

# **MAJOR ACCIDENT COMMISSION (SFK)**

**under the Federal Minister for  
the Environment, Nature Conservation and Nuclear Safety (BMU)**

## **Guideline**

**to outline a major-accident prevention policy and a safety  
management system pursuant to Article 9 (1) a and Annex III of  
the “Seveso II” Directive**

**prepared by the Working Group on  
Management Systems**

**SFK-GS-24GB**

# **GUIDELINE**

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**to outline a major-accident prevention policy and a  
safety management system in accordance with Article 9  
(1) a and Annex III of the “Seveso II Directive”**

adopted at the 31<sup>st</sup> meeting of the Hazardous Incident Commission, 12 October 1999

The Hazardous Incident Commission (SFK – Störfall-Kommission) is a commission under the Federal Minister for the Environment, Nature Conservation and Nuclear Safety (BMU) pursuant to § 51a of the Federal Immission Control Act (Bundes-Immissionsschutzgesetz).

Its office is housed within the company of GFI Umwelt - Gesellschaft für Infrastruktur und Umwelt mbH.

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# 1 Introduction

## 1.1 The new Seveso II Directive

On 14 January 1997, the Council directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances was published in the EU's Official Journal (OJ L 10 p.13ff). This new directive, known in Germany as the Seveso II Directive replaces the Seveso Directive. Many elements of the new directive will be implemented via an amendment to the Federal Immission Control Act<sup>1</sup> (BImSchG) and an amendment to the 12<sup>th</sup> Ordinance of the Federal Immission Control Act (Hazardous Incident Ordinance)<sup>2</sup>.

The new directive does not only introduce new obligations for operators, it also introduces new concepts. One significant new concept is that of an "establishment"<sup>3</sup>, which corresponds to the concept of "establishment"<sup>4</sup> as defined in Art. 3 (5a) of the BImSchG:

"An establishment as used herein shall mean the whole area under the control of an operator where hazardous substances within the meaning of Article 3 No. 4 of Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJEC 1997 No. L 10, p. 13) are present or planned to be present or will be present in one or more installations, including common or related infrastructures or activities including storage as defined in Article 3 No. 8 of the Directive in the quantities specified in Article 2 of the Directive, if there is reason to assume that the said hazardous substances will be generated when certain industrial chemical processes get out of control; the establishments, hazards and activities referred to in Article 4 of Directive 96/82/EC shall be exempted from this provision."

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<sup>1</sup> Fifth amendment to the BImSchG, 19 October 1998. (Federal Law Gazette Part I, p 3178ff of 26 October 1998).

<sup>2</sup> In progress

<sup>3</sup> Henceforth "establishment" will always mean establishment as defined by the directive as well as in Article 3 (5a) of the BImSchG.

<sup>4</sup> The use of the term "establishment" in existing technical regulations (for example guidelines issued by professional associations) does not have to correspond to this definition.

The directive does not apply to certain establishments, hazards and activities named in Article 4 of the Seveso II Directive in spheres which are not covered by the directive. Examples include: military installations, mines, the transport of dangerous substances (including via pipelines), and also the hazards created by ionising radiation.

It is not up to individual installations to observe the obligations laid down in the directive; rather the obligations apply to the establishment, which may include one or more installations, adjoining installations and infrastructural equipment, irrespective of whether they require a licence under immission control law.

As with the previous Hazardous Incident Ordinance, the directive states that those operators in charge of establishments where large quantities of hazardous substances are present have “extended obligations”. A significant new obligation for these operators is the obligation to produce a safety report which, in addition to the details provided in previous safety analyses of the installation, must show that a “major-accident prevention policy” has been implemented, and that there is a safety management system in establishment (Article 9 (1) a)).

The following additional operator obligations are also part of the extended obligations:

- Where a safety report in accordance with Art. 9 of the directive has to be produced for the establishment, the major-accident prevention policy and the safety management system have to be documented in this safety report. The safety report is to be made available to the public in line with Art. 13, with the exception of details of trade or industrial secrets.
- In the event of the modification of an installation, storage facility, any other part of the establishment, a process, or of the nature and quantity of dangerous substances which could have significant repercussions on major-accident hazards, the policy, the safety management system and also the safety report must be reviewed, and where necessary revised, and the competent

authorities must be informed of any changes which have been made (Article 10).

