

INSTITUTE FOR SYSTEMS INFORMATICS AND SAFETY

**GUIDANCE ON
INSPECTIONS**
**AS REQUIRED BY ARTICLE 18
OF THE COUNCIL DIRECTIVE 96/82/EC
(SEVESO II)**

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(Editors)

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1. Introduction

Council Directive 96/82/EC (*Seveso II*) is aimed at the prevention of major accidents involving dangerous substances, and the limitation of their consequences for man and the environment, with a view to ensuring high levels of protection throughout the Community in a consistent and effective manner. The Directive places requirements on the operator of a Seveso II establishment to take the measures necessary for the prevention of major accidents and to limit their consequences for man and the environment. The Directive also includes a requirement for the Member States to ensure that Competent Authorities organise a system of ongoing inspections, or other measures of control, to examine whether operators are complying with their duties under the Directive. This latter requirement is the subject of this Guidance Document.

The requirements for 'Inspections' under the responsibility of the Competent Authorities is an area that has been amended and strongly reinforced in the '*Seveso II*' Directive. The '*Seveso I*' Directive only contained one brief paragraph on inspection but the new Directive contains an entire Article on this subject. This development has been made in recognition that an effective inspection regime in Member States is necessary to achieve the objectives of the Directive. To this end the Directive now sets out explicitly the features of the inspection regime that should be provided by Competent Authorities and lead to increased consistency in enforcement at European level. Its purpose is elaborated by Recital (16) of the Directive which states:

'Whereas differences in the arrangements for the inspection of establishments by the competent authorities may give rise to differing levels of protection; whereas it is necessary to lay down at Community level the essential requirements with which the systems for inspection established by the Member State must comply;'

This document is intended to provide further explanations and guidance to assist with the interpretation of the requirements on 'Inspections' contained within Article 18 of the Directive. The document is intended to consider the requirements of the *Seveso II* Directive, which mainly focus on the **organisation and principles** of Inspections and is not intended to be a comprehensive general guide on *how to inspect* per se.

This guidance has been prepared specifically to cover the requirements of the Seveso II Directive. It has been developed with the intent of being consistent and compatible with other similar initiatives such as the work carried out by the European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL) on developing minimum criteria for (environmental) inspections. The scope of the IMPEL work is broader and covers other environmental legislation.

This guidance reflects the interpretation of the Directive as agreed by the European Commission and the Member State Authorities. This guidance is not legislation - it should not be considered mandatory and does not preclude other reasonable interpretations of the requirements of the Directive.

2. The Objectives of Inspections/Control Measures

This document refers to inspections/control measures carried out under the responsibility of the Competent Authority to meet the requirements of Article 18 of the Directive. The provision of inspections/control measures by the Competent Authority does not in any way diminish the duty on the operator to ensure that all necessary measures have been taken to prevent major accidents and to limit their consequences.

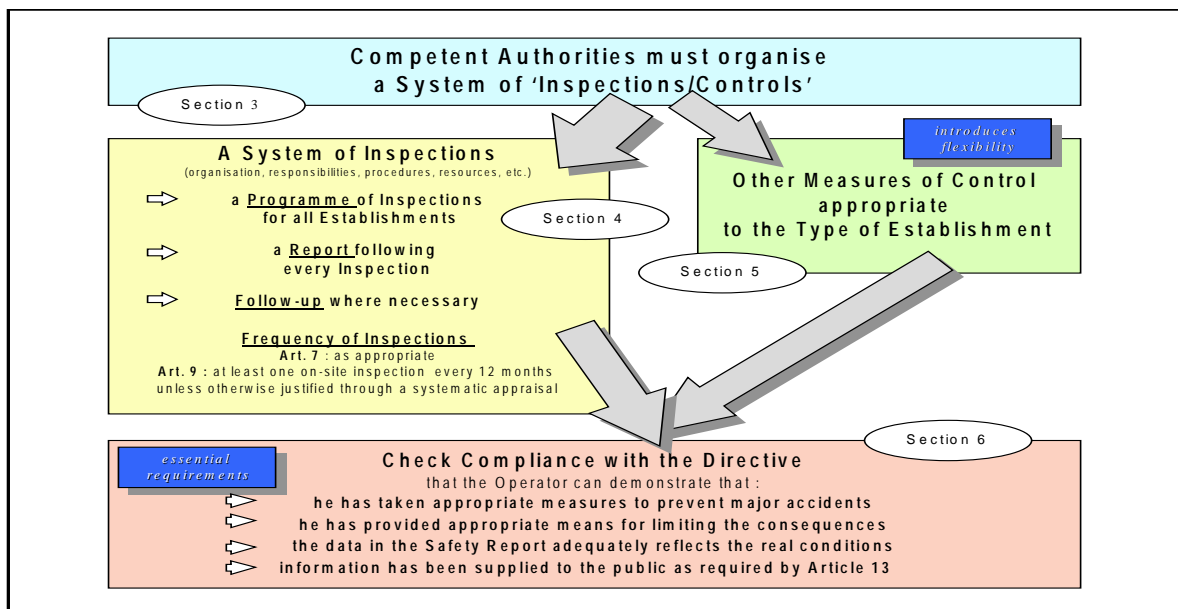
The basic purpose of inspections/control measures is to periodically check if establishments are being operated in the manner envisaged by the Directive, in other words if a high level of protection for man and the environment is being achieved and is capable of being maintained.

Inspections/control measures must be sufficient for a planned and systematic examination of the systems being employed at the establishment, whether of a technical, organisational or managerial nature.

Article 18 requires that inspection/control measures, in particular, ensure:

- 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 the information has been supplied to the public pursuant to Article 13 (1).

Figure 1. The requirements of Article 18



3. The Organisation of Inspections/Control Measures

In many Member States, there will be several Competent Authorities appointed to carry out duties laid down in the Directive. It is recommended that Member States draw up a document explaining the roles of the different authorities and arrangements for co-ordination between them, particularly with regard to inspections. It is also recommended that this explanatory document be made available to all interested parties.

