality) then a description of the topics discussed should be shared by the company. The documentation should also indicate who attended these meetings.

Many inspectors felt that large companies with small sites were generally more compliant with requirements than smaller companies. Large companies tend to carry out very detailed risk assessments. What they have then done as a result of the assessment is integrated into their daily work.

SMEs and lower-tier establishments

The core competence of SMEs and lower-tier establishments is not usually process safety. Moreover, in lower-tier establishments there are often a wide range of economic activities. Typical for these types of facilities are the food and beverage industries and warehousing. Major accident hazards are not perceived as being directly related to the core business activities. This means that there may not be any formal safety management system in place, which presents a challenge. It is also difficult where the focus of safety is on occupational health and safety and not on chemical process safety. This type of establishment not only needs the right personnel, but also there needs to be an understanding among all staff of the risks presented by the hazardous activities. Inspectors should be aware that many SMEs and lower-tier sites can have less awareness of safety in particular in regard to some of the following issues:

- There is a particular concern in regard to adequate training of both staff and contractors on the purpose, content and implementation of safety management systems. In particular, subcontractors often have no knowledge of Seveso-type risks, presenting a huge challenge to the process safety management system.
- Whilst training certification can be checked there is a need to look at an operator's management system horizontally, rather than a fragmented approach, i.e., looking at specific aspects of health and safety in isolation.
- Often the health and safety expertise of SMEs is outsourced with a reliance on certification to check the expertise. This is also a problem when subcontracting. There is a need for operators to become the "intelligent customer". Where "health and safety" is contracted out to a consultant it is necessary to question how this reflects what happens in the company, and how much is what the consultant believes happens or even believes should happen.
- Generally when inspecting very small companies with consultant-delivered procedures it is best to talk to the employees to understand the processes.

- It is important to identify the employees' awareness of the hazards and how these hazards are reflected in the operating procedures. The inspector should direct questions about the safety management system to aid in assessing how well they have been trained.

Important considerations

When the SMS procedures have been outsourced

A serious concern amongst inspectors is that the development of the SMS and writing of the documentation is often outsourced. This paperwork then remains on the shelf. It is important to verify implementation of the SMS at companies, for example, interviewing employees, observing operations and noting accessibility and visibility of safety information, following the paper trail for certain actions (e.g., audit and lessons learned follow-up), etc. In all cases, it is not sufficient to rely on written procedures but it is particular important to take a very thorough approach to SMS verification when dealing with employers whose SMS procedures are outsourced.

Employee training

The organization of personnel training is an important issue of the general topic of "organization and personnel". Both operator employees and contractor employees need to be aware of process safety issues and companies must monitor whether their procedures for organizing and training their employees and organizing contractors are functioning.

Some questions an inspector might ask of the operator in this regard could be the following:

CASE STUDY: RELEASE OF CARBON MONOXIDE LEADING TO A FATAL ACCIDENT

An accident in the steel processing industry at an upper-tier Seveso establishment led to one fatality and two injured as a result of a carbon monoxide release during maintenance work by a contractor company on a gas cooler for converter gas.

In the gas cooler cellar water fed from a mixing vessel was passed through a motor driven shut off valve and one of two parallel water filters to the gas cooler. Each of the water filters had a manual shut-off valve before and after it to allow maintenance. Due to the failure of the manual shut-off valves to close fully due to the build-up of sediment in the valve body water could flow out of the system (no hydrostatic seal) and converter gas could escape.

Deficiencies in the safety management system which were identified are:

- Shut-down and permit-to-work rules exist, but different safety check lists exist and the results are dependent on which check list is chosen.
- The foreman of the contractor company was trained with respect to the hazards of gas (carbon monoxide), however, he received no information as to how to respond to a gas alarm.
- There was no documented training of the other two contractor employees.
- The internal emergency plan contained no description of the action to be taken in the event of a carbon monoxide gas alarm.

- The carbon monoxide gas alarm in the control room was poorly designed from an ergonomic perspective.

Following the accident the measures which were taken included:

- A siphon water trap to prevent gas breaking through was installed.
- A separate display for gas alarms in the control room was also installed.
- Shut-off valves were replaced.
- The operating procedure was revised to reflect the lessons learned from the accident.
- The safety check-list was revised.
- The shutdown and permit-to-work rules were revised.
- Spot checks on contractor employees were implemented as standard practice for contractor training.
- At upper-tier establishments, training for all external workers and visitors was established with regard to:
  - Dangerous chemicals used
  - Safety measures
  - Reporting and emergency muster locations

- It became mandatory that contractor training on safety measures for workers is documented.

- How are decisions made about who should be trained and what the training should cover?
- To what extent are employees trained to understand hazards? What is the minimum safety training required for all employees? What additional safety training is offered to some job functions, if any, and for which functions specifically?
- How is training organized? Is there both routine training provided at regular frequencies as well as ad hoc training? How often is safety training targeted or a part of various training events?
- Are safety topics regularly included in all types of training? Are there training opportunities for addressing specific safety issues (e.g., hazard awareness) and if so, what are they?

Contractor communication and training

It is necessary to discuss with the contractor team about their work and associated safety procedures. Just as for employees, the operator should proactively provide contractor employees complete information on the hazards associated with their work and control measures to minimise the risk of accident. They should also be informed about what to do if they recognize an unsafe or abnormal situation, if a near miss or accidental release occurs, and in an emergency. There also needs to be sufficient contractual, legal control regulating how the contractor fits into the safety structure of the customer. Inspectors should be able to recognize whether the operator's SMS and the contractor's safety procedures are consistent. Inspectors may wish to look at contractor certification, e.g. SCC[4], as a confirmation of competence.