- Since the safety report, , must be reviewed and where necessary updated at least every five years, or at the request of the competent authorities whenever new facts emerge, particularly new technical knowledge about safety matters, this also applies to the policy and to the safety management system, as well as to the documentation in the safety report (Article 9 (5)).
- If the competent authority identifies a risk of a “domino effect”, it must ensure that the operators affected modify their policies and safety management system accordingly. (Article 8 (2))
- When an establishment is inspected by the competent authority, the authority may review the policy and the safety report and also the documentation contained in the safety report (Article 18).

## **1.2 Aim and structure of these guidelines**

As stated above, operators of establishments which have to meet the extended obligations of the Seveso II Directive must, in line with Article 9 (1), demonstrate that:

*“a major-accident prevention policy and a safety management system for implementing it have been put into effect in accordance with the information set out in Annex III;...”*

In accordance with Article 9 in conjunction with Annex II, the information in the safety report regarding the safety management system and the establishment organisation must fulfil the requirements laid down in Annex III (Principles for the major-accident prevention policy and the management system).

This guideline provides advice on how to implement the above requirements. The guideline was drawn up by the SFK Management Systems working group, and was approved by the Commission at their session on 12<sup>th</sup> October 1999. This guideline only refers to the Seveso II Directive.

Those establishments which only have to fulfil the basic obligations only need to draw up a major-accident prevention policy. There is a separate guideline to help with this (SFK-GS-23).

Article 9 of the Seveso II Directive, together with Annexes II and III sets out the specific requirements for the policy and the safety management system. A few additional requirements are laid down in other articles (e.g. Article 18 on the official inspection of establishments), and also from the directive as a whole. The directive establishes **what** the operator needs to deal with. As far as possible, these kind of direct requirements are presented in these guidelines as italicised quotes from the original.

The operator is free to decide **how** he meets these requirements, but he must give details of his approach in the safety report. The guideline seeks to clarify and gives advice on what kind of measures are appropriate for meeting the requirements of the directive, such as how to conclusively demonstrate that the requirements are being met.

In the light of the wide range of establishments covered by the directive, the advice given in this guideline can only provide guidance, and it is not intended to be the last word or a binding list of instructions for the operator. The operator should nonetheless take into account the fact that the explanations, advice and recommendations in this guideline are the results of intensive discussions between the experts who represent different social interest groups within the Hazardous Incidents Commission. Following this guideline will therefore help to create more acceptable documentation.

The Seveso II Directive does not lay down any rules about presentation, such as structure and layout. This means that when drawing up the documentation, the

operator has the opportunity to take into account specific circumstances, and if appropriate, can include existing documents as part of the safety report. Section 3.1 deals with the issue of how to integrate the safety management system itself.

Given that the safety report must be inspected, that the report must be made available to the public (Article 13), and the need to keep staff informed, it is advisable to design documentation for the policy and the safety management system in such a way that it can stand alone, albeit there may be a few specific and necessary references to other documentation.

## **2 The major-accident prevention policy**

According to the provisions laid down in Annex III, the operator has to produce the policy as a written document, which deals specifically with the overall objectives and general principles of his procedures for limiting the risk of hazardous incidents.

The document should specifically include the following points:

- formulation of a company policy, which states that the prevention of hazardous incidents and the limitation of the effects of hazardous incidents which, despite all efforts do occur, is a high priority in the company objectives.
- presentation of the basic approach to implement this objective, for example in the form of guidelines which are part of company policy.

Coestablishment based on trust is one of the most important pre-conditions for an effective safety management system. Managers are therefore advised to draw up company policy and the accompanying guidelines in conjunction with staff. The employees' right of co-determination, which can be particularly valid in the case of working conditions regulations contained in the safety management system, must be respected. It is recommended that management signs the relevant documents.

In addition to the company policies and any accompanying guidelines, the policy must also state:

- a) what risks of hazardous incidents are present in the establishment
- b) what provisions have been made for preventing these, or limiting their effects, and
- c) in which way it is ensured that these measures are implemented properly.

The answers to a) and b) are supplied in other sections of the safety report, particularly in the installation-specific safety analysis. c) refers to the presentation of the safety management system which is dealt with in section 3.

### **3 The safety management system (SMS)**

#### **3.1 Fundamental principles**

The safety management system (SMS) is part of the implementation of the major-accident prevention policy.