The requirements of Article 18 of the Seveso II Directive can be described by the schematic diagram shown in Figure 1. The diagram also indicates the sections of this document where different aspects are addressed.

The Competent Authorities may choose to develop both sides of the diagram shown in Figure 1 to a certain extent. In other words, they may choose to elaborate both a 'system of inspections' and 'other measures of control' to a greater or lesser extent dependent on which best fits with their needs. However it seems likely that some significant development of the left side of the diagram, that is a system of inspections, is necessary to achieve the objectives of Article 18. Where 'other measures of control' are used, they should aim to provide a degree of control at least equal to what could be expected from a system of inspections.

The Directive requires that inspections or other control measures shall not be dependent on receipt of the Safety Report or any other report submitted. However, full benefit should be taken of all information including such reports when available.

4. A System of Inspections

4.1. General Requirements

The system of inspections is required to comply with the following conditions (Article 18 (2)):

- there shall be a **Programme of inspections** for all establishments (see sections 4.2 & 4.3);
- following each inspection, a **report** shall be prepared by the Competent Authority (see section 4.4);
- where necessary, every inspection carried out by the Competent Authority shall be **followed up** (see section 4.5) with the management of the establishment, within a reasonable period.

The system of inspections should include the organisational structure, responsibilities, practices, procedures and resources for developing and implementing an effective and consistent programme of inspections.

4.2. Development of a Programme of Inspections

The Directive requires that a Programme of inspections shall cover all establishments i.e. both Article 7 ('lower tier'), and Article 9 ('upper tier') establishments. In this context, it will be necessary for Competent Authorities to develop and maintain an up-to-date list of all establishments covered by the Directive.

Inspection Programmes should take into consideration :

- a) The requirements of the national laws, regulations and administrative provisions which implement the Directive;**
- b) Local or national priorities following an assessment of the major issues concerning major hazard establishments, where applicable;**
- c) Where relevant, a general assessment of data and knowledge from previous inspection activities or other sources of information or appraisal on the state of compliance of establishments with the relevant legal requirements related to major accident hazards;**
- d) An assessment of where inspection is most needed. The following considerations, for example, may influence setting priorities for particular establishments or particular installations/systems within an establishment, where the information is relevant to major-accident hazards:**

Consideration of hazard or risk potential:

- ✓ appraisal of hazards and risks;
- ✓ size and complexity of the establishment;
- ✓ for Article 9 establishments, inspections that may be connected with the examination of the Safety Report or associated follow up;
- ✓ lessons learnt from accidents, incidents or near misses at similar activities/establishments.

Consideration of information and performance:

- ✓ establishments or installations which have not previously been inspected;
- ✓ experience gained by the results of previous inspections or through evaluation procedures related to reports and permits;
- ✓ the reports of performance monitoring, auditing and review of the operator's Safety Management System;
- ✓ report of an accident;
- ✓ reports of incidents and near misses;
- ✓ complaints received;
- ✓ new knowledge about scientific or technical matters.

Consideration of changes:

- ✓ receipt of details of a modification under Article 10 of the Directive;
- ✓ change of ownership;
- ✓ report of modifications, rebuilding, plant extensions, etc.;
- ✓ establishments subject to frequent process chemistry changes;
- ✓ major changes in staffing levels.

The programme of inspections must cover all establishments but the following factors may give rise to some differences in the approaches to inspection of Article 7 and Article 9 establishments:

- the need to use resources efficiently and effectively may give rise to different approaches and strategies for Article 7 and Article 9 establishments in order to achieve proportionate and targeted inspection activities;
- more emphasis may need to be given to information gathering during the inspection of Article 7 establishments, since less documentation exists than for Article 9 establishments;
- for Article 7 establishments, the considerations outlined above (par. 4.2.d) will help to determine an appropriate frequency of inspections;
- more detailed information sources relevant to the preparation of inspection activities, e.g. a Safety Report, are available for Article 9 establishments;
- for Article 9 establishments the programme must entail at least one on-site inspection made by the Competent Authority at least every 12 months OR be based upon a systematic appraisal of major-accident hazards of the particular establishment concerned to determine an appropriate frequency of inspection. In the latter case evaluation of the SR and consideration of the factors above (par. 4.2.d) may be relevant to a systematic appraisal[#];
- where a systematic appraisal is used to determine the frequency of inspections of Article 9 establishments, the Competent Authority should provide a clear and structured approach for performing such appraisals, including judgement criteria.

4.3. Implementation of a Programme of Inspections

A Programme or Programmes for Inspections may be established at national, regional or local levels, but Member States shall ensure that their overall Programme or Programmes apply to all establishments within their territory and that Competent Authorities are designated to carry out such inspections.

The Programme shall be sufficient for a planned and systematic examination of the:

- ‘*Technical*’ systems, and
 - ‘*Organisational and Managerial*’ systems
- being employed at each establishment.

The overall Programme must deliver an examination of all three elements (technical, organisational and managerial) for each establishment. Each individual ‘inspection/control’ activity does not need to address all three elements but in most cases, all three elements are likely to be connected and separate examinations may not be relevant in practice.

A Programme of inspections is expected to contain at least the following information:

- Details of the geographical area covered by the Programme;
- Definition of the time period covered by the Programme;
- Identification of all establishments within the geographical area covered by the Programme;
- The planned schedule for inspections of each establishment;
- Scope of the inspections planned for each establishment;
- Details of, or reference to, provisions and procedures for reviewing the Programme as necessary.

Details of, or reference to, provisions and procedures for dealing with ‘non-routine’ or ‘reactive’ inspections should also be addressed (for example, in response to accidents, incidents, complaints). For ‘non-routine’ or ‘reactive’ inspections,

[#] *The Commission’s Guidance document on the preparation of a Safety Report [13] (Annex III) contains further considerations on the appraisal of major-accident hazards and may provide a useful supplement to this guidance.*

Member States should aim in particular for such inspections to be carried out in the following circumstances:

- a) to investigate serious complaints relevant to major-accident hazards, as soon as possible after such complaints are received by the authorities;
- b) to investigate major accidents, incidents and serious occurrences of non-compliance, as soon as possible after these come to the notice of the relevant authorities.