[4] Safety Health and the Environment (SHE) Checklist Contractor

Defining and demonstrating success

Common success factors

The ease with which the company empowers the organization and its personnel to maintain and continuously improve safety often depends on the following key factors:

- *The size and core activity of the company.* Chemical manufacturing sites generally have a better understanding of the need to understand chemical hazards and risks than those industries where the chemical hazard is an ancillary operation to the main economic activity.

- *Sufficient resources allocated to safety critical activities*. Such resources include not only financial means, but also time, staffing levels, and empowerment of those tasked with carrying out the activities.

- *The involvement of contractors and temporary workers.* When contractors frequently perform work on site, it creates an added challenge for safety management. Contractors are not particularly bound into the company safety culture and there is only a limited degree to which individual performance standards and behaviours can be reformed and adapted to reflect the safety climate onsite more closely.

- *Leadership.* Management commitment must be embedded at the very top of the organization and be present throughout the whole management chain. Such leadership involves not only communicating expectations, but also personally behaving accordingly, and listening and responding to feedback from employees.

- *Availability and involvement of employee representatives*. They can play an important positive role in making the SMS work as it should, particularly in larger organizations, because they have established mechanisms for exchanging and channelling information in both directions between management and the workforce.

What does success look like?

The following are examples volunteered by participants from their inspection experience:

- Safety is a management agenda item – it appears as a regular and important item at managerial meetings, not just safety meetings.
- Major hazards are addressed systematically in identifying competency, training, procedures and control measures.
- Safety critical tasks have been systematically identified and documented.
- There is sufficient evidence that employees and contractors are involved in the development and delivery of training and procedures.
- Training records reflect the implementation of training to address the identified needs and testing of competence is routinely conducted as follow-up to training or when replacing staff in a safety critical function.
- Interviews with employees confirm that procedures described in written documents are understood and followed.
- Selection and management of contractors and temporary workers reflects competency requirements identified for safety critical tasks (certification, qualifications and experience).
- Contractor supervision and follow-up is a routine part of company procedure and appropriately includes attention to risk management and safe work practices (the intelligent customer).

3.2 IDENTIFICATION AND EVALUATION OF MAJOR HAZARDS AND RISKS

Risk assessment is the cornerstone of the SMS. It is a continuous process in the global life-cycle of a company. The aim of the identification and evaluation of major hazards and risks is to ensure proper control of low probability, high consequence events.

The risk assessment consists of several parts. The inspector should verify that each of the tasks has been conducted systematically and comprehensively. Hazard identification is the first part but the risk assessment does not end there. The operator needs to complete the other stages of the risk assessment: consequence assessment, risk ranking and evaluation.

There are also clear requirements within the Directive that an operator must be able to demonstrate that appropriate control measures have been taken with respect to the outcome of the risk assessment. It is therefore important to check the quality of the risk assessment and that the staff assigned to the task has the necessary competency for risk assessment in all roles. The quality of the control measures themselves should be evaluated separately from the risk assessment with criteria relevant for the specific measure.

To ensure an objective and comprehensive risk assessment, the company must adopt a systematic approach and apply suitable methods for hazard identification, consequence assessment and the final assessment and ranking. These choices need to take account of the processes involved and the size and complexity of the company. The process for the identification and evaluation of major hazards and risks must include a frequency for reassessing the process as well as situations that might trigger a reassessment (e.g. accidents, new knowledge, modifications) outside the scheduled intervals.

In most Seveso countries, inspectors do not approve the risk assessment, but check that it is systematic, complete and an accurate reflection of the existing situation. Inspectors can conduct spot checks on specific processes (by observation, looking at records, talking to

employees, etc.) to verify the details of the hazard identified as well as an associated scenario (if any). It is also important to ascertain that all hazards have been identified by exploring the operator's rationale and process for identifying hazards and ranking risks.

The competent authority should make it clear that the operator is ultimately responsible for the risk assessment. If a risk assessment is approved as a competent authority, then there is a risk of incurring blame if something was missed which led to an accident.

Special considerations for different types of sites

Upper-tier sites

At upper-tier establishments, the hazard identification and risk assessment are often carried out by the company's own personnel or by a central service unit within a multi-site or multinational concern. In these cases, the following principles should be considered for the Seveso inspection:

- It is of particular importance to justify the use of the particular risk assessment technique (HAZOP, FMEA, LOPA, etc.) and to assess the competency of the risk assessment team(s).
- The responsibilities of risk assessment dictate that the team should possess sufficient knowledge and experience in the operations under assessment and the necessary technical competences for making such an assessment. For this reason, they should include operating personnel, for example, at foreman level, to make judgements with precise information on how the plant is operated, along with experts from appropriate engineering or other relevant competences.
- The site should be able to demonstrate that risk assessments are updated and revised at appropriate intervals. The establishment should have defined processes which set the frequency of revision, considering potential external triggers

(e.g., process changes, accidents, new knowledge, etc.) that may make a revision necessary.

