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Report of the OECD Workshop on Audits and Inspections Related to Chemical Accident Prevention, Preparedness and Response

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Series on Chemical Accidents

No. 8

Report of the OECD Workshop on Audits and Inspections Related to Chemical Accident Prevention, Preparedness and Response

Madrid, Spain, 6 – 9 March 2001

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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REPORT of the OECD WORKSHOP on AUDITS and INSPECTIONS RELATED TO CHEMICAL ACCIDENT PREVENTION, PREPAREDNESS AND RESPONSE

(Madrid, Spain, 6 - 9 March 2001)

Some other OECD publications related to Chemical Accident Prevention, Preparedness and Response:

Guiding Principles for Chemical Accident Prevention, Preparedness and Response: Guidance for Public Authorities, Industry, Labour and Others for the Establishment of Programmes and Policies related to Prevention of, Preparedness for, and Response to Accidents Involving Hazardous Substances (1992) [Under Revision]

International Directory of Emergency Response Centres (first edition, 1992) [prepared as a joint publication with UNEP-IE; under revision]

Report of the OECD Workshop on Strategies for Transporting Dangerous Goods by Road: Safety and Environmental Protection (1993)

Health Aspects of Chemical Accidents: Guidance on Chemical Accident Awareness, Preparedness and Response for Health Professionals and Emergency Responders (1994) [prepared as a joint publication with IPCS, UNEP-IE and WHO-ECEH]

Guidance Concerning Health Aspects of Chemical Accidents. For Use in the Establishment of Programmes and Policies Related to Prevention of, Preparedness for, and Response to Accidents Involving Hazardous Substances (1996)

Report of the OECD Workshop on Small and Medium-sized Enterprises in Relation to Chemical Accident Prevention, Preparedness and Response (1995)

Guidance Concerning Chemical Safety in Port Areas. Guidance for the Establishment of Programmes and Policies Related to Prevention of, Preparedness for, and Response to Accidents Involving Hazardous Substances. Prepared as a Joint Effort of the OECD and the International Maritime Organisation (IMO) (1996)

New OECD Series on Chemical Accidents:

- No. 1, Report of the OECD Workshop on Risk Assessment and Risk Communication in the Context of Chemical Accident Prevention, Preparedness and Response (1997)
- No. 2, Report of the OECD Workshop on Pipelines (Prevention of, Preparation for, and Response to Releases of Hazardous Substances (1997)
- No. 3, International Assistance Activities Related to Chemical Accident Prevention, Preparedness and Response: Follow-up to the Joint OECD and UN/ECE Workshop to Promote Assistance for the Implementation of Chemical Accident Programmes (1997)
- No. 4, Report of the OECD Workshop on Human Performance in Chemical Process Safety: Operating Safety in the Context of Chemical Accident Prevention, Preparedness and Response (1999)

No. 5, Report of the OECD Workshop on New Developments in Chemical Emergency Preparedness and Response, Lappeenranta, Finland, November 1998 (2001)

No. 6, Report of the OECD Expert Meeting on Acute Exposure Guideline Levels (AEGLs) (2001)

No. 7, Report of the Special Session on Environmental Consequences of Chemical Accidents (2002)

Internet Publication, Report of CCPS/OECD Conference and Workshop on Chemical Accidents Investigations (2002)

Special Publication, International Directory of Emergency Response Centres for Chemical Accidents (2002)

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About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups made up of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The work of the OECD related to chemical accident prevention, preparedness and response is carried out by the Working Group (formerly Expert Group) on Chemical Accidents, with Secretariat support from the Environment, Health and Safety Division of the Environment Directorate. The objectives of the Chemical Accidents Programme include exchange of information and experience, analysis of specific issues of mutual concern in Member countries, and development of guidance materials related to chemical accident prevention, preparedness and response. As a contribution to meeting these objectives, over a dozen Workshops have been held since 1989.

As part of its work on chemical accidents, the OECD has issued several Council Decisions and Recommendations (the former legally binding on Member countries), as well as numerous Guidance Documents and technical reports (see partial list on page 5 and 6). Publications include the OECD's Guiding Principles for Chemical Accident Prevention, Preparedness and Response; Guidance Concerning Chemical Safety in Port Areas (a joint effort with the IMO); Guidance Concerning Health Aspects of Chemical Accidents; the joint IPCS/OECD/UNEP/WHO publication, Health Aspects of Chemical Accidents; and the joint OECD/UNEP International Directory of Emergency Response Centres (currently being revised by the OECD, UNEP-TIE and the Joint UNEP/OCHA Environment Unit).

The Environment, Health and Safety Division produces publications in seven series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Emission Scenario Documents**, **Pesticides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; and **Chemical Accidents.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's web page.

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

This report is available electronically, at no charge.