A programme can be executed by a combination of planned inspections notified to the operator in advance and ‘surprise’ visits where the operator has no advance warning. The advantage of visits notified in advance is that the operator’s relevant resources can be made available in an efficient manner. In addition, there may be potential for timing inspection visits for maximum mutual benefit and efficiency, for example, to inspect maintenance activities during a periodic shutdown, or to co-ordinate with the operator’s own schedule for internal or external audit and review of the Safety Management System. However the possibility of surprise visits should also exist and be implemented as necessary.

4.4. A Report following an inspection

The reports produced following an inspection form a vital function. They provide a picture of the level of compliance with the Directive and the results of an evaluation of the safety systems being employed by the operator at the establishment. The report should provide:

- details on the scope of the inspection and the parts of the establishment covered;
- findings on the evaluation of the (inspected) systems being employed;
- findings about the operator’s compliance with the requirements of the national laws, regulations and administrative provisions which implement the Directive and, where applicable, with other legal requirements if relevant to preventing major accidents (e.g. requirements related to the design and inspection of equipment/hardware);
- details of any measures agreed with the operator including time limits for their implementation;
- a conclusion on whether any further action should follow at this time, such as some form of formal enforcement action, further discussion with the operator, follow-up inspection activities including further site visits, or other feedback necessary to the operator about matters of concern and requirements for remedial measures. A follow-up plan including timescales should be prepared (it can be included as part of the report or referred to as a separate action plan).

Inspection reports should be kept for a relevant period of time for a build-up of inspection history, which can be used to review Programme priorities as necessary. It may also be necessary for information from the inspection report to be sent to other Competent Authorities within the Member States where relevant.

4.5. Follow up where necessary

Relevant text from the Directive:

Where necessary, every inspection carried out by the competent authority shall be followed up with the management of the establishment, within a reasonable period of time following the inspection.

The report of inspection should have identified those cases where it was necessary to develop/agree an action plan with the operator to further demonstrate that all necessary measures have been taken or to take remedial measures which are necessary. In such cases, it will normally be necessary to follow up the inspection findings with the management of the establishment to confirm that the action is being carried out. In any case, it is normally expected that the results of the inspections will be made clear to the operator. It is also recommended to consider arrangements for the results and conclusions of the inspection activities to be communicated to the personnel of the establishment in an appropriate manner.

The follow-up should normally involve formal communication such as a letter or, where necessary, legal enforcement procedures. Where relevant, plans for checking the implementation and effectiveness of corrective actions should be carried out in accordance with timescales recorded in the inspection report or follow up plan.

5. Other Measures of Control

The Directive clearly states that it is the Competent Authorities who must organise a system of inspections, or other measures of control. Furthermore, section 2 of Article 18 refers to:

- ‘..... inspection made by the Competent Authority ...’
- ‘..... report shall be prepared by the Competent Authority’
- ‘..... inspection carried out by the Competent Authority

Bodies to assist the Competent Authority

Article 16 of the Directive foresees the possibility that Member States can appoint, if necessary, bodies to assist the Competent Authority at a technical level. In this context, the Member State will be expected to exercise appropriate controls to ensure the competence and independence of such bodies. It is known that existing inspection arrangements in some Member States make use of authorities (e.g. local or regional authorities) who are not the designated *Competent Authorities* under the Directive or are assisted by private third party organisations for certain tasks. The text of the Directive referring to ‘other measures of control’ allows this flexibility. However the Competent Authorities are ultimately responsible for ensuring that adequate and sufficient inspections/control measures are in place.

Where ‘other measures of control are used’, they should:

- ✓ be sufficient for a planned and systematic examination of the systems being employed at the establishment, whether of a technical, organisational or managerial nature;
- ✓ aim to provide a degree of control at least equal to what could be expected from inspection systems;
- ✓ not be dependent on receipt of the Safety Report or any other report submitted (however, full benefit should be taken of all information including such reports when available).

Section 7.3 of this document deals with taking account of the results of audits & reviews of the Safety Management System undertaken by others. It is possible that arrangements of this kind could also be assessed and monitored as a provision under ‘other measures of control’.

6. The ‘Content’ of Inspections/Control Measures

6.1. General

The basic purpose of inspections/control measures is to carry out a planned and systematic examination of the technical, organisational and managerial systems being employed at the establishment to check if the operator can demonstrate that all measures have been taken to prevent major accidents and limit their consequences so that a high level of protection for man and the environment is being achieved.

The Competent Authorities are expected to provide inspectors with sufficient knowledge and training to make ‘inspection’ consistent and effective. In particular, it is necessary to have some ‘criteria’ in mind in order to evaluate whether an operator can demonstrate that all appropriate measures have been taken. In this context, Competent Authorities are expected to develop and/or utilise appropriate criteria for the examination of technical, organisational and managerial systems and develop specific tools and methods to be used by inspectors (e.g. manuals, checklists, risk criteria, relevant databanks and software, etc.) as necessary to ensure the adequacy of the checks and evaluations performed.

6.2. ‘Demonstration of appropriate measures to prevent major accidents and for limiting their consequences’

The Directive requires the operator to take all necessary measures to prevent major accidents and to limit their consequences and provides a structure for a Major Accident Prevention Policy and management system based on the following elements:

- organisation and personnel
- identification and evaluation of major hazards
- operational control
- management of change
- planning for emergencies
- monitoring performance
- audit and review

Inspection can be carried out effectively by examination of the operator’s technical, organisational and managerial systems with this basic framework in mind.

In the first instance, it is necessary to check that a Major Accident Prevention Policy (MAPP) has been drawn up. Secondly, it is necessary to check that the operator can demonstrate that the policy is properly implemented by appropriate management systems. A separate Commission Guidance document[#] gives details on the requirements of the Directive on policies and management systems for Article 7 (‘lower tier’) and Article 9 (‘upper tier’) establishments, which can be used as necessary to guide the inspector. Thirdly, it is necessary to check that the management system provides the appropriate measures and hardware in practice.