- There needs to be a clearly defined communication between different risk assessment teams, since many large sites may have different teams covering different processes. There should also be a mechanism to communicate the risk control measures in effect to all relevant units within the company, how they work and the role of various staff members in maintaining their functionality.
- Where the services of consultants are used, the site should have established criteria regarding their competency and qualifications and a well-defined policy on the frequency and nature of their interface with the company, with particular attention to how results of assessment are interpreted to implement recommendations for site risk management.

Lower-tier sites

For lower-tier establishments, it is important for inspectors to understand how the risk assessment is organized as a system as well as how it is executed. Some important points relate to the tendency in lower-tier establishments to rely heavily on the work of consultants. This practice raises questions on the degree of involvement of the company in the risk assessment process as well as imposes a particular importance on the competency of the consultants involved. It also implies a need for extra attention to how consultants are selected and how their tasks are defined. In particular:

CASE STUDY: CARBON DISULPHIDE TANK EXPLOSION

An explosion occurred 2.9.2009 in a carbon disulphide tank while subcontracted employees were washing it out. Two employees were injured, one of them sustaining bad burns.

The contributory factors can be considered in terms of various levels in a systems approach, using an AcciMap.

At a societal level: chemical safety legislation in Finland is inadequate in bankruptcy cases.

At the company level: The facility was bankrupt, the plant was no longer functioning and the personnel had been decreased. In addition the terms of the cleaning contract were insufficient.

At the level of the plant management / co-operation with the plant manager: This was the first time that nitrogen had been used when cleaning the tank; the subcontractor had no experience of cleaning a carbon disulphide tank; there was inadequate risk analysis, inadequate working procedures and a lack of supervision of the plant.

At the level of the subcontractor's actions, communication, instrumentation and design: Whilst nitrogen blanketing the tank the nitrogen flow was not measured, the oxygen content was not measured and a small quantity of carbon disulphide was still inside the tank. Following the washing there was no protective water layer left. The length of the washing hose had not been measured which meant that the nozzle could impact with the wall of the tank.

At the lowest level, the incident, conditions and physical factors: an explosive gas-air mixture had evolved which came into contact with an ignition source leading to an explosion with a pressure wave and flames. This resulted in two injured and the partial collapse of the building.

Carbon disulphide is a hazardous substance with a flash point of – 30 °C, an explosive range of 1 % - 50 %, the self ignition temperature is 100 °C and the ignition energy very low.

The explosion was caused by inadequate nitrogen blanketing of the tank. The working procedures were inadequate. Whilst the subcontractor had assessed the occupational safety (health) hazard of the washing procedure the process safety hazards had been neglected. The likelihood of an explosion had not been analysed in detail.

- As lower-tier sites may have a lack of risk assessment skills within their own staff there is a greater possibility that they will be less expert in choosing the proper consultants. To ensure the necessary competence is hired, lower-tier sites need to be attentive to consultant qualifications and experience, and the inspector should look for signs that good criteria have been established, e.g., a requirement for accreditation by a professional association or other credential.
- Lower-tier sites often are faced with contractors who have the necessary competence but are not familiar or aware of the range of operating conditions (normal and abnormal). Hence, close co-operation between the site and the contractor are vital to an effective execution of the risk assessment. Both the operator and the consultant should invest considerable effort in identifying the key aspects of the process relevant to the risk assessment.
- Lower-tier sites may apply strict limits to the scope of work assigned to the contractor. Inspectors should be attentive to potential gaps in the risk assessment performed by the consultant. The consultant may be given only a restricted mandate to assess the effects of changes or proposed changes on the hazards and risks within the establishment, for example, in which situation, some processes and risks on the site might be overlooked by the assessment.

Small and medium enterprises

As with many lower-tier sites, the risk assessment for SMEs is usually carried out by a consultant since also most SMEs have limited expertise in conducting a risk assessment. Hence, similar considerations as described for lower-tier sites apply to SMEs regarding the choice of the consultant, the scope of work assigned to the consultant, and the necessity for a highly collaborative relationship between consultant and operator.

In addition, the relative size and type of operation should be taken into account in both defining and executing the risk assessment. The following considerations generally are specifically relevant to SMEs:

- The method of risk assessment needs to be appropriate to the level of risk and to the complexity of the establishment. Small sites with few processes may require only a simple methodology. Some organizations have also issued guidance and toolkits on hazard identification and risk assessment of SMEs (e.g., the International Labour Organization, the International Council for Chemical Associations, etc.).
- Likewise, recommendations for control measures should be developed that can be effective in the context of the operator's resources and expertise.
- The assessment should establish a clear link between the recommended control measures and the identified risks. A good practice is to present the identified risks in the form of a table together with their appropriate control measures. For example, the maintenance and inspection schedules should immediately be placed alongside the findings from risks identified as being associated with potential failures in mechanical integrity.

Important considerations

The role of management

Top management should be involved in the risk assessment at some level, or at least be aware that risk assessments are being carried out, ensuring follow-up on the outcomes of risk. In particular, since the management is responsible for managing resources, by necessity it plays a role in ensuring adequate resources are allocated to maintain the proper control measures to address the risks. Prioritisation of resources in this regard should also be linked with prioritization of control measures based on the risk assessment.

The role of management and level of involvement may depend on the size of the site and also the size of the company. Top management in a large scale enterprise is usually very complex. For such sites the leadership's role is normally to assign responsibilities to operational management for conducting the risk assessment and implementing resulting recommendations. It is then operational management that should establish the risk assessment objectives and ensure implementation. While top management do not have to review the results of every risk assessment, the top management need to know what the main risks are, and which gaps or operating risks exist in their installation. The safety management system needs to assure that there are processes that assure sufficient communication and feedback processes Inspectors need to ask these questions.