For the complete text of this and many other Environment, Health and Safety publications, consult the OECD's web page (http://www.oecd.org/ehs/)

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The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organisations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organisation. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

This report presents the main output of the OECD Workshop on *Audits and Inspections related to Chemical Accident Prevention, Preparedness and Response*, which took place in Madrid, Spain, on 6–9 March 2001. The Workshop was hosted by the government of Spain and co-sponsored by the European Commission.

Approximately 110 experts attended the Workshop, representing eighteen Member countries, two non-Member countries, the European Commission, industrial organisations, academia and other stakeholders (see List of Participants in Annex 2).

The Workshop had the following objectives:

- learning from experience about audits/inspections programmes (including follow-up and enforcement) and improve sharing among companies, countries and other stakeholders;
- providing input for the on-going revision of the OECD *Guiding Principles on Chemical Accident Prevention, Preparedness and Response.* This is particularly important in view of the use of the *Guiding Principles* worldwide; and
- helping identify areas where further international co-operative effort would be worthwhile.

The first part of the report consists of the Workshop Conclusions and Recommendations. This is followed by the Discussion Document (see Annex 1) prepared for the Workshop. An earlier version of the Discussion Document was presented at the Workshop; it was revised in light of comments received during the Workshop.

The OECD's Working Group on Chemical Accidents recommended that this report be forwarded to the Joint Meeting of the Chemicals Committee and Working Party on chemicals, Pesticides and Biotechnology, for consideration as an OECD publication. The Joint Meeting agreed that it should be made available to the public. It is published under the authority of the Secretary-General of the OECD. [to be added after declassification by the Joint Meeting]

The documents in this publication have not been endorsed by, and do not necessarily reflect the view of, the OECD or its Member countries.

WORHSHOP ON AUDITS AND INSPECTIONS RELATED TO CHEMICAL ACCIDENT PREVENTION, PREPAREDNESS AND RESPONSE (Madrid, Spain, 6 - 9 March 2001)

CONCLUSIONS AND RECOMMENDATIONS

I. Introduction

- 1. The Workshop focused on the specific issues related to audits and inspections in the context of chemical accident prevention, preparedness and response¹. However, it was recognised that audits and inspections are mechanisms for helping to monitor and assess the technical and management systems in place in a hazardous installation. In this regard, the Workshop emphasised that all such installations should have in place safety management systems including a number of specified elements. As further elaborated below, audits are just one element of a complete safety management system.
- 2. Furthermore, the Workshop recognised the common goal of audit and inspection programmes to support the continuous improvement of safety at installations handling hazardous substances.² This does not diminish the fact that the primary responsibility for the safety of installations rests with the operators. While realizing that every installation handling hazardous substances contain some degree of risk, they should be operated at a level of risk that is considered tolerable by the community while striving for a target of zero accidents.
- 3. The Workshop addressed the hierarchy of "monitoring" activities by industry, public authorities and others, for example ranging from:
 - continuous assessment of normal environmental, health, and safety management in a facility,
 to:
 - self-assessment by the facility, to;
 - a corporate audit of the facility, to;
 - third party audits, to;

inspections by public authorities.

These activities provide a "check" to see if the elements of the safety management system are in place and being appropriately applied to achieve the specified goals and objectives. In this hierarchy, each layer would, in effect, check any of the ones below.

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¹ The scope of the Workshop, and the activities of the OECD Chemical Accidents Programme, involve all installations at which hazardous substances are produced, processed, handled, stored, used or disposed of in such a form and quantity that there is a risk of an accident which could cause serious harm to health or the environment. Thus, it addresses installations where chemical are produced or processed (with chemicals defined broadly to include, e.g., petroleum-based products) and other industrial or commercial operations at which hazardous substances are handled, used or stored.

² This does not diminish the fact that the primary responsibility for the safety of a hazardous installation rests with the operator of the installation.

- 4. Audit and inspection programmes can differ in terms of their objectives and approaches but some common elements, critical to success, can be defined. Specifically, such programmes should be defined in terms of a "feedback" loop (i.e., plan, do, check, act), designed to achieve continous improvement, which consists of a number of elements, e.g.:
 - clearly defined goals;
 - an identifed scope, recognising that if it is too broad then it may be difficult to achieve the desired objective;
 - a schedule (including, e.g., a plan of action with time frames);
 - appropriate expert(s) who are trained and qualified for the specific tasks and goals;
 - a review of appropriate documentation as well as interviews with key personnel (including process operators);
 - an identification of deficiencies and proper practices;
 - a formal report of findings;
 - management review to clearly define responsibilities for follow-up actions and a means for ensuring that the actions are carried out; and
 - a demonstration that the follow-up actions have been carried out.