Member States should ensure that inspections will include checking of compliance of organisational and managerial systems with the requirements of the Directive, assisted by a suitable ‘benchmark’ such as the Commission Guidance document on a MAPP and SMS (mentioned above) or other suitable guidance. The Commission MAPP/SMS Guidance may also provide some useful guidance relating to the examination of that part of the ‘technical system’ dealing with procedural matters. In addition, inspection of the ‘technical system’ should also include checks that the operator has identified relevant major-accident hazards and include some evaluation of the technical measures taken by the operator for the prevention and mitigation of major accidents. In this context, the Competent Authority should ensure that

[#] *Guidelines on a major Accident Prevention Policy and Safety Management System, as required by Council Directive 96/82/EC [4] (Annex III).*

sufficient technical information/knowledge is available to inspectors for such inspections to be effective.

The operator has to be able to demonstrate that appropriate preventive and mitigation measures have been taken. Therefore the operator has to demonstrate that :

- all major accident hazards have been identified;
- the consequences to people and the environment have been assessed;
- hazards have been avoided or reduced where practicable;
- there is a clear link between the hazards identified and the preventive and mitigation measures taken;
- the preventive measures are able to prevent foreseeable failures which could lead to a major accident;
- the mitigation measures are able to limit the consequences of foreseeable accidents;
- these measures take account of the full life cycle of the installations involved.

The issues to be addressed in hazards identification and some methods of analysis are listed in the Commission Guidance document for the preparation of a Safety Report (see ref. 13, Annex III). In general, although this particular reference document is written for Article 9 establishments, the guidance on hazard identification is also very relevant to establishments covered by Article 7 ('lower tier' establishments).

Annex II provides an example of issues to be considered in the content of inspections, in the form of questions which may help inspectors to make judgements on the operator's systems. This Annex is based upon information extracted from the Guidance Documents on Safety Reports and the MAPP and SMS, and on examples provided by experts in the Working Group which developed this guidance. The Annex is written in the form of relevant questions, many of which are open questions that will lead to supplementary questions and/or verification of documents or hardware. The suggestions are not intended to be exhaustive or compulsory for all inspections. However, this guidance could provide a basis for further development of a guide for inspectors within each Member State where relevant.

One particular feature of the new Seveso II Directive is that the operator is required to implement arrangements to monitor, audit and review the performance of the management system employed. The results of performance monitoring, audits and reviews can be a major source of information to assist the Competent Authority in defining inspection priorities, determining if the management system is effective and perhaps also the frequency of inspections. Key parameters to be considered include the relevance, completeness, quality and quantity of proactive and reactive performance measurements and the recommendations and follow up action arising from audits and reviews. Further details on industrial practice and common performance measurements can be found in the literature (see Annex III). Section H of Annex II gives further details of possible inspection- questions related to an internal audit.

Annex III includes references to documents that provide further information on 'demonstration of appropriate measures to prevent major accidents and for limiting their consequences'.

6.3. Checks to confirm data and information contained in Safety Reports and any other Reports

Confirmation of data and information contained in Safety Reports or any other reports submitted can be undertaken through e.g.:

- a) interviews to gain information about the operation of systems to control risk, management practices;
- b) examining documents as means of understanding the systems for controlling risk and making judgements on the relevance, adequacy and completeness of such systems;
- c) visual observation of physical conditions and systems of work to examine compliance with legal requirements and to verify the effectiveness of risk control measures.

Confirmation of data and information contained in Safety Reports or any other reports submitted should cover in particular the description of the safety relevant sections and of the systems and components which are important for safety. These descriptions are essential to allow a better understanding of the hazard analysis, clearly describing the relationship between the hazard sources and their prevention, control and mitigating measures, including the testing,

maintenance and inspection systems and relevant documentation.

Confirmation of data and information contained in Safety Reports or any other reports submitted should also include confirmation of important factors relevant to the main results and arguments of the hazard analysis and risk assessment. The original assessments should be accessible to the Competent Authority on request.

Experience gained during the development of the Safety Reports and the use of relevant assessment tools may provide valuable information to prevent major accidents or limit their consequences.

6.4. Checks to confirm that information has been supplied to the public

Relevant text from the Directive:

Article 13 (1) of the Directive requires that Member States shall ensure that information on safety measures and on the requisite behaviour in the event of an accident is supplied, without their having to request it, to persons liable to be affected by a major accidentetc.

For Article 9 establishments, the inspection system or other measures of control must provide for checks that these requirements have been met, e.g. :

- that the relevant information has been supplied to the public;
- that the information has been reviewed at least every 3 years and updated at least every 5 years.

6.5. Checks to confirm planning for emergencies

For all establishments, the MAPP is required to take account of the principles in Annex III of the Directive. Annex III (c) (v) - *planning for emergencies* - of the Directive requires the operator to adopt and implement procedures to identify foreseeable emergencies by systematic analysis and to prepare, test and review emergency plans to respond to such emergencies. An inspection should include consideration of such aspects taking into account the proportionate nature of the requirement for establishments covered by Article 7 ('lower tier' establishments).

For those establishments covered by Article 9 ('upper tier' establishments), additional requirements on emergency plans are given by Article 11 of the Directive. In particular, Article 11 (4) requires that Member States shall ensure that internal and external emergency plans have been reviewed, tested, and where necessary revised and updated by the operators and designated authorities at suitable intervals of no longer than three years. The review shall take into account changes occurring in the establishments concerned or within the emergency services concerned, new technical knowledge, and knowledge concerning the response to major accidents. Member States may integrate checks that the requirements of Article 11 have been met into their inspection activities where relevant.