The relevance of accident lessons learned to the risk assessment

It is useful for the inspector to ask the company whether it has researched past accidents in conducting the risk assessment. Relevant findings from past accidents should be used as input since the lessons learned often influence and provide new information to improve standards and codes of practice. This area of inquiry is of particular importance because there is a lack of awareness outside of the large chemical and petrochemical companies about previous accidents and their findings and the lessons learnt from them. Thus, outside of the major actors in these two sectors, the resources for learning from

accidents are not used, even though the vast majority of the lessons learned are not specific to a particular industry but would apply to any site's safety management system.

Defining and demonstrating success

Success factors

- *Competence.* Large companies often have the advantage of maintaining in-house competence in performing risk assessments. However, other sites will have to outsource the risk assessment and in these cases it is important for the operator to have precise understanding of what qualifications are required to perform the job well and hire only consultants that show evidence of having these qualifications.
- *Use of experience and feedback*. The assessment needs to take account of and use feedback from past experience on site as well as relevant information from external sources. Onsite sources of feedback include the history of past accidents and near-misses, findings from inspections and audits, and maintenance records. Involvement of site employees in the development of the risk assessment can help ensure that the relevant information is communicated for this purpose. Lessons learned from accidents in the same industry or sites with similar processes should also be taken into account. Potential domino effects should also be considered in both directions, that is, as an incoming risk from nearby establishments (triggering an onsite accident sequence), or as a risk imposed from the site on nearby establishments if the consequences of an onsite accident might affect them.
- *Ownership of the risk assessment.* Site management must take on board the outcomes from the risk assessment, including appropriate follow-up on recommendations.

- *Awareness and communication of risks.* The site management must take responsibility to communicate the risks and control measures identified in the risk assessment to all personnel who may have a role in managing risk and ensuring the control measures function. It is essential that all employees are aware of the risks and consequences related to their activities within the establishment. Hence, this communication should equally cover departments in supportive roles, such as procurement and human resources and also the interfaces with contractors.

What does success look like?

The following are examples volunteered by participants from their inspection experience:

- Risk assessment drives control processes for managing all of the following:
    - Operating procedures
    - Equipment
    - Training
    - Inspections and maintenance
    - Emergency planning
- Identification and evaluation of major hazards and risks are clearly proportionate in the site's risk management approach.
- Employees and contractors are aware of the risks associated with their work and their role in controlling them.
- The site risk assessment and individual process risk assessments are fully documented, including the process followed, results and information used to produce the outcome. Control measures and associated actions recommended by the risk assessment should be documented including follow-up (when and how they were implemented).

- There is a systematic selection and application of risk assessment methods and the consequence analysis was conducted by a competent expert.
- The off-site risk is communicated transparently to senior management and all stakeholders.

3.3 MANAGEMENT OF CHANGE (MOC)

Seveso site operators often are not sufficiently aware that failure in the management of change is one of the most common causes of accidents. Every accident that occurs is proof that the safety management system is not 100% working to control the risks as it should. Sometimes the accident may be caused by latent errors, that is, from a change that was implemented many years ago but never communicated or documented or assessed in any way, and the associated risk only became evident when the accident occurred.

Thus, it is clear that both small and large sites should establish a procedure for management of change. The procedure should exist as a formal written policy with appropriate guidance as to what changes should be considered for the procedure. The policy should also define what is a safety relevant change. Furthermore, the process for establishing that a change is a safety relevant change should be very clear. Safety relevant changes should be considered as any change that can potentially change the process or site risk profile. Hence, a safety relevant change is any type of change that could have impact on the operation, including equipment, process, personnel, organizational, temporary and permanent changes, and changes arising from regulatory changes (e.g., ATEX). However, the policy should also give criteria for what kinds of changes do not need to undergo the MoC process. As a general rule, if a piece of equipment is maintained within the operating envelope, then such a change need not be considered a change.

In addition, the MoC policy should address all the following elements:

- Each responsibility, that is each step of the procedure, should be assigned to specific job functions. These responsibilities should include authorization, initiation, and approval of the risk assessment process and also for the change process selected following the risk assessment. The policy should also include a process to verify that the change was implemented as recommended by the risk assessment with the recommended control measures in place (if any) and that safe operation can take place.
- The entire process should be transparent from the point that the change has been identified as a potentially safety relevant change all the way to the final step which should consist of verification that the change has been implemented correctly.
- The required competencies of all involved in the MoC process should also be specified.
- The system should address whether permanent changes and temporary changes are handled differently – often permanent changes are documented better than temporary ones.
- The policy should require documentation of the change and verification that the change has been documented. All relevant written operating procedures should be modified as necessary to reflect the change.
- Changes to process drawings as a result of the MoC should be considered as part of the documentation that may need modification. Often accidents have occurred due to work being carried out using an incorrect drawing.
- The process for communicating changes should be outlined, including the specific job functions that should be informed and for what purpose.
- The MoC process needs to clarify the point at which the change is considered as completed, that is, when should the proper

authorization of a completed change take place, verifying that the change physically conforms to the intended change and that it has been documented.

Special considerations for different types of sites

Upper-tier sites

It is expected that the upper-tier site will address changes in the risk assessment process, “Have all risks been considered?” Also, it should be clear what conditions or activities trigger the requirement for a risk assessment. The risk assessment should not just consider the implementation of the change, but also the work needed to effect the change itself.