Annex III does not lay down a basic structure – i.e. the organisational and establishment processes – for the SMS. With a view to a holistic management system, it is useful to link the SMS to other existing or planned management systems in the company. If a holistic management system is already in place, the SMS should be integrated into it.

This allows the operator to take company-specific factors into account, for example, the SMS can be integrated into existing management systems which comply with OHRIS (Bavarian design), ASCA-based systems, ISO 9000 ff, ISO 14001, EMAS (an environmental audit system), or can be built onto these, or can make use of other existing management structures. When implementing an installation-specific SMS,

certain factors can be necessary in order to ensure that implementation takes place throughout the whole establishment.

The safety report as required by Article 9 must demonstrate in a way that can be verified that the SMS at least complies with the requirements and procedures set out in Annex III. Obviously, the SMS also has to meet all the conditions necessary to fulfil all the legal requirements (laws, ordinances, accident prevention regulations, licences and legal conditions).

## **3.2 Organisation and staff**

### **3.2.1 Text of the Seveso II Directive**

Annex III c (i) states that the SMS must deal with the following:

- *defining the areas of activity and responsibility of those staff responsible for monitoring the risks of hazardous incidents at all levels of the organisation.*
- *establishing the training needs in this area, and taking appropriate measures to resolve this.*
- *the inclusion of staff and subcontractors.*

### **3.2.2 Establishing the principal responsibility of the operator**

The operator, i.e. the management, is responsible for devising the SMS and for ensuring it is adhered to. Responsibility can be delegated where appropriate, and if fully documented, particularly in the area of respecting and fulfilling legal requirements and company regulations. However, delegating responsibility does not release the management from a regular monitoring and up-dating of the SMS.

If the company management comprises several people, a decision must be reached on who carries this responsibility. This does not affect the management's overall responsibility.

It is possible to refer to an appropriate notification made in accordance with Art. 52 (a) 1 of the Federal Immission Control Act.

### 3.2.3 Structural organisation

The structural organisation of the SMS must be detailed, providing a clear assignation of tasks, functions and competences at the different levels of the company. Organisation charts and job descriptions are particularly suitable for this task.

At all levels of the company hierarchy, staff must know what exactly they are responsible for and what rules apply to the “interfaces” with the areas of responsibility of others. This means defining tasks, areas of responsibility (where necessary with local delimitation), and liability within the organisation, with particular attention given to safety and how to deal with the risk of hazardous incidents. When transferring such responsibilities, it is necessary to verify that the tasks can in fact be accomplished with the transferred authorisation.

Particular tasks which must be covered by the SMS are:

- respect of the legal requirements, including conditions arising from licences, authorisations and permits,
- respect of internal safety, procedural and working instructions,
- ensuring management instructions become establishment practice (e.g. safety principles),
- selection of suitable staff for the job,
- staff training and regular safety-awareness training,
- involving third party companies and their subcontractors in establishments,
- monitoring behaviour of both internal and contracting staff, to ensure that they are being safe,
- immediate notification of any disruptions or identified hazards in their area of responsibility to the respective superior or any other person/body that may be responsible,

- regular reports to the responsible superior regarding disruptions and hazardous incidents; any lack of safety which has been identified in the installation or in the organisation, and the measures planned or already implemented to resolve this, and
- organisation and maintenance of the SMS.

The hazardous incidents officer as per Article 58 a) of the BImSchG has a particularly significant role in carrying out and monitoring these tasks.

The relevant regulations should include line organisation and the organisation of safety officers, and should also go into detail about how they are to cooperate. Regarding the information above, it is possible to refer to the appropriate notification made under Art. 52 (a) 2) of the BImSchG.

#### **3.2.4 Establishmental organisation**

Details must be given of the principle used in the SMS to deal with establishment processes in order to comply with the Seveso II Directive (particularly establishment processes which cover more than one function or department). This covers establishment processes throughout the SMS, so detailed descriptions are not necessary in this section. However, the document must demonstrate that important establishment processes which are directly linked to the structural organisation are dealt with (in particular the question of delegating responsibility, which includes the constant availability of checking which function has been assigned to which management personnel).

### **3.2.5 Committees**

Where committees are set up as part of the SMS, it is necessary to describe their composition and responsibilities, and also to address the issue of how they cooperate with one another and with other committees when necessary.

### **3.2.6 Qualifications and training**

The document should explain how the needs of the various groups for training, specific qualifications (particularly in the case of staff who have a role in plant safety, such as the safety officers), and further training are met within the framework of SMS; what routine procedures have been introduced; the focus of these routines; what is done to ensure that staff attend training, and what record is made of their attendance.