7. Other related matters

7.1. Interface between inspections/control measures described in Article 18 and the examination of Safety Reports as described in Article 9(4)

As presented in section 6.3, inspection includes checking of data and information contained in the Safety Report for Article 9 establishments. In fact there is a two-way interface between 'inspection' (Article 18) and examination of the Safety Report (Article 9(4)), i.e.:

- The findings from inspection will assist in an examination and evaluation of the Safety Report;
- The information in the Safety Report will assist in determining the appropriate scope, methods and priorities for inspections.

Inspections/controls must be carried out in any case and should not be dependent on receipt of the Safety Report. However, for Article 9 establishments, examination of the Safety Report and of the results following its assessment can represent a major input to the efficient planning, scope and content of an inspection. The Competent Authority should coordinate the findings from both activities. In particular, prioritisation of inspection activities can be related to the examination of the Safety Report or to the follow up of the conclusions of such examination.

7.2. Inspection following a major accident

The Directive requires that the Competent Authorities should :

- collect, by inspection, investigation or other appropriate means, the information necessary for a full analysis of the technical, organisational and managerial aspects of the major accident;
- take appropriate action to ensure that the operator takes any necessary urgent, medium and long term remedial measures;
- make recommendations on future preventative measures.

The information and lessons learned from accidents should be effectively disseminated with the aim of preventing a recurrence of similar accidents. The information and knowledge from lessons learned should also be used when reviewing the overall Inspection Programme, and may lead to adjusting priorities and the scope of inspections as necessary.

7.3. Taking account of the results of audits & reviews of the Safety Management System undertaken by others

The legal requirement for an operator to monitor the performance of, audit and review its management system was discussed in section 6.2 of this document as a major source of relevant information. The Guidance document on Safety Management Systems mentions that appropriate personnel should be selected for auditing, bearing in mind the need for expertise, operational independence, and technical support. Specifically trained persons within the operating company or specialist third party organisations may be necessary.

The Safety Management System may also involve integration with a management system which addresses other matters. In cases where an operator uses an integrated management system approach for example, for the environment, health & safety of workers, and perhaps quality, this may be supported by reference to benchmarks and standards such as EMAS, ISO 14001 or ISO 9001. The results of monitoring, auditing and reviewing against these benchmarks will be another potentially relevant and valuable source of information. For certain of these benchmarks, in addition to an operator's audit, the management system may have been considered by external certifiers/verifiers. The Competent Authority should

be able to take account of such information, where available, in order to maximise the efficiency of the inspections. However it will be incumbent upon the operator to demonstrate that the management system has been fully developed to cover major-accident controls and meets the requirements of the Directive.

7.4. Interface between inspections/control measures described in Article 18 and the Prohibition of Use as described in Article 17

The inspection system or other measures of control should provide for dealing with situations which may lead to the prohibition of use or bringing into use of any establishment, installation or storage facility, or any part thereof, where the inspection identifies that the measures taken by the operator are seriously deficient or where reports or other information are not provided.

Annex I

Relevant text from Article 18 (Inspections) of the SEVESO II Directive (Council Directive 96/82/EC)

1. Member States shall ensure that the competent authorities organise a system of inspections, or other measures of control appropriate to the type of establishment concerned. Those inspections or control measures shall not be dependent upon receipt of the safety report or any other report submitted. Such inspections or other control measures shall be sufficient for a planned and systematic examination of the systems being employed at the establishment, whether of a technical, organisational 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. The system of inspection specified in paragraph 1 shall comply with the following conditions:

(a) there shall be a Programme of inspections for all establishments. Unless the competent authority has established a Programme of inspections based upon a systematic appraisal of major-accident hazards of the particular establishment concerned, the Programme shall entail at least one on-site inspection made by the competent authority every twelve months of each establishment covered by Article 9;

(b) following each inspection, a report shall be prepared by the competent authority;

(c) where necessary, every inspection carried out by the competent authority shall be followed up with the management of the establishment, within a reasonable period following the inspection.

3. The competent authority may require the operator to provide any additional information necessary to allow the authority fully to assess the possibility of a major accident and to determine the scope of possible increased probability and/or aggravation of major accidents, to permit the preparation of an external emergency plan, and to take substances into account which, due to their physical form, particular conditions or location, may require additional consideration.

Other Related Text from the Directive:

Article 9 (4) (actions related to the evaluation of the Safety Report)

Before the operator commences construction or operation, or in the cases referred to in the second, third and fourth indents of paragraph 3, the competent authority shall within a reasonable period of receipt of the report:

- communicate the conclusions of its examination of the safety report to the operator, if necessary after requesting further information, or
- prohibit the bringing into use, or the continued use, of the establishment concerned, in accordance with the powers and procedures laid down in Article 17.

Article 10 (modifications)

In the event of the modification of an installation, establishment, storage facility, or process or of the nature or quantity of dangerous substances which could have significant repercussions on major-accident hazards, the Member States shall ensure that the operator:

- reviews and where necessary revises the major-accident prevention policy, and the management systems and procedures referred to in Articles 7 and 9,
- reviews, and where necessary revises, the safety report and informs the competent authority referred to in Article 16 of the details of such revision in advance of such modification.

Article 11 (4) (emergency plans)

Member States shall ensure that internal and external emergency plans are reviewed, tested, and where necessary revised and updated by the operators and designated authorities at suitable intervals of no longer than three years. The review shall take into account changes occurring in the establishments concerned or within the emergency services concerned, new technical knowledge, and knowledge concerning the response to major accidents.

Article 14 (2) (following a major accident)

Member States shall require the competent authority:

- (a) to ensure that any urgent, medium- and long-term measures which may prove necessary are taken;
- (b) to collect, by inspection, investigation or other appropriate means, the information necessary for a full analysis of the technical, organisational and managerial aspects of the major accident;
- (c) to take appropriate action to ensure that the operator takes any necessary remedial measures; and
- (d) to make recommendations on future preventive measures.

Article 17 (prohibition of use)

1. Member States shall prohibit the use or bringing into use of any establishment, installation or storage facility, or any part thereof where the measures taken by the operator for the prevention and mitigation of major accidents are seriously deficient.