Lower-tier sites

If a lower-tier site does not belong to the chemical processing or petrochemical sector, it may not be aware of the need and importance of a management of change process. It may also be that the risk assessment for a safety relevant change on many lower-tier sites is outsourced to a consultant and therefore, the MoC policy may represent an extra inconvenience and/or added cost.

Small and medium enterprises

Implementing MoC is often a challenge in small companies because the owner requires a high degree of flexibility and does not necessarily see the need to consider the impacts of changes. Often there is no documentation of changes in a small company. Moreover, small operators may also try to avoid management of change due to the added cost of the risk assessment or the potential increased cost of the change following a risk assessment.

Important considerations

Management of change and aging of installations

Aging of installations is not just a maintenance issue. Often equipment may not be available for a number of reasons (e.g., obsolete technology, the supplier is no longer in business, etc.). Sometimes equipment can deteriorate, for example, ultraviolet light will harden plastic over time, stress loading of pressure vessels can weaken equipment, or equipment simply reaches the end of its life. These types of changes may require replacement of equipment whose function is central to the process. Moreover, replacement of parts is often not simply the exchange of one piece of equipment for another (like for like). It may be an upgrade that imposes changes on interfacing parts of the process or it may even require a process re-design. The material composition may have changed and may have an effect on downstream processes. Once a piece of equipment changes the operating process, this is an operational change.

Personnel changes

When planning to assess organizational changes in inspections, the first question the inspector should ask is whether the company carries out a risk assessment for organizational changes. Inspectors should avoid the temptation to view this as mainly a human resources issue. Organizational change affects all departments and therefore, any inspection of this aspect should view how the change is assessed from the perspective of the entire operation of the site. There may be risks of which human resources could not be aware (and they may not have been identified if the management of change process was not conducted).

The process of managing organization of change should include identification of safety critical roles and the workload, competences and specialised training associated with each role. An analysis should be conducted in regard to how changes in staff and staff assignments to identify potential risks and control measures. A targeted training

programme is not always sufficient to reduce the risk induced by the change. The risk analysis should serve as the basis for determining whether additional competency, training or a different workload distribution is required.

Major organizational changes, such as those arising from mergers and acquisitions or significant economic downturn, will have an impact on the safety management system. As a general rule, if a plant is managed with the same people, then it may have a better chance of running smoothly despite the transition. However, if site management changes, the impact of the change is much more difficult to assess and requires relatively greater attention to the change process and potential risks, from management and inspectors alike.

Aging of staff is a change which occurs over time and the loss of experience should be addressed by the company in considering the implementation of a process for maintaining corporate memory.

Involving human resources

When a company is profitable, there is less likelihood that changes in human resources will be significant and therefore any increase in potential risk of the site will be limited. However, if a company is not profitable, certain process areas may become isolated for a number of reasons, such as managerial change that reduces attention on certain parts of the plant more than others, or selling off of parts or processes resulting in a loss of staff who may have important experience and competency for the processes that remain.

Major organizational changes can have a substantial impact on risk management and control of major hazards, and hence, in these situations, there is often a need for the company to involve the human resources department. The human resources department may be important in assessing the implications of the change, projecting it out over the short and medium-term and communicating it to management and other staff as might be appropriate. Culture can be positively or

negatively affected by a change. Sometimes culture may even compensate for increased risk from organizational change.

The participants provided some examples of actual situations on Seveso sites in which human resources staff played a key role in management of change. For example, the competent authority advised that a lower-tier establishment should involve human resources in identifying safety critical tasks and functions critical to emergency response. The human resources staff were responsible for verifying that the change in workload was manageable and realist. Hence, it became the job of human resources staff to convince the inspector that the operator could run the plant safely following the organizational change.

As another example, a high risk upper-tier establishment went into liquidation. The competent authority informed the operator that the regulator intended to assess how the new management would cope with the start-up of a new plant while downsizing. The site dealt with managing human resources using human factors guidance and tools created by the UK Health and Safety Executive addressing the risk of fatigue (http://www.hse.gov.uk/humanfactors/topics/specific2.pdf) . The regulator made no objection to the start-up of the new plant since the operator had documented how the site would assure that the assigned workloads and competences were appropriate.

A change in the shift pattern was also noted by participants as a particular challenging human resources issue with a potentially high learning curve.

Defining and demonstrating success

Common success factors

- *Size of the company.* Small, simply structured companies with a limited number of hazardous substances and processes may have very few significant changes in the whole lifetime of the company. However, they should be attentive to change events, few as they may be, that could affect their process risks. For example, a small site that does not pay attention to

aging factors or potential impacts of maintenance changes could be still quite vulnerable to accident risks.

- *Complexity and severity of risk.* Complexity and severity are often correlated with size. As sites increase in size, they can accommodate larger volumes of substances and more processes. Other enterprises may by their nature have rapidly changing processes and chemicals (for example, batch processors) and thus "Management of Change" is an essential aspect of doing business.

- *Clear and correct definition of safety relevant changes.* One of the greatest challenges of management of change is recognizing a safety relevant change. The definition should take account of organizational, personnel and technical changes, including progressive change and temporary changes.