Where third parties and subcontractors are used, it is necessary to explain how the contracting staff are included in the system of training.

### **3.2.7 Involvement of staff and where appropriate of third parties and subcontractors**

Staff and their representatives should be involved in planning and implementing the SMS. The documentation must show in what way staff knowledge has been used in each part of the SMS, and how staff are involved in defining and introducing technical and administrative safety measures (in order to increase the effectiveness and acceptance of these measures). In addition, details are to be given of how to include staff suggestions and advice on safety-related matters.

Where co-determination is affected, employee representatives are to be involved. To increase the efficiency of the measures adopted, they should also be regularly included over and above the legally-required minimum.

The document must explain how the SMS provides for information on risks arising from certain sections of the establishment and safety measures to be passed on to

temporarily employed staff, to outside companies and subcontractors if these are used. Procedures must be established which deal with coordination between external and internal staff (for example, release procedures and keeping records), and also with the areas of responsibility and work supervision. It must also explain how subcontractors can put forward suggestions and advise the operator on safety-related matters.

### **3.3 Identifying and assessing the risk of hazardous incidents**

#### **3.3.1 Text of the Seveso II Directive**

Annex III (c) ii) states that the following points are to be dealt with by the SMS:

*“identification and evaluation of major hazards - adoption and implementation of procedures for systematically identifying major hazards arising from normal and abnormal establishment and the assessment of their likelihood and severity.”*

#### **3.3.2 Remarks on identification and assessment**

The SMS must ensure that the potential for hazardous incidents is identified and that the probability and severity of these incidents is assessed. Suitable systematic methods should be used to achieve this. All sections of the establishment, and where appropriate external sources of potential hazards, are to be taken into account. Appropriate measures should be taken on the basis of the risk assessment.

The safety examination for identifying and assessing risks<sup>5</sup> should take place for all relevant planning and establishment stages of sections of the establishment, particularly installations. In doing this, both the establishment as defined by the normal operation and disruptions are to be considered. The SMS

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<sup>5</sup> In accordance with German Industry Standards (DIN) VDE 31000 Section 2 (December 1987 edition), in general, risk is not defined quantitatively. It is rare that it can be quantified as a combination of the frequency and extent of the damage.

provides the more detailed definitions on which the identification and assessment of risks of major accidents are based.

If existing installations already have a system for safety evaluation and analysis (as per the Second General Administrative Provision implementing the Hazardous Incident Ordinance), these can be used as a substantial part of the systematic identification and assessment of risks.

The relevant findings for individual sections of the establishment and the installations therein, together with the ensuing action to be taken, are to be detailed in the appropriate section of the safety report in accordance with Article 9 and Annex II.

The company in question should establish in the SMS the general approach to complying with these obligations. The following points could be particularly significant when doing so:

- At what juncture or what time are procedures to identify and assess the risk of major accidents to be carried out?
- What methods will be used in each case, and what will be examined?

Examples of systematic methods for identifying potential risks are:

- PAAG or HAZOP procedures
- “What if “ procedures
- Checklists

Systematic procedures for evaluating incident probability include, among others:

- Matrices (e.g., Zurich, Bützer)
- Indexing (e.g., Dow, MOND)

- Z-factor methods
- cause-consequence analysis
- analysis of course of events
- fault-tree analysis
- risk graphs as per German Industry Standards (DIN)19250 and
- metric method

- In which way is up-dating of the methods ensured?

- Who carries out the examination?

It is advisable to always have a team carrying out the examination. There should be fixed requirements regarding the knowledge and skills of people employed to do this.

- How can staff be involved?

- How can findings and information from relevant breakdowns and hazardous incidents within the plant and at other plants be used in the examination?

- Where does information from audits and other monitoring come in?

- How are the results to be written up/documentated?

- How are the results dealt with basically?

Particular attention should be given to:

- action to be taken as a result of the findings
- responsibility for implementation

- follow-up
- informing staff, and where appropriate other operators and the authorities, about the results
- measures to be taken in the area of training and
- overall use/application of the findings.