II. Audits

- 5. The term "audit" is used to describe different types of self-assessment activities carried out within a company. The Workshop did not attempt to define all types of audits, nor to identify the specific elements of an audit. However, it was agreed that companies should establish audit programmes, consisting of several levels of audits, in order to check various technical and management systems within a facility. For example, an audit at the plant level can provide detailed understanding of the daily activities of process operators and provide insights by those familiar with the systems; whereas an audit conducted by corporate headquarters or a third party can identify potential problems that might be overlooked by those directly involved in the operations, identify potential problems in company's organisational structure or in its audit system, and help generate new ideas for improvements.
- 6. An audit can serve a number of purposes. For example, it can provide: a management or strategic tool to define priorities for the allocation of resources; a mechanism for sharing of information and experience on best practices; a support to line management in the implementation of their responsibilities; input into a dialogue with public authorities and the public; and a mechanism to determine if company or legal requirements are being met.
- 7. The members of an audit team should be chosen based on the needs and objectives of the audit and should, as appropriate, include representatives of various functions such as operations, maintenance, engineering, safety, health and environment.
 - The auditors should have practical experience and be well-trained to identify potential hazards in the facility. Training programmes should be designed to help auditors identify both deficiencies and good practices in the facility, understand how losses can result from deficiencies and record results. It was suggested that training could benefit by providing specific examples of good and bad practices, and field inspections techniques.

- The importance of including workers and their representatives in the development of audit programmes, and in audit activities, was stressed.
- It was also suggested that the public could be involved in audit activities. This could help to improve the level of trust between those responsible for operating a hazardous installation and the local community.
- 8. The audit should be designed to identify the actual status of the technical and management systems, through appropriate verification.
 - In addition to identifying any deficiencies or potential problems in the installation, the audit should also recognise successful actions, learning experiences, and improvements made with respect to safety.
- 9. Members of the audit team should be involved in the development of audit programmes, in order that they have a sense of "ownership" of the results of the audit.
- 10. Workshop participants emphasised the importance of interviewing key employees during audits, including operators. Such interviews help to check that the employees understand the operating procedures and are carrying out their tasks according to these procedures and provide insights as to whether the employees recognise the hazards involved and their role in controlling them. In addition, the interviews help to determine whether there is an appropriate flow of information in the company (i.e., there are two-way channels for information exchange) and to learn from employee experience.
- 11. Several tools were identified to support various aspects of audit activities including, for example:
 - risk-based tools and models which can help prioritise resources for audits; and
 - automatic monitoring, reminder, verification, and sign off procedures to support audit followup actions.
- 12. Companies should consider creating a system for improving the exchange of information and experience among installations within the company, as well as between companies, in order to improve the skill of auditors. This could include, as appropriate, exchange of audit teams (or joint visits) or sharing of audit reports.

III. Inspections

- 13. The Workshop recognised that inspections are a critical element in ensuring the overall safety of hazardous installations, by both checking to see whether relevant regulations, standards and practices are being met and whether safety management systems are in place and function appropriately. They also provide a means for learning how to improve safety management systems. Another important benefit from inspections is that they provide a basis for public confidence about the safety of hazardous installations.
 - Inspections are a key element, but only one part, of the control system of public authorities.
 Others elements include, for example, permitting, documentation, and reviews.

- 14. The Workshop noted that inspections may not be able to examine all safety-related aspects of a hazardous installation in great detail. Therefore, the primary function of an inspection should be to assess the management systems and, specifically, to consider whether they adequately address all necessary elements (in other words, to determine whether the company is fulfilling its responsibilities with respect to safety).
 - Inspections will undertake "deep drilling" (i.e., more detailed reviews) as part of an overall inspection plan (e.g., where authorities establish specific priority areas from a strategy plan) as well as in response to poor performance or other identified concerns (e.g., where the inspection reveals potential problems or there are concerns based on the authorities' review of the safety report).
- 15. In this regard, it was recognised that the role of inspectors has been changing over time. The traditional role of the inspector, to ensure compliance with all requirements, has broadened so that inspectors also play an important role in helping companies to identify potential problems (even if not subject to legal requirements) and to provide information about ways to improve safety performance.
 - It was noted that the overall quality and value of inspections have improved. This appears to be due, in large part, to better training and recruitment of qualified personnel.
 - Furthermore, inspection authorities are also involved in other, related activities designed to further the general objective of supporting improvements in safety, such as developing guidance for the establishment and implementation of audit programmes, providing consultation services, and facilitating voluntary self-audit programmes.
- 16. It was noted that competent authorities should establish programmes for inspections on an annual, or multi-year basis, establishing goals and priorities (e.g., to focus during one year on a particular subject such as multi-operator sites) and setting out timetables.
 - In setting goals and priorities, the authorities should take into account past performance of hazardous installations with respect to safety, as well as the nature and extent of hazards involved in the installations.
 - Normally, the inspection programmes would include provision for scheduled inspections, as well as for "spot checks" as suitable (e.g., where there is an area of concern). Participants stated that both types of inspections have an important function.
 - An important benefit of setting out plans well in advance is that it provides the opportunity for authorities to train and equip their inspectors to effectively carry out the plans.