- *Clear procedures for assessing risks associated with change.* The risk assessment is one of the most important activities within the MoC process. It is critical to involve personnel who have experience and are knowledgeable about the process or processes affected by the change. The risk assessment should be proportionate to the dimension or complexity of the change. For example, more sophisticated risk assessment tools, such as event trees, failure mode effects analysis, or other models should be applied to changes that are particularly significant, or that could have potentially multidimensional impacts.

- *Attention to control of temporary changes*. Temporary changes should be managed to ensure they are not forgotten and become permanent by default. The safety management system should impose specific controls in this regard, such as requiring a mandatory expiration date, fixed intervals for checking their integrity, or higher level attention (e.g., management report) when they are in a place beyond a certain time limit. Without such controls, there is a risk that after a

period of time the change is not reversed and the original problem resurfaces.

- *Documentation of change and maintenance of corporate memory*. Precise information on changes should be recorded in all relevant documentation, process plans, diagrammes, and operational procedures, in such a way that it is clear why a particular modification was made. Results of the risk assessment of the change and recommended control measures should be documented and included in other relevant documentation, including operating procedures and the safety report.

What does success look like?

- Within the policy of the company a safety relevant change is clearly defined.
- The MoC process has a systematic hazard identification and evaluation process.
- MoC procedures are known by all personnel and applied systematically.
- Initiated changes are tracked all the way through to close-out and all changes are documented in procedures, piping and instrumentation diagrammes (P&ID), etc.
- Temporary changes are closed out and do not become permanent by default.
- Responsibilities are defined for initiating and authorising changes as well as approval on completion.
- The MoC process is led by management.

3.4 MONITORING PERFORMANCE, AUDIT AND REVIEW

Whether the company has an audit team for process safety (at company or corporate level) is one of the key questions for the assessment of the SMS suitability for monitoring, auditing and reviewing performance. The team should have responsibility for planning and conducting audits, setting audit intervals, determining the content of the audit and ensuring that actions are tracked. Of importance is that the audit team is independent of the operations section which is being audited.

Sometimes a company will not have a formal audit or monitoring system but other audits and routine offer feedback on safety performance. For example, sometimes data collected for other purposes (e.g., quality control) may contain data relevant to safety performance. Some sites may include these data as part of the monitoring and feedback system. Audits that have a focus on the prevention of major accidents may also be relevant, but the Seveso inspector should be aware of the differences and limitations of ISO certification audits, internal audits, and insurance audits as opposed to process safety specific audits.

The role played by Seveso-inspectors in raising awareness of the top-level management for the need to monitor and evaluate safety performance and to provide resources to do so is possibly significant. Questions that inspectors can pose that address the roles played by the company management include:

- How does the company monitor its safety performance? Have the figures changed? If so, why? It is important that the management shows commitment to monitoring performance and that practical follow-up takes place and is not just looking at figures.
- Are near-miss reporting procedures and processes in place to make use of the opportunity to learn?

- Do processes for collecting and assessing improvement proposals by staff exist?
- Does a positive failure culture exist (is failure an opportunity for improvement or punishment)?
- Are aspects of a learning organization part of the performance monitoring, audit and review processes?
- Are there regular meetings to follow-up on incidents?
- Are maintenance tasks on schedule or are they lagging behind?
- Is training up-to date and appropriate?
- Does the company use checklists and if so, are they appropriate? How often are they reviewed? Where companies use checklists to assist them in their review inspectors should ask whether they are appropriate and how often the checklists are reviewed.
- Is the lack of accidents and near-misses over a period of time appropriate?
- What is the quality and systematic approach to following-up on accidents and near misses?
- How are near-misses taken into account?
- How does the company follow up on recommendations from the competent authority, from internal audits and others?

For the question of audit and review, the inspector should try to understand how plant safety is integrated into the existing system of evaluating company performance, e.g. annual review. This process should be a documented procedure and note should be taken of the role of a parent company or corporation where existing. Some but not all participants doubted as to whether inspectors could gain a valuable perspective with regard to plant and process safety from external certification such as ISO 14000.

Special considerations for different types of sites

Upper-tier sites

Inspectors experience that large companies complain about the number and frequency of audits. Moreover, inspectors are not always certain that there is an appropriate level of involvement of management. Audits should be reviewed by the top management and the efficiency of measures should be monitored. Performance can be monitored using indicators, and here the focus should be on leading indicators. However, it is a challenge to have a clear picture of what an indicator system should look like in different settings, such that it is a challenge to assess whether the indicator system is sufficient.

Some strategies for Seveso inspectors in assessing whether the SMS is adequately monitored include:

- Seveso inspector should ask questions about the structure and process of internal and external audits and reviews and check their implementation.
- The Seveso inspector should question why a particular indicator has been chosen – what is the company expecting from the indicator, what is its purpose?
- The Seveso inspector should check whether the company has performance indicators for the critical parts of the SMS, such as management of change, maintenance, permits, etc.

Lower-tier sites and small and medium-size enterprises

It was recognized that achieving effective monitoring of performance and carrying out audits and review can be a substantial challenge in SMEs and many lower-tier sites. This situation arises often due to their size and also in part due to lack of resources or a failure to appreciate the importance and value of having regular feedback on safety strengths and weaknesses. Many SMEs may have no internal or

external audit system and the Seveso inspection is possibly their only "process safety audit". In fact, for many SMEs business operations are decided on a day-to-day basis and not seen as part of a systematic process.

In general it is recommended that small companies have external audits so that internal bias does not interfere with important learnings and recommendations.