Member States may prohibit the use or bringing into use of any establishment, installation or storage facility, or any part thereof if the operator has not submitted the notification, reports or other information required by this Directive within the specified period.

2. Member States shall ensure that operators may appeal against a prohibition order by a competent authority under paragraph 1 to an appropriate body determined by national law and procedures.

Annex II

Examples of issues to be considered in the content of inspections

The following sections give some suggestions for the content of inspections relevant to an examination of the operator's systems. This Annex is based upon information extracted from the Guidance Documents on Safety Reports and the MAPP and SMS, and on examples provided by experts in the Working Group which developed this guidance. The Annex is written in the form of relevant questions, many of which will lead to supplementary questions and/or verification of documents or hardware. The suggestions are not intended to be exhaustive or compulsory for all inspections. However, this list of questions could provide a basis for the development of an appropriate guide for inspectors within each Member State where relevant.

There is an interface between inspection and examination of the Safety Report for Article 9 establishments as discussed in section 7.1 of this Guidance Document. In this context, the suggested 'inspection' questions in this annex have an overlap with examination of the Safety Report and the Competent Authority may consider that some of the questions are better dealt with as part of their evaluation of the Safety Report.

A. Major Accident Prevention Policy and Management System

- Has a MAPP document been prepared and made available (via the Safety Report for Article 9 establishments) to the Competent Authorities?
- Does the MAPP document include the operator's overall aims and principles of action?
- Does the MAPP take account of all principles contained in Annex III of the Directive?
- Is there evidence that the MAPP has been developed and endorsed at an appropriate senior level in the operator's organisation and that there is a senior level commitment to implementation and periodic review of the MAPP and Management System?
- Who is responsible for ensuring the MAPP is implemented and it is kept up to date?
- Has the policy (and SMS) been disseminated and explained throughout the company and has the method used been effective?
- Is it only a policy? - that is, has the policy been translated into clear and meaningful objectives which are known and understood by all relevant personnel?
- Is the policy and its implementation and monitoring a regular item on the agenda of management meetings?
- Are there any supporting standards and references (e.g. manuals) to assist managers in their control on implementing and monitoring of the policy?
- Can the operator show that a management system, and other appropriate means and structures, are in place and operational at the establishment to implement the MAPP?
- Is there a manual or other document describing the SMS?
- Does the SMS include programmes covering procedures for managing the following:
 - ✓ Ensuring utilisation of appropriate technical and safety standards;
 - ✓ Design and design modification of installations;
 - ✓ Ensuring appropriate controls including pre start-up checks for new installations or installations returning to service following shut-down;
 - ✓ Modifications;
 - ✓ Periodic safety studies;
 - ✓ Purchasing procedures;
 - ✓ Organisation rules & communication;
 - ✓ Working with contractors/third parties;
 - ✓ Operational procedures and personal protection;
 - ✓ A permit to work system;
 - ✓ Periodic inspection;
 - ✓ Maintenance;

- ✓ Emergency planning;
 - ✓ Recording and investigating accidents or near misses;
 - ✓ Training (management and employee);
 - ✓ Programme evaluation procedures.
- Does the management system address the issues contained in Annex III of the Directive? *(Note: for lower tier establishments, the link to Annex III is via taking account of the principles contained within Annex III within the MAPP and developing appropriate management systems - this somewhat more flexible link is intended to be proportionate and should be borne in mind when conducting inspection activities).*

B. Organisation and Personnel Issues

- Is there a clear source of safety advice available where necessary? (e.g. special advisors, safety department)
- Is there any reference manual with guidance to management on safety matters?
- Have the roles and responsibilities of personnel involved in the management of major hazards been clearly defined, at all levels in the organisation?
- Who do safety personnel report to? - Is this appropriate?
- Have all persons involved with the management of major hazards been identified and assigned their role and responsibility?
- Are sufficient resources available to implement the operator's MAPP effectively?
- Can the operator show that the skills and abilities needed have been identified and therefore that the roles and responsibilities are appropriate? - e.g. is there evidence that persons assigned a certain role and responsibility have the necessary competence to fulfill their role?
- Does the Company have a safety committee where relevant? - If so, is the safety committee fully involved in developing & co-ordinating programmes and monitoring policy?
- Is safety performance reflected in the annual appraisal of performance of staff?
- Is safety performance reflected in the Company's annual report?
- Who receives, approves and addresses safety related documentation?
- Has the accountability, authority and interrelation of all personnel who manage, perform or verify work affecting safety been defined, particularly for staff responsible for:
 - the provision of resources, including human resources, for SMS development and implementation;
 - action to ensure staff awareness of hazards, and compliance with the operator's safety policy;
 - identification, recording and follow-up of corrective or improvement actions;
 - control of abnormal situations, including emergencies;
 - identifying training needs, provision of training, and evaluation of its effectiveness;
 - co-ordinating the implementation of the system and reporting to top management.
- Do top-down and bottom-up procedures exist to enable all personnel to identify safety concerns and how effectively are they followed ?
- Can the operator show that employees and, where appropriate, contractors, have been involved in determining the MAPP and its implementation?
- Can the operator show that human factors have been taken into account in assessing the measures to prevent major accidents and to limit their consequences?
- Can the operator show that training needs are identified and that such training is provided?
- Can the operator show records of personnel who have received training and the programmes and material used in those training courses?
- Can the operator show organisational arrangements for awareness of and compliance with relevant regulations and relevant codes of practice? (are these included in managers' job descriptions ?)
- Are there procedures for the selection and management of contractors?
- Can the operator show that, where appropriate, contractors receive the necessary information and training to enable them to be aware of the hazards involved and satisfy the MAPP?
- Can the operator show organisational arrangements for gathering and documenting knowledge related to incidents or 'near misses' and for implementing the lessons learnt?

- Can the operator show organisational arrangements for keeping up to date with new technical knowledge about safety matters, for example arising from analysis of accidents or developments in knowledge concerning the assessment of hazards?
- Does the operator keep a record of data related to such knowledge acquired during the operation of the establishment ?