(See also section VI below on "Co-operation Among Inspection Authorities")

17. The Workshop recognised that inspections can serve different objectives such as check of compliance with requirements, enforcement of laws and regulations, and on-site validation of safety reports.

- 18. It was recommended that public authorities develop standardized protocols and forms, to promote a structured approach to inspections and to inspection reports. This will allow improved understanding of trends over time and facilitate exchange of information and experience.
 - Protocols should address the steps included in the inspection (from preparation, to the on-site visit, through reporting and follow-up).
- 19. It was noted that the inspections should be carried out by an inspector or inspectors supported by experts, as needed, to address the specific hazards of the installation.
- 20. The participants stressed the importance of follow-up to inspections to ensure that shortcomings identified are addressed in an appropriate and timely fashion, and that there is verification of actions taken. In this regard, it was suggested that there are a number of different tools available to public authorities for follow-up action items, depending on the severity of the concerns including, for example: notifications of changes to be made; identification of agreed actions and timetables; citations and fines; and, in the most severe cases, shutdown of facilities.
 - A concern was expressed that follow-up to inspections is often delayed (including reviews by public authorities to ensure actions identified in the audit report have, in fact, been carried out). Further efforts may be needed to ensure that the operating company and authorities take the appropriate actions to close the loop in a timely manner.
- 21. The Workshop addressed the use of third parties (independent of government and the operating company) delegated to undertake technical or systems inspections on behalf of public authorities. A specific issue that was raised was the need to ensure the quality of such third parties (for example, through certification or accreditation schemes).
 - It was emphasised that the public authorities retain their legal responsibilities for the inspections; they cannot delegate their responsibilities to the third party inspectors.
 - It was noted that care should be taken to avoid the potential for conflicts, in particular where such third parties engage in both consulting as well as inspection services.
 - The Workshop recognised that different countries (and companies) have different ways of organising their inspection activities and their relationships to audits. In addition to more traditional third party inspections, one example involved "user inspectorates", consisting of employees of a company, who are guaranteed as being independent to undertake inspections within that company.

IV. Reviews

- 22. In addition to regularly checking the implementation of established safety management systems and technical standards, through audits and inspections, the Workshop agreed that there is a need to:
 - regularly review the adequacy of those management systems and standards, and revise them
 as appropriate, to help ensure that they continue to make sense and are consistent with best
 practice. Therefore, the objective of the audits/inspections should be the continuous

- improvement towards meeting established measures/standards, whereas the review should lead to the continuous improvement of the measures/standards; and
- periodically review the audit and inspection processes to help ensure that they continue to be appropriate and fully implemented. This may include benchmarking.

V. Relationship between Audits and Inspections (and between Industry and Public Authorities)

- 23. It was agreed that government inspectors and the regulated industry should co-operate, and should undertake to work closely in the planning and conduct of audits and inspections.
 - In this regard, it was noted that a good system of regulations provides a necessary foundation
 for co-operation, and levels of trust, between industry and public authorities. The regulations
 provide the leverage needed to ensure that the public authorities can protect the interests of
 the public and employees.
- 24. The Workshop recognised the value of co-operation and co-ordination between authorities and industry. While they recognised that co-operation could cause some difficulties, there was agreement that the following benefits outweighed those difficulties:
 - improving the efficiency of inspections and thereby make best use of limited resources (including manpower);
 - providing a basis for the authorities to decrease the frequency, or change the nature of, inspections based on information provided to authorities;
 - improving the ability of the parties to learn from each other, with the result that they are better able to carry out their roles and responsibilities (e.g., the audit process can be improved based on the advice of the inspecting authority); and
 - increasing the level of trust and involvement among stakeholders (including employees and the public).
- 25. Co-operation between authorities and industry can take different forms, including improved coordination of activities and communication about areas of mutual interest and openness in discussing the results of audits, future inspection plans, and time schedules. In addition, co-operation can also help authorities build on the results of company or third party audits.
 - The Workshop agreed that co-operation should not be extended to such a degree that audits and inspections are combined or integrated, as this could lead to a possible reduction in objectivity.
- 26. In undertaking to co-operate with companies, public authorities should ensure that this co-operation does not influence their ability to enforce the laws, nor should they be seen as having diminished their independence through such co-operation.