### **3.4 Establishmental control (monitoring the operator)**

#### **3.4.1 Text of the Seveso II Directive**

Annex III c (iii) states that the following points are to be dealt with by the SMS:

*“establishmental control - adoption and implementation of procedures and instructions for safe establishment, including maintenance, of plant, processes, equipment and temporary stoppages.”*

#### **3.4.2 General remarks**

The SMS must ensure that for all safety-related procedures:

- there are written work and operating instructions
- staff are informed in writing or orally in an appropriate way
- the work and operating instructions are exercised in practice where necessary, and
- is monitored, to see whether they are reasonable and viable, and whether they are obeyed.

The inclusion of temporarily employed staff, outside companies and subcontractors should be taken into consideration when drawing up work and operating instructions.

When drawing up this section of the SMS, it is important to remember that work and operating instructions are required under a number of other German regulations, as for example the Working Conditions Act and the accompanying ordinances, the Hazardous Substances Ordinance, the Safety of Equipment Act and various accident prevention regulations.

### **3.4.3 Work and operating instructions**

Work and operating instructions can be related to the workplace, the activity, or the substances handled. According to context and validity, they should resolve the following issues in particular:

- competence and responsibility
- start of the installation or facility
- normal operation of installations, facilities and work materials
- handling of hazardous substances and preparations
- recognising disruptions, procedure for establishing the cause and both methods and responsibility for resolving the disruptions (return to normal operation)
- fixed-term or special operating circumstances
- operation during maintenance and cleaning
- close down of the installations and facilities under normal conditions
- procedures for installation stoppages
- procedure in the event of operational disruptions and in emergencies, including emergency stoppages, first aid procedures and appropriate disposal of wastes.

Where there are extensive procedures and protection measures, it has always been worthwhile to expand work and operating instructions with checklists or step-by-step lists (where this is not provided for by a process control system).

The SMS has to ensure that work and operating instructions:

- address all the relevant findings from the “Identification and assessment of the risk of hazardous incidents”
- are amended or renewed each time processes, establishments or working arrangements are modified, or when pertinent legal requirements are altered
- even without this kind of external necessity, are regularly reviewed and updated, making use of operating experience
- all the necessary information for the safe operation of the installation and facilities are available to staff in comprehensible form and language
- are available at all times to all staff who are directly or indirectly affected, and
- contain regulations for shift handovers in accordance with the legal requirements.

#### **3.4.4 Training**

The SMS should ensure that not only there is regular training on the content of the operating and work instructions, but that special instructions are provided

- before new or modified installations, facilities or work materials begin to operate
- before new or transferred staff take up related functions
- before processes, establishments or working arrangements are modified
- before different substances or operating media are used

- before major disconnections, closures or other activities which are particularly hazardous
- after incidents involving accidents, damage or emissions
- when legal requirements have an effect on establishment processes
- in the event of any other changes which have to be made to the operating and work instructions, for whatever reason

In addition to specific instruction, further training activities can be useful, and even necessary.

## **3.5 Safe implementation of modifications**

### **3.5.1 Text of the Seveso II Directive**

Annex III (c) iv) states that the following points are to be dealt with by the SMS:

*“management of change - adoption and implementation of procedures for planning modifications to, or the design of new installations, processes or storage facilities;...”*

### **3.5.2 Safe implementation of modifications**

This section of the SMS includes both modifications in the strict sense of the term (planned, or necessary at short notice because of special circumstances), and the planning of new installations within the establishment. To cover the full establishment life of an installation, a procedure or a storage plant, this should consider construction and commissioning (as the meeting point between planning and establishment), maintenance and also closure and dismantling.

The SMS should resolve the following points in particular:

- The competences/responsibilities and procedure for the safe implementation of modifications in the broader sense of the term, as defined above, are to be established in writing.
- Defining which modifications have an impact on safety. For this purpose an evaluation procedure has to be defined. In doing this, it is advisable to consider all of the modifications in the context of the SMS at first, but to make the effort needed to prepare, approve and implement the modifications dependant on the relevance to safety. For example, a list of modifications could be drawn up, based on operating experience, which the manager, foreman or even the shift leader could authorise themselves.
- Ensuring that modifications during the operating period remain within the limits of the relevant permits, or that appropriate notice of modification or authorisation is given in time.
- Tracking the legal requirements and legislation as well as the state of the art with regard to potential consequences for the planning, establishment or decommissioning of installations, processes or storage facilities. Establishing areas of competence and communication channels.
- Establishing how the findings from the identification and assessment of the risk of hazardous incidents (see 3.3), of near misses and of unsafe circumstances can be taken into account when making new plans, modifications and decommissioning.
- Considering the possible consequences of modifications for general systems, such as pipeline systems for raw materials, energy supplies, disposal facilities and other infrastructural establishments and emergency organisations.
- Ensuring that when the establishment is constructed and taken in operation, the implementation conforms to the plans.