C. Identification and evaluation of major hazards

- Do the procedures adequately cover all design activities, including those in collaboration with contractors/third parties?
- Who sets the standards or level of protection to be provided, when in collaboration with contractors/third parties?
- Are operations and safety personnel involved in the design process?
- Does the design procedure identify the safety critical components of the designed installation?
- Does the design procedure ensure that safety critical components are included in an appropriate inspection and maintenance programme?
- Does the design procedure contain a preliminary hazard evaluation which will prompt hazard elimination and reduction, and maximise 'inherent safety' where possible?
- For activities selected by the inspector, can the operator :
 - ✓ identify the hazards?
 - ✓ identify the initiating events and scenarios that can lead to a major accident?
 - ✓ provide evidence of a systematic risk analysis of the safety critical elements?
 - ✓ show the measures taken?
 - ✓ justify why the measures are considered appropriate, including reference to risk assessment criteria?
- Can the operator demonstrate that consideration of the appropriateness of measures includes:
 - ✓ a clear link between the identified major accident hazards and the measures taken?
 - ✓ a hierarchical approach to the selection of measures to be used? e.g. Hazards should be avoided if practicable or reduced at source through the application of inherently safe practices
 - ✓ Evidence that the measures provided should prevent reasonably foreseeable failures which could lead to major accidents?
- Can the operator explain his assessment and judgment criteria for defining appropriate measures?
- Can the operator demonstrate why the criteria used are appropriate? e.g. Has the operator a general awareness of various possible criteria and benchmarks (e.g. best available technology, good engineering practice, qualitative or quantitative risk matrices or criteria, etc.) and can give reasons why a particular method of analysis has been selected?
- Where applicable, can the operator show that the expected human behaviour within preventive and mitigation measures is reasonable?
- Can the operator show compliance with relevant regulations and relevant codes of practice?
- Has the operator particular criteria to decide the degree of redundancy, diversity and separation required for the prevention, control and mitigation measures?
- Has the operator defined particular criteria for the reliability of components and systems, where applicable?
- Has the operator defined standards with respect to the containment of dangerous substances?
- Can the operator show that safe operating limits of plant and equipment have been determined?
- Can the operator show that the following matters have received appropriate consideration:
 - ✓ layout of the plant should limit the risk during operations, inspection, testing, maintenance, modification, repair and replacement;
 - ✓ utilities that are needed to implement any measure should have suitable reliability, availability and survivability;
 - ✓ appropriate measures should be taken to prevent and effectively contain releases of dangerous substances;
 - ✓ all foreseeable direct causes of major accidents should have been taken into account in the design of the installation;
 - ✓ there should be evidence to show how structures important to safety have been designed to provide adequate integrity;
 - ✓ the containment structure should be designed to withstand the loads experienced during normal operation of the plant and reasonably foreseeable operational extremes during its expected life;
 - ✓ materials of construction used in the plant should be suitable for their application;
 - ✓ the implementation of appropriate design codes and standards related to construction of plant and systems , including relevant certification requirements;

- ✓ adequate safeguards should be provided to protect the plant against excursions beyond design conditions;
- ✓ there should be evidence to show how safety-related control systems have been designed to ensure safety and reliability;
- ✓ the design of alarm systems, including the strategy for handling multiple alarms during abnormal operation;
- ✓ there should be evidence to show how systems which require human interaction have been designed to take into account the needs of the user and be reliable;
- ✓ there should be systems which are implemented for identifying locations where toxic and flammable substances could be present and how the equipment has been designed to take account of the risks;
- ✓ evidence of the functional calculations needed to confirm the capability of the measures to cope with the design-basis;
- ✓ installations should be constructed to appropriate standards to prevent major accidents and reduce loss of containment;
- ✓ the results of any relevant incident investigations and near-miss analyses should be fully considered and linked to possible major accident causes and determination of appropriate control measures.

D. Operational control Issues (including maintenance)

- Do all relevant permits for operation exist, where applicable?
- Can the operator show that safe operating procedures have been established and documented to cover all reasonably foreseeable (normal and abnormal) operating conditions?
- Can the operator show that safe operating procedures cover the most important risks inherent in the installations ?
- Are safe operating procedures in place for commissioning, operation, inspection, testing, maintenance and decommissioning?
- Can the operator show that the safe operating limits for plant and equipment will not be exceeded during normal and abnormal operation?
- Can the operator show that procedures are in place to monitor, record and investigate any excursions beyond safe operating limits and implement lessons learnt?
- Can the operator show that process control systems are adequate, including during abnormal situations, taking account of human factor limitations?
- Can the operator show that an appropriate (preventive) maintenance scheme is established for all safety critical installations and systems to prevent major accidents or limit their consequences, in particular for at least :
 - ✓ Equipment in hazardous atmospheres e.g. electrical equipment;
 - ✓ Safety-related control and alarm systems and indicators;
 - ✓ Utilities (electricity, steam, water, etc.) necessary for safe operation;
 - ✓ Relief and vent systems;
 - ✓ Pressure systems and other containment tanks for dangerous substances;
 - ✓ Leak detection systems.
- Is there a comprehensive list of safety-critical components (equipment, material, structures, etc.) and is this list reviewed periodically?
- Can the operator show that safety-critical plant and systems are examined and tested at appropriate intervals by an appropriate person with the necessary competence?
- Can the operator show that a system is in place to analyse the results of periodic examinations and maintenance, including arrangements for further investigation, repairs or changes to safe operating limits where necessary?
- Can the operator show appropriate procedures for maintenance that take account of any hazardous conditions within the working environment?

E. Management of change Issues

(see references in Annex III for more extensive coverage of management of change)

- Can the operator show that there is a system in place for ensuring modifications are adequately conceived, designed, installed and tested?
- Are engineering policies or other requirements included in such system ?