- 27. The Workshop recognised the benefits that could be achieved by a company as a result of their willingness to co-operate with public authorities in the area of audits and inspections. In order for co-operation to be successful, the operator must be competent and willing to address safety issues in a serious way.
 - It was noted that if companies wish to reap the benefits of such co-operation, they should be willing to share the outcomes of audits with the authorities. In this regard, the question was raised about whether companies should be willing to reveal the problems identified in audits. It was suggested that such information could be an indication that the audits are serious efforts that are functioning properly.
 - Voluntary initiatives can play an important role, especially where the inspecting authority is in a formative stage.
- 28. It was noted that the chemical industry has moved towards the integration of the management of safety, health and environmental issues in order to address these in a more efficient and effective way. Therefore, it was suggested that public authorities should consider making parallel efforts, and improve coordination in various aspects of health, safety and environment, where doing so would result in clear benefits.³

(See also section VI below on "Co-operation Among Inspection Authorities")

VI. Co-operation among Inspection Authorities (within a country)

- 29. Chemical accident prevention, preparedness and response by definition involves a number of different authorities (e.g., those responsible for health, safety, environment, civil protection, etc.) at national, regional and local levels.
 - Therefore, the Workshop noted the importance of co-operation among relevant authorities in order to maximize efficiency and minimize duplication of effort (especially given limited resources) and to most effectively contribute to the management of risk.
 - Co-operation provides a number of related benefits, including an opportunity to: learn from each other; share resources, expertise and tools; benefit from different perspectives; minimise the likelihood of different authorities reaching conflicting advice or conclusions; facilitate improvements of regulations/standards; aid in conflict resolution (e.g., between safety and environment); and improve understanding and trust between authorities. Thus, co-operation should lead to greater consistency in approaches and results, between inspection teams within a country.
 - As a result, in some cases there is political impetus, as well as self-interest, in pursuing further co-operation.
 - The industry also benefits from such co-operation. For example, co-operation could result in more targeted inspections, avoidance of duplication, and consistency in approach by the

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³ The OECD Secretariat announced that another workshop is scheduled to address questions related to the Integrated Management of Safety, Health, Environment and Quality. It will take place 26-29 June 2001 in Seoul, Korea.

various concerned authorities. This should lead to fewer interruptions in business activities and allow employees to more effectively participate in inspections.

- 30. There was consensus that effective co-ordination of inspections among the various concerned authorities requires hard work, in order to establish mutual understanding of the different cultures, laws, and structures of each of the authorities.
 - It was recognised that the authorities should seek to co-ordinate during the various phases of the inspection process, as appropriate (e.g., preparation, on-site inspection, report and followup).
- 31. As part of the steps necessary for effective co-ordination, authorities should establish:
 - a clear division of tasks, with identification of roles and responsibilities for various aspects of the inspections;
 - mutual understanding among the authorities of all relevant aspects of the authorities' culture including their legal instruments, policies, and procedures;
 - co-ordinated training activities;
 - clear lines of communication; and
 - an identified mechanism for dealing with conflicts.
- 32. It was agreed that a co-ordinated inspection does not imply that the inspection is fully integrated. Rather, the objective should be to avoid duplication of effort and to share the burden of those aspects of inspections where there is a shared interest.
 - It was recognised that certain aspects of inspections are more suited for co-operative efforts than others. This is largely dependent on the nature of the laws involved, and the culture of the different inspection authorities. For example, it was suggested that, as a general rule, it is much more difficult to co-ordinate non-scheduled inspections than scheduled inspections.
 - While it may be difficult, efforts should be made to co-operate when enforcement is contemplated to ensure accurate and proportionate enforcement actions.
- 33. An issue was raised about the allocation of responsibility for inspections within a country and, in particular, for those cases in which local authorities are responsible for inspections based on national legislation. In some cases, the inspection authority at local level is charged with undertaking the inspections, without having the appropriate structures in place and/or the necessary resources. Furthermore, there may be insufficient co-ordination between the various competent authorities.

VII. Special Needs of SMEs and Hazardous Installations not part of the Chemical Industry

- 34. The Workshop recognised that the larger companies within the chemical industry are likely to have well-developed safety management systems in place, which will allow them to benefit from cooperative arrangements with public authorities. It was suggested that smaller enterprises, or companies that are not part of the chemical industry, are less likely to have such safety management systems in place and generally have limited staff and resources specifically dedicated to safety issues (and, therefore, cannot be responsive to multiple inspections). In fact, they may not even be aware of the actions needed to meet requirements and to operate in accordance with approved safety objectives. As a result, many countries have made significant effort to provide targeted support for SMEs and companies outside the chemical industry. For example:
 - industry associations, and suppliers of chemicals, are making an effort to assist SMEs and other companies in accordance with product stewardship principles, on request;
 - industry associations have developed guidance on safety management systems for SMEs; and
 - one public authority has established a consultation service targeting SMEs, separate from their enforcement activities, with the provision that companies using this service must abate the problems identified by experts provided.