- Establishing safety measures and controls for implementing the modifications and for test runs.
- Providing information and training for staff, and where necessary, for external staff concerned or staff from adjoining installations.
- Documenting the modifications, including revising the operating documentation and any documentation available to the authorities.
- Monitoring possible consequences of the modifications and implementing corrective measures in the event of unforeseen harmful consequences for working conditions and environmental protection.
- Monitoring decommissioned installations until they are disassembled, including retaining expert knowledge regarding the installation and the substances present.
- Proper disposing of the remaining contents of the installation, of any objects created during the disassembly, and of the disassembled installation components.

## **3.6 Emergency plans**

### **3.6.1 Text of the Seveso II Directive**

Annex III (c) v) states that the following points are to be dealt with by the SMS:

*“planning for emergencies - adoption and implementation of procedures to identify foreseeable emergencies by systematic analysis and to prepare, test and review emergency plans to respond to such emergencies;...”*

### **3.6.2 General remarks**

Internal emergency plans are to be produced in line with the requirements set out in Article 11 and Annex IV (1) of the directive. In accordance with Article 11 and Annex IV (2), the information required for external emergency plans is to be provided to the competent authorities. Staff are to be involved in drawing up the internal emergency plans. The public must be heard when devising external emergency plans.

### **3.6.3 Implementing the emergency plans**

This section of the SMS contains a description of the procedure for identifying foreseeable emergencies, and for drawing up, testing and reviewing the internal emergency plans (alert and disaster control plans), and for the identification and passing on of information required from the operator for drawing up external emergency plans. Annex IV of the directive determines which data and information are to be included in the emergency plans.

Therefore, the SMS should determine the following, in particular:

- The procedure for identifying foreseeable emergencies, based on a systematic analysis. This must ensure that all installations and storage facilities are systematically examined for potential technical, organisational or human failures which could cause an emergency situation. Here, it is possible to build to a large extent on the findings from section 3.3 on the identification and assessment of the risk of hazardous incidents, from which additional scenarios can be drawn, notably the failure of the preventative measures provided for in this section. See also the Third General Administrative Provision implementing the Hazardous Incident Ordinance.
- The group of people who will carry out this analysis. As with section 3.3, teamwork is recommended. In the event of insufficient internal expertise, outside resources have to be brought in.
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- The different competences for carrying out the analysis, and for devising, testing and reviewing the resultant emergency plans.
- The procedure for devising internal emergency plans.

The following issues must be resolved:

- areas of responsibility, including the procedure for handing over these responsibilities from one person to another
- participants (a team is recommended for this as well; staff must be included)
- documentation
- updating documentation
- informing and training staff and other workers, and the internal hazard prevention organisations (see Article 6 (1) of the Hazardous Incident Ordinance)
- providing information to the external hazard prevention organisations and where appropriate those inhabitants who are affected
- identifying the safety equipment, resources, communication links needed by staff and by the crisis committee, if there is one
- testing the emergency plans

Particular attention should be given to establishing the following:

- responsibilities for setting up a plan for drills, and for carrying out and evaluating drills
- establishing those groups to be involved in the drills, with particular consideration of the staff, external assistance organisations and agencies, hazard prevention organisations and where appropriate, the inhabitants

- Reviewing the emergency plans.

In doing this, the following issues must be resolved:

- responsibilities
- intervals at which routine review takes place
- the criteria for an immediate review (for example, based on the experience of drills and real accidents, a change in requirements or resources for external hazard prevention organisations, assistance organisations and agencies, changes in the law)
- identifying, working on and conveying the information required for drawing up external emergency plans (Planning data).

To do this, the following issues must be resolved:

- a decision regarding coestablishment with the authorities and external hazard prevention organisations by identifying the information needed
- responsibilities for identifying, compiling and communicating this information to the authorities
- responsibilities for keeping information up-to-date
- responsibilities for maintaining constant contact with the authorities regarding this matter.