Important questions for an inspector to ask are therefore:

- Does the company have an audit process?
- Does the company follow its safety performance with a process in place to receive and review feedback regularly?
- Does the company follow-up and ensure that established control measures to maintain plant and process safety are implemented and continuing to function as intended? The inspector might also seek to verify control measures in practice.

  Examples of control measures could include good housekeeping (e.g., tidy and clean premises, appropriate clean-up of waste and minor spills, etc.), records of the maintenance of safety equipment such as gas detectors and alarms, posting of operating instructions and safety precautions, explicit signage in regard to what is not permitted (no smoking, entry for authorized personnel only, etc.).

Important considerations

Safety performance indicators

Many participants noted that the inspection should include a review of the quality of the safety performance indicators, if the company formally maintains such a feedback system. They offered a number of suggestions to inspectors on evaluating such systems as part of SMS inspection:

- The company must use indicators based on its own operations and experience with them. Hence, the operator should be able to explain to the inspector as to why they are considered effective indicators for the site. Inspectors should also question why the companies have chosen particular topics for indicators and how the management has determined that they are important.
- Inspection of the SMS should be based on more than just the output from the indicators. Qualitative feedback, e.g., from audits, occurrence of near misses and accidents, should also be regularly reported with lessons and recommendations extracted and incorporated into the safety management system.
- Companies should report on competency and training in their indicators. Several examples of measures of training are provided in various guidance documents that have been published by industry and government on safety performance indicators.
- Are the right questions being asked? When collecting data on near misses a high collection rate should make the operator proud, at least in the early stage of the programme. There is a need to compare smaller incidents (near misses) to the number of accidents.
- The quality of the analysis of feedback is important. To evaluate analytical quality, inspectors can inquire about the analytical process, e.g., who performs the analysis, the methods used, and how feedback is selected for analysis (for example, if a dataset is large or certain data are generated continuously). They may also ask to see an example of a report summarising results of an analysis and associated recommendations for follow-up.

Responsibility for the SMS

Responsibility for the SMS should be distributed over a number of positions within the management chain, i.e., operational staff, middle and top management. Responsibility should involve the whole of the line management and there should be a process embedded in the SMS to check periodically that assigned personnel understand and are performing the tasks allocated in a competent and timely manner.

It may be that a small site might have one person responsible for the SMS, but for most sites it is not recommended. Involving key management and staff ensures a shared ownership of the SMS. In the case, where responsibility is concentrated in one person, the SMS is often taken less seriously. It has been observed that other staff even feel that the person who is responsible for the SMS is someone "without a proper job", and as a consequence the person and position has a low standing within the company. The Seveso inspector should be prepared to raise this issue as a potential problem with site management, raising awareness in regard to better strategies that optimize the use of staff resources in areas relevant to their competence and responsibilities in order to make the SMS a dynamic and "living" part of site operations.

Defining and demonstrating success

Common success factors

- *Focus on relevant processes and functions.* The audit should be targeted to those aspects of operations that which influence major accident prevention and preparedness. The audit process should be also based on a clear understanding of the role of studied activities in safety performance and their performance expectations.
- *Availability of resources.* Effectiveness of an audit is also a function of resource constraints. The use of trained and experienced auditors, as well as making adequate time for the audit, will determine the credibility and reliability of the final

results. When internal audits are outsourced, the quality of the outcome will depend on having adequate funding to buy the necessary time and competence to perform the task properly.

- Management commitment. A successful audit requires support from management throughout all phases, particularly to ensure that action items generated from the audit are adequately addressed. A constructive management attitude also encourages a level of attention and rigour, improving the quality of the audit.
- *Quality of audits and monitoring.* Audits themselves should require performance standards. Criteria for judging the quality of an audit include:
    - evidence of procedures for controlling risks,
    - evaluation of how successfully procedures have been implemented,
    - evaluation of effectiveness of procedures achieving safety performance targets (if appropriate),
    - evidence of procedures to identify and reduce problems,
    - observations on non-conformities and substandard practices,
    - observations highlighting examples of good practice.
- *Appropriate selection of process safety performance criteria and indicators.* There is considerable guidance available on selection of performance monitoring criteria, particularly for safety performance indicators. Some characteristics that should be considered include :
    - Tangibility (able to communicate a tangible measure of performance, either qualitative or numeric) ,

  - Validity (has validity as a safety performance measure),
  - Reliability (gives consistent feedback on the same underlying conditions) ,
  - Sensitivity (can detect changes in time for corrective action),
  - Transparency (is readily understandable by users).

- *Use of findings to drive improvement.* The purpose of a process safety audit is to provide feedback into the SMS system as a whole. The feedback goes beyond a qualitative evaluation of safety performance; it presents insights into deficiencies in the safety management system. The audit findings should normally include recommendations for immediate corrective actions but also recommendations to explore address potentially systemic problems.

What does success look like?

In identifying success the inspector needs to look for

- Evidence, via documentation, observation and interviews, that the appropriate behaviours and activities have taken place within the company.
- Senior management views the audit as an important activity contributing to continuous improvement rather than just a compliance activity.
- Management is involved in meetings to prepare for audits and discuss results and follow-up.
- The audit process completes the entire feedback loop of the so-called Deming-Cycle, i.e., Plan-Do-Check Act completed.
- All elements of the SMS are reviewed and results of the audit are fed back into the SMS system as a whole.