VIII. Improving Trust

- 35. The Workshop discussed the value of improving the transparency in the conduct of inspections and audits, including making available the relevant policies, programmes, and outcomes, to help establish and maintain the trust among stakeholders (public authorities, industry, employees, the public and others).
 - The Workshop noted that evidence indicates that improved public awareness of risks leads indirectly to improved safety.
 - It was recognised that there is a need to assist the public to further understand the nature of "risk" and the risks posed by hazardous installations.
- 36. There was a consensus that both industry and public authorities should make a concerted effort to make available to the public relevant information in a form that can be readily understood and to provide opportunities for dialogues between stakeholders (industry, public authorities, employees and the public).
 - Participants described various activities to improve transparency. For example, many authorities are using the Internet to make their activities available to the public. In this regard, the authorities may post copies of their inspection programmes as well as inspection reports (with appropriate safeguards for confidential business information).
 - In addition, many companies are increasing the amount of environmental, health and safety information made available to the public, consistent with Responsible Care principles, for example through publication in annual environmental and safety reports and on their web sites.

IX. International Co-operation

- 37. Participants recognised the value of sharing of information, within countries and internationally, concerning the methodologies and tools related to inspections and audits as well as the outcome of specific inspections and audits. It was suggested that efforts be made to promote such activities on an ongoing basis, and develop mechanisms that could be used.
- 38. It was suggested that further efforts be made to share experience with countries on a global basis (beyond the OECD Member countries). In particular, it was noted that some countries with economies in transition and developing countries are in the process of establishing inspection systems, as well as related institutional structures and procedures, and therefore should benefit greatly from co-operative activities.

X. Areas of Future Work

- 39. The Workshop recognised that further efforts should be made to support SMEs and companies outside the chemical industry to develop and implement appropriate safety management systems.
 - Industry and public authorities should make efforts to help SMEs and companies outside of the chemical industry address risks related to chemical accident prevention, preparedness and response. While public authorities can address those aspects identified during individual inspections, suitable approaches are required for SMEs and non-chemical companies, to help them to recognise their hazards and adopt appropriate safety management systems.
 - In addition, there needs to be increased initiative on the part of SMEs to request help or participate in available programmes
- 40. The Workshop discussed the value of increasing harmonization in relevant laws, as well as developing consistent approaches to inspections, both within countries and between countries. More consistent approaches would provide the benefit of allowing companies and public authorities to learn from each other.
 - It was recognised that there cannot be complete uniformity of approaches to laws and to inspections, at least over the short term, due to differences in culture and legal systems, as well as different regional factors such as population density.
- 41. The Mutual Joint Visit programme on inspections within EU countries was commended and it was suggested that this programme be continued and expanded in the future to include non-EU countries.
 - Additional efforts could be made to improve sharing of experience among inspectors through, for example, the establishment of international networks of inspectors for various aspects of chemical safety.

- 42. Efforts should be made to use more leading performance indicators, as one way to measure safety and determine whether actions being taken are actually leading to reduced risk. Furthermore, such indicators could help to focus audits and inspections on the areas of the highest priority.
 - It was recognised that the development and application of such indicators is difficult.
 - It was noted that the OECD is in the process of developing guidance on the development and application of safety performance indicators for authorities, industry and the community. This guidance should be published in 2002.
 - More work is needed to better understand the relationship between safety management systems and safety performance indicators, and actual improvement in performance.
- 43. OECD should consider undertaking further efforts (perhaps in the form of an international Workshop with participation from countries with economies in transition and developing countries) designed to share the experience gained in the context of the Chemical Accident Programme and to facilitate implementation of international agreements and programmes.

ANNEX 1

OECD WORKSHOP ON AUDITS AND INSPECTIONS RELATED TO CHEMICAL ACCIDENT PREVENTION PREPAREDNESS AND RESPONSE

Madrid, Spain, 6 – 9 March 2001

DISCUSSION DOCUMENT

Prepared by Keith Cassidy

The opinions expressed in this document do not necessarily represent the opinion of the OECD or its Member countries and should, therefore, be viewed as solely those of the author, except where the text and/or context clearly indicates otherwise.

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EXECUTIVE SUMMARY

The following Discussion Document was designed to introduce, and to stimulate debate at, the OECD Workshop on "Audits and Inspections" held in Madrid in March 2001. The Workshop also addressed themes such as 'performance indicators', 'learning from experience', and 'sharing of information', specifically as they relate to audits and inspections.

The approach used by the author in preparing the pre-Workshop version of this Discussion Document was to describe briefly the issues to be considered, and then to focus, by way of comments (which some may consider challenging) or by posing questions (which were highlighted in the text of the pre-Workshop version), on those matters that might warrant fuller presentation and further discussion at the Workshop. This post-Workshop revision of the Document contains essentially much of the same text, but summarises the questions raised (whilst indicating the pre-Workshop location of many of the questions in the main body of the text); and also consolidates elements of Workshop presentations and discussions into the overall narrative. A representative selection of the detailed questions posed in the Workshop version of the Discussion Document is now located at the end of this Document, which is new to this version of the Discussion Document.