### **3.7 Quality assurance (Monitoring the effectiveness of the SMS)**

#### **3.7.1 Text of the Seveso II Directive**

Annex III (c) vi) states that the following points are to be dealt with by the SMS:

*“monitoring performance - adoption and implementation of procedures for the ongoing assessment of compliance with the objectives set by the operator's major-accident prevention policy and safety management system, and the mechanisms for investigation and taking corrective action in case of non-compliance. The procedures should cover the operator's system for reporting major accidents or near misses, particularly those involving failure of protective measures, and their investigation and follow-up on the basis of lessons learnt;”*

### **3.7.2 General remarks**

Part of the SMS's role is to constantly monitor the efficiency of the policy, the SMS and the safety measures. The results of this monitoring are to be compared with the safety targets that had been set. In particular, this includes

- an active monitoring of whether the plans and targets which had been set were achieved, and whether safety measures are implemented so as to be preventative, rather than only being taken after hazardous incidents or accidents and
- precautions to be taken to record disruptions to normal operation that could endanger the public and the neighbouring area, or where the findings could help to improve establishment safety, and also for notifying the operator as appropriate, and for investigating these accidents (reactive monitoring)

### **3.7.3 Active monitoring**

Active monitoring covers all elements of the SMS. This includes in particular examining the construction and establishment of safety-critical sections of the installation; constant monitoring of installation safety and regular maintenance under safety-technological aspects; taking the required safety precautions to avoid operating errors; preventing wrong action by providing appropriate operating and safety instructions, and by means of training in line with Art. 6 (1) of the Hazardous

Incident Ordinance; and also monitoring behaviour to ensure that it is safety compliant.

The examination, monitoring, maintenance and possible reparations are to be documented in line with the requirements laid down in Art. 6 (2) of the Hazardous Incident Ordinance.

In existing systems for recording suggested improvements, comments on how to increase safety should be particularly encouraged. If appropriate, this kind of system should be introduced.

#### **3.7.4 Reactive monitoring**

An effective system for reporting major accidents and other safety-related incidents is to be provided, and should be initiated in accordance with standardised requirements. An investigation procedure is also necessary, which must be capable of identifying not only the direct causes, but also all the fundamental failures which led to the incident.

The SMS should contain precautions that give particular attention to disruptions in safety equipment (including establishment disruptions and organisational errors). These must be investigated and analysed in an appropriate manner, and lead to measures to ensure that the experience gained from the disruption will be used in the future (including making the information available to the staff responsible).

The findings from accidents, near misses, unsafe circumstances and unsafe behaviour should be systematically recorded, evaluated and made available for the purpose of sharing experiences. These experiences should not only be used within the company, but should be made available to others.

The operator has to establish who is responsible for initiating the investigations and for taking remedial action in the event of a failure to observe SMS principles. In

particular, a revision of the instructions or of the system should be considered, if this can prevent a repetition of the incident.

It is necessary to ensure that relevant information gained through the monitoring activities is included as an important element of the audit and evaluation procedure (see below).

### **3.8 Monitoring and analysis (Audit and review)**

#### **3.8.1 Text of the Seveso II Directive**

Annex III (c) vii) states that the following points are to be dealt with by the SMS:

*“adoption and implementation of procedures for periodic systematic assessment of the major-accident prevention policy and the effectiveness and suitability of the safety management system; the documented review of performance of the policy and safety management system and its updating by senior management.”*

#### **3.8.2 General Remarks**

In addition to the monitoring detailed in section 3.7, the operator should undertake regular reviews (audits) of his policy and his safety management system. The results of the review are to be evaluated. The policy and the safety management system are to be optimised on the basis of this evaluation.

#### **3.8.3 Audits**

The audit aims to ensure that organisation, processes and procedures – regarding their definitions and their actual implementation – are in line with the major-accident prevention policy and the SMS, and also with both external and internal requirements. The audit’s results should be used to determine what

improvements should be made to the individual sections of the SMS and to their implementation.

In principle, it must be possible for independent third parties to carry out the SMS audit.

#### **3.8.4 Audit plan**

The operator should draw up and use an audit plan. This plan should be reviewed at appropriate intervals, and should contain the following:

- details of the areas and activities to be audited
- the frequency of the audit for each of the areas in question
- who is responsible for each audit
- details of resources and staff that are required for each audit, providing for the necessary expertise, independence and technical support (see below)
- the audit protocols to be used (what questionnaires, checklists, open and/or structured interviews, measurements and observations can be included)
- the procedure for reporting the findings of the audit
- the follow-up procedure (using the audit to improve the SMS) and
- who is responsible for maintaining the audit system.