ANNEX 1: REFERENCES

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ANNEX 2: DELEGATE CONTACT INFORMATION

Participants

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Maureen Wood	MAHB, EC-JRC	Ispra	European Commission

ANNEX 3: PROGRAMME OF THE WORKSHOP

Wednesday, 27 October 2010

Time		Speaker
12:00		Registration / Lunch
13:00	Conference Opening	Mr Freund State Ministry for Environment, Energy, Agriculture and Consumer Protection Hesse, Germany
		Mrs Maureen Wood European Commission, Joint Research Centre, Ispra, Italy
		Mr Baron Regional President Darmstadt, Hesse, Germany
	Organization / Information	Mrs Dagmar Dräger RP Darmstadt, Hesse, Germany
	Session I **Introduction and Definitions**	
13:30	Safety Management Systems (SMS) – General Requirements and Safety Performance Indicators	Mr Mark Hailwood State Institute for Environment, Monitoring and Nature Conservation Baden-Württemberg, Germany
14:00	SMS - Assessment of Effectiveness	Dr Peter Schmelzer Bayer HealthCare

14:30	Safety Culture and Safety Leadership	Mrs Maureen Wood European Commission, Joint Research Centre
15:00		Coffee
	Session II **SMS Impact on Accidents**	
Time		**Speaker**
15:30	In this session six presentations are given covering accidents in the Member States where deficiencies in the SMS have contributed to the cause of the accident or the extent of its effects. The aim is to highlight the relevance of safety management within the prevention of major accidents. • NOx accident Netherlands, Jan Slijpen • Changing a hose coupling led to an explosion, Claes Petersén • Release of carbon monoxide leading to a fatal accident, Birgit Richter • Carbon disulphide tank explosion, Anne-Mari Lähde • Explosion of a sulfuric acid tank, Julie Arnaud • Dead contractors after TiCl4 release, Michiel Goethals	Moderation: Mrs Anne-Barbara Furness RP Darmstadt
17.30	Explanation of the working groups	

Thursday, 28 October 2010

Time

Workshops in 3 parallel working groups:
What questions need to be asked by inspectors when determining the effectiveness of a safety management system?
Considering:

- the requirements of Annex III, Seveso II Directive [96/82/EC]
- the specific situation with regard to the complexity of operation and the risks presented by:
    1. Small and Medium-sized Enterprises (SMEs),
    2. Large scale enterprises and corporations (upper-tier)
    3. Large scale enterprises and corporations (lower-tier)

Each group should spend ca. 60 minutes discussing the individual topics. Following this, each group will have ca. 10 minutes to present their results in plenary followed by a 30 minute plenary discussion.
Each group will cover one of the industry groupings listed above. A list of guide questions to channel and orientate the thought processes for each topic will be provided.
The groups should develop sets of questions suitable for assessing the SMS workshop topic (from Seveso II, Annex III).
The groups should provide an indication of typical expectations for the answers to these questions, which demonstrate adequate compliance with the re-quirements of Annex III.

09:00 **Workshop I: Organization and Personnel**
Group work

10:00 3 x group presentations

1. Small and Medium-sized Enterprises (SMEs)
2. Large scale enterprises and corporations (upper-tier)
3. Large scale enterprises and corporations (lower-tier)

10:30 Plenary discussion
11:00 Coffee
11:30 **Workshop II: Identification and Evaluation of Major Hazards and Risks**
Group work
12:30 Lunch
13:30 **Workshop II continued:**
3 x group presentations
1. Small and Medium-sized Enterprises (SMEs)
2. Large scale enterprises and corporations (upper-tier)
3. Large scale enterprises and corporations (lower-tier)

14:00 Plenary discussion
14:30 **Workshop III: Management of Change**
Group work
15:30 Coffee
16:00 **Workshop III continued:**
3 x group presentations
1. Small and Medium-sized Enterprises (SMEs)
2. Large scale enterprises and corporations (upper-tier)
3. Large scale enterprises and corporations (lower-tier)

16:30 Plenary discussion
17:00 End of 2nd day

Friday, 29 October 2010

Time		
9:00	**Workshop IV: Monitoring Performance, Audit and Review** Group work	
10:00	3 x group presentations 1. Small and Medium-sized Enterprises (SMEs) 2. Large scale enterprises and corporations (upper-tier) 3. Large scale enterprises and corporations (lower-tier	
10:30	Plenary discussion	
11:00	Coffee	
11.30	Summary of Workshop Results and Final Discussion	Chair: Mrs Maureen Wood
13:00	End of conference	

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European Commission Joint Research Centre – Institute for the Protection and Security of the Citizen (IPSC)

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Abstract
The safety management system is now considered a central component of modern process safety management. With the entering into force of the Seveso II Directive , the EU Member States have ever since been required to ensure that the operator of an establishment falling under the requirements of the Directive draws up a policy for the prevention of major accidents. Public authorities are required to carry out inspections of the establishments, including the site's organizational and managerial systems, and this latter responsibility is normally executed through an audit of the SMS. Auditing the SMS is a significant challenge for authority inspectors for a number of reasons. In particular, even when a logical audit system has been well-defined by authorities, substantial questions remain concerning how far to carry the logic, how to recognize where important gaps are present, how to be confident that implementation in practice with management claims, etc. For this reason, a workshop for Seveso inspectors on this topic was organized in Fulda, Germany in 2010 to share knowledge and experience among inspectors for use in benchmarking good practice in inspection and control of SMS demonstrations. This document summarizes the most important observations and conclusions emanating from these discussions.

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