Section 1 of the Discussion Document, **INTRODUCTION AND BACKGROUND**, sets the scene for the Workshop, describing the processes of audit and inspection in the broader context of the management and control of risks posed by hazardous chemical activities, and introducing the OECD *Guiding Principles* in the international co-operative scene. Reference is also made to the roles of the wide and varied range of stakeholders involved. The terms *audit, inspection*, and *review* are defined, for the purposes of the Workshop only.

This section also points to the first 3 Appendices to the Discussion Document, which relate to:

- Aspects of risk control and risk management (Appendix 1);
- The OECD Guiding Principles (Appendix 2), and their place in the wider international context; and
- Some issues relating to terminology and definitions (**Appendix 3**). (This Appendix also suggests additional definitions of words and phrases used in this Document, <u>again for the purposes of the Workshop only</u>).

Section 2, on AUDITS AND AUDITING, opens with a description of the role of audits, in the context of management system failures which have the potential to lead to major chemical accidents. The benefits of audits are considered, as are important elements of their structure, design and use. A representative selection of audit methodologies and models is given, followed by a discussion of audit approaches and their validity in 'root cause' analysis of accidents and incidents. The relative merits of internal/external, and active/reactive audits are then addressed, along with the roles and responsibilities, and the necessary qualifications and experience of those who undertake audits. Consideration of the place of audit approaches in wider process safety and environmental reviews leads to a brief initial reference to 'audit performance indicators' and their benchmarking; and to the potential for risk-based auditing, in the context of risk both to people and to the environment. Many commonalities between audit approaches used by operators or third parties, and assessment methods used by inspectors are identified. Finally, the considerable implications of the use of audits in small and medium-sized enterprises (SMEs), in 'emerging' and/or 'developing' states, or in a context of 'community' and other stakeholder awareness and involvement, are also noted.

The section raises many important questions on audits, with particular emphasis on:

- their design, applicability, validation and robustness;
- their value, both as a practical preventative tool and in terms of their cost-efficiency and cost-effectiveness; and
- the potential for their further development and use.

Section 3 then considers issues relating to **INSPECTION AND INSPECTING.** An initial look at the philosophy of regulation and inspection leads to a summary of the purpose, objectives and the important elements of inspections. This is followed by an analysis of the wide variety of national approaches to inspections (along with the many elements of commonality which also occur); and of the relationships between health, labour, environmental and other regulatory authorities at local, regional and national levels. International regulatory relationships are then considered, along with the need for further mutual co-operation and collaboration, possibly involving other stakeholders.

The roles and responsibilities of inspectors, as well as their required qualifications and experience, are also addressed. Following the approach used in section 2, the subjects of 'inspection performance indicators' and their benchmarking, commonalities between inspection and audit approaches, and the potential of risk-based inspection are briefly analysed. A short critique of 'self regulation' leads to consideration of regulatory and enforcement discretion, and is followed by an analysis of the implications of the involvement of 'third parties' in various aspects of the inspection and other regulatory processes. This raises the issue of the resource implications of inspection systems, and leads on to the difficult question of charging for elements of the regulatory process. Successes and failures associated with inspection reporting and follow-up, and the potential for improvement, are briefly addressed. Section 3 concludes by paralleling the discussion in the previous section on implications for SMEs, for 'emerging' and 'developing' states, and for 'community' and other stakeholder awareness and involvement.

Many wide-ranging issues are raised, with important questions on, e.g.:

- the tensions between harmonisation and independence of regulatory standards and approaches to inspection;
- mutuality and co-operation;
- the difficulties of achieving adequate regulatory transparency; and
- the resource implications, cost effectiveness/efficiency and benefits of the regulatory and associated inspection process.

Section 4 is a relatively brief section considering SAFETY PERFORMANCE INDICATORS AND THEIR RELATIONSHIP(S) WITH AUDITS AND INSPECTIONS. Beginning with a general introduction to the subject, the text then looks at trends in the development of measurement techniques used in audit and in inspection approaches, and identifies commonalities. This leads to a description of the types and variety of such performance indicators, and on to their sources and availability. Other relevant performance indicators (environmental, quality, etc.) are also identified. The question of quantification, and the links between performance measurement and risk assessment are then considered, accompanied by brief references to relevant benchmarking, standards, anchor points and other associated criteria.

The discussion on issues raised in Section 4 is supplemented and extended in **Appendix 4:** "Some further notes and questions on performance indicators and measurement, benchmarking, standards,

anchor points and performance criteria". This Appendix also identifies and poses a number of critical questions in this context.