- Is there a definition of what constitutes a change?
- Is a risk analysis of the modifications included?
- Are changes in resources managed adequately in relation to safety issues ?
- Does the system cover temporary and urgent operational changes in addition to permanent changes?
- Have responsibilities been clearly assigned for who can initiate, plan, authorise and implement changes?
- Are the changes properly documented?
- Are the safety implications of proposed changes always addressed, including information and training requirements, changes to operating procedures, subsequent monitoring, etc.?
- Are procedures for the management of change applied to all relevant changes, including changes made during the design and construction of new installations, processes and storage facilities?
- Do the procedures ensure that the operator reviews and where necessary revises the MAPP, management system and Safety Report and informs the Competent Authority where required by Article 10 of the Directive?
- Have the organisational, technical or managerial systems employed in the establishment been changed so that existing authorisations or permits are no longer valid?

F. Planning for emergencies (see comments in section 6.5)

Can the operator:

- a. describe the organisation of the emergency response in the event of a major accident and provide evidence that the necessary measures have been taken on-site;
- b. provide evidence that there is an emergency plan in writing to address all possible emergencies for all major accident scenarios;
- c. provide evidence that suitable and sufficient provisions have been made for co-ordination and communications during the emergency response;
- d. provide for arrangements for alternative services in case of interruption of normal emergency systems;
- e. describe the internal and external resources which can be mobilised by the operator to limit the consequences of a major accident to man and the environment;
- f. demonstrate that consideration has been given to the effects of the emergency response actions in order to minimise the overall impact of the accident on man and the environment;
- g. provide evidence that sufficient personnel (emergency team) can be made available within appropriate timescales to carry out the mitigatory actions required by the internal emergency plans;
- h. provide evidence that equipment that can be mobilised to mitigate the consequences for a major accident is likely to be fit for purpose when called upon for use;
- i. provide evidence that suitable and sufficient personal protective and rescue equipment is available in the event of a major accident;
- j. provide evidence that suitable and sufficient fire fighting and fire protection provisions can be mobilised in the event of a major accident;
- k. provide evidence that suitable and sufficient provisions can be mobilised to minimise the release of, and mitigate the consequences of, airborne toxic and/or flammable substances in the event of a major accident;
- l. provide evidence that suitable and sufficient resources can be mobilised to minimise the consequences of loss of containment of a hazardous substance(s) to ground or water (including Controlled Waters);
- m. demonstrate that adequate consideration has been given to the environmental impact of fire fighting activities;
- n. provide evidence that suitable and sufficient provisions for monitoring and/or sampling can be mobilised in the event of a major accident ;
- o. demonstrate that, where relevant, suitable and sufficient provision has been made for monitoring wind speed and direction, and other environmental conditions, in the event of a major accident;
- p. provide evidence that suitable and sufficient provisions have been made for the restoration and clean up of the environment following a major accident;
- q. provide evidence that suitable and sufficient provisions have been made to mobilise first aid/medical treatment during the emergency response;
- r. provide evidence that suitable and sufficient provisions have been made to mobilise any ancillary equipment, which

- may be required during the emergency response;
- s. provide evidence that suitable arrangements have been made for the maintenance, inspection, examination and testing of the mobilisable resources and other equipment to be used during the emergency response;
- t. provide evidence that suitable arrangements have been made in the safety management system for training of individuals on-site in the emergency response;
- u. provide evidence that procedures have been made and adopted to test and review emergency plans (note: the Competent Authority may wish to witness tests, as an inspection activity);
- v. have supplied information to outside services and organisations to enable the external help and emergency plan to be activated and effectively implemented;
- w. summarise those measures of protection and intervention, which have been used as the basis for drawing up the internal emergency plans.

G. Monitoring Performance

- Is the operator monitoring his performance as foreseen by Annex III (vi) of the Directive?
- Can the operator show that procedures for the ongoing assessment of compliance with the objectives set by the MAPP and Management System have been adopted and are implemented in practice?
- Can the operator show that the relevance, completeness, quality and quantity of performance measurements are adequate?
- Can the operator show performance measurements/monitoring corresponding to all elements in the Management System?
- Can the operator show that non-compliance with the MAPP and management system will be identified, investigated and corrective action taken?
- Can the operator show that the procedures are implemented in practice to cover the operator's system for reporting major accidents or near misses, particularly those involving failure of protective measures, and their follow up on the basis of lessons learnt?
- Is it clear who is responsible for initiating investigation and corrective action in the event of non-compliances?
- Are the results of performance monitoring documented, retained and presented as a major input to audits and reviews?

H. Audit and Review

- Have audits and reviews been carried out as foreseen by Annex III (vii) of the Directive?
- Which elements of the Management System have been included in the audits and reviews?
- Are the results of performance monitoring related to this establishment provided as a major input to audits and reviews?
- Is there an evaluation of compliance with standards, codes of practice, etc.?
- Is there evidence to show the competence, experience, training and, where relevant, the independence of auditors?
- Is the audit frequency reasonable?
- Is there clear documentation relating to the auditing procedure, methodology and results, in particular concerning:
 - ✓ Scope of the audit;
 - ✓ Objectives of the audit,
 - ✓ References, benchmarks and standards;
 - ✓ Checks and verifications performed;
 - ✓ Resources available for the audit;
 - ✓ Organisation of the audit,
 - ✓ Results of the audit.
- The assessment of the internal audit may also include, as appropriate:
 - ✓ Discussion with audit team leaders/members;
 - ✓ Interviews with relevant managers and personnel to check their involvement with the audit;
 - ✓ Independent checks to confirm, on a sample basis, the overall reliability of the audit;
 - ✓ Consideration of whether the conclusions drawn from the audit are justified.
- Have the results of audits been properly utilized in conducting reviews of the operator's overall policy and strategy for

the control of major-accident hazards?

- Has senior management been responsible for reviews?
- Is there evidence that changes are made to give improved performance when necessary?
- Has the review adequately assessed the allocation of resources?

Annex III

Bibliography

This is an example of titles with reference to inspection systems which contain further references[#] on documents relevant to inspection programmes, methodologies, procedures, codes and standards, etc. This list of documents is in chronological order and is based on bibliographies proposed by the members of the Technical Working Group:

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