#### **3.8.5 Requirements to be met by the auditors and their activities**

The auditors and their activities are required to comply with the following, whereby German Industry Standard (DIN) EN ISO 8402 (August 1995 edition) and DIN ISO 10011 sections 1-3 (all June 1992 edition) are to be applied as appropriate:

- unbiased execution of duties
- for internal auditors, prohibition of discrimination in accordance with Art. 58 (1) BImSchG
- examination of whether safety-related legal requirements are being observed
- collection and analysis of sufficient relevant evidence to be able to come to a conclusion regarding the system being audited
- attention is to be paid to indications suggesting a factor which may influence the audit findings and which may make further reviews necessary and
- interviews are to be held with staff from various levels in the company hierarchy and with various functions, to review the implementation of the SMS and the appropriateness of the major-accident prevention policy, paying particular attention to the staff from areas of particular significance when evaluating the SMS, such as worker representatives and company representatives.

The following conditions must be respected when carrying out the audit:

- adequate documentation and other information must be available for evaluating the effectiveness of the SMS
- adequate examination of the system
- adequate staff training and
- adequate participation by the staff/works council.

### **3.8.6 Review**

The review is to be understood as an essential investigation by the company management, in which the major-accident prevention policy and all aspects of the

SMS are to be reviewed at appropriate intervals in order to ensure that they are in agreement. The findings of the monitoring (section 3.7) and of the audit (section 3.8.3) are to be specifically included.

This review should provide information to determine whether the policy or the objectives themselves need to be modified. It should also resolve the issue of allocating resources for implementing the SMS , and should take into account changes in terms of company organisation, technology, standards and legislation.

- In particular the SMS should establish:
  - areas of responsibility within the management
  - deadlines
  - documentation, including the distribution of the report
  - action to be taken.

It is advisable to carry out the review, the evaluation and the decision whether to continue with the policy and SMS at management level, and to document it.

## Annex

### List of Members:

The following persons belong to the SFK Management Systems Working Group:  
(Status August 1999)

Dipl.- Chemiker Bahr (ab Juni 1998)	Industriegewerkschaft Bergbau, Chemie, Energie
Dr. Ehret	BASF AG
RD Friedrich	Ministerium für Umwelt, Raumordnung und Landwirtschaft NRW
Dipl.- Ing. Guterl (ab November 1998)	Berufsgenossenschaft der chemischen Industrie
Dr. Heuter (bis Februar 1998)	Deutscher Gewerkschaftsbund
Frau Horster	Bund für Umwelt und Naturschutz Deutschland e.V.
Prof. Dr. Jochum (Vorsitzender)	Gerling Consulting Gruppe GmbH
Konstanty (ab Juni 1998)	Deutscher Gewerkschaftsbund
Dr. Kutscher (bis November 1998)	Berufsgenossenschaft der chemischen Industrie
Dr. Nitsche (ab November 1998)	Umweltbundesamt
Dipl.-Ing. Paul (ab November 1998)	RWTÜV Anlagentechnik GmbH
Dr. Poppendick	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Prof. Dr.-Ing. Schulz- Forberg	Bundesanstalt für Materialforschung und - prüfung
Frau Dr. Sundermann- Rosenow (bis November 1998)	Umweltbundesamt
Dr. Wiesner (bis November 1998)	

## **Geschäftsstelle der SFK:**

Dipl.-Ing. Freund

Gesellschaft für Anlagen- und  
Reaktorsicherheit (GRS) mbH

## **Meetings:**

The following meetings of the SFK Management Systems Working Group have taken place:

1. meeting	on	April 21 <sup>st</sup> 1997	in	Ludwigshafen
2. meeting	on	June 19 <sup>th</sup> 1997	in	Köln
3. meeting	on	September 2 <sup>nd</sup> 1997	in	Dresden
4. meeting	on	November 18 <sup>th</sup> 1997	in	Ludwigshafen
5. meeting	on	March 12 <sup>th</sup> 1998	in	Köln
6. meeting	on	July 13 <sup>th</sup> 1998	in	Köln
7. meeting	on	October 9 <sup>th</sup> 1998	in	Köln
8. meeting	on	January 27 <sup>th</sup> 1999	in	Köln
9. meeting	on	June 22 <sup>nd</sup> 1999	in	Köln

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