Major questions for consideration include:

- the problems of benchmarking etc.,
- the need for consensus on the various types of relevant criteria, and
- the potential for co-ordination of outputs by and/or for the various stakeholders.

Section 5 considers the subject of CO-ORDINATED AND INTEGRATED INSPECTIONS

AND AUDITS. The substantial progress which has occurred over recent years in co-ordinating various components of, and targets for, audits (safety, environment, quality etc.) is noted, as is the move towards more or fully integrated audit approaches. A similar movement although, in general less well-developed, is noted in the field of inspection. In both cases, advantages and disadvantages are identified. Important questions posed relate to current difficulties, and to the future potential advantages and disadvantages, of the adoption of approaches combining and/or integrating audit and inspection procedures (for both regulator and regulated). The potential match between co-ordinated/integrated approaches to audit and inspection, and the move of operators towards integrated risk management, is noted. The current difficulties of involving more stakeholders in integrated approaches are recognised.

Section 6 looks at **LEARNING FROM EXPERIENCE, AND IMPROVED SHARING OF INFORMATION.** Issues considered involve the apparent lack of corporate memory, the need for open analysis of lessons learned from incidents and the subsequent availability of such information, and the repeating nature of failure in accidents root causation. The types, sources and availability of accident, incident, event and reliability, regulatory, insurance and other data are examined, along with current major sources of such data. Wider access to improved data is considered, along with current failure to share data even at the local level. The main questions posed involve:

- how the wide range of information currently, and potentially available, may be maximized with respect to quality and relevance; and
- how the information might then be most efficiently and effectively shared amongst all relevant stakeholders.

Section 7 is a brief final **SUMMARY OF THE MAIN ISSUES** considered in the Discussion Document.

It is followed by a substantial **BIBLIOGRAPHY AND LIST OF REFERENCE SOURCES** (which is, nevertheless, representative rather than comprehensive of such wide ranging issues), and by four **Appendices** on, respectively:

- Aspects of risk control and risk management;
- The *OECD Guiding Principles*;
- Some issues relating to terminology and definitions; and
- Some further notes and questions on performance indicators and measurement, benchmarking, standards, anchor points, and performance criteria.

Although each of these Appendices is 'stand alone', the substantive text of the Discussion Document contains many references to their content.

A selected **KEYWORD INDEX** closed out the original Discussion Document. However, this revised version also contains an additional chapter, **SUPPLEMENT to DISCUSSION DOCUMENT (Workshop Version)**, which details and textually locates a representative selection of the questions which were contained in the main body of the narrative of the pre-Workshop version of the Discussion Document.

1. INTRODUCTION AND BACKGROUND

1.1 Setting the Scene

The intention of the first version of this Discussion Document was to provide a framework (and hopefully a stimulus), and to set the stage, for the presentations and discussions at the OECD Workshop on Audits and Inspections, held in the Escuela Nacional de Proteccion Civil, near Madrid, in March 2001. This version of the Discussion Document has been revised and updated, to take account of the Workshop discussions, conclusions, and recommendations.

As well as the issues of Audits and Inspections, the workshop also considered Performance Indicators, Learning from Experience, and the Sharing of Information. These are all very broad issues, and this Document does not pretend to be definitive or all embracing in addressing them. Whilst an extensive list of references is also attached, it is representative rather than comprehensive, in terms either of the Workshop subjects as addressed in the Document, or of the subjects more generally.

The approach adopted by the author was to identify and briefly to describe those issues which appeared to him to be relevant and then to focus, either by way of comment which some may consider challenging, or by posing questions, on those issues which seemed to him to warrant further scrutiny. (In the original version of this Document, the questions were highlighted in the body of the text. In this revised version, the core issues and questions raised are summarised at the end of each Section, but there is also an indication in the text (Q) of where most of the relevant questions (or sets of questions) were raised, at the specific point in the text of the first version of the Discussion Document. A representative selection of the questions themselves is listed, by Section, at the end of the Discussion Document which is new to this version of the Document.

Sometimes, lengthier descriptions and discussions of the subjects and issues addressed at the Workshop are to be found in Appendices to this Document; but generally, detailed description is left to be accessed via the Bibliography and References.

The author has discussed aspects of this Document, during and after drafting, with some members of the Workshop Organising Committee, with the OECD Secretariat, and informally with other selected experts internationally (and is most appreciative of the advice and assistance he has received from these sources). However, the Document does not necessarily reflect the views of the OECD, its Member countries, or those individuals (identified or not) or the interests they represent, unless the text or context expressly indicates otherwise.

1.2 Principles of Risk Management and Risk Control

The principles and practice of risk management and risk control are central to the issues addressed by the Workshop (indeed all the subjects on which the Workshop focussed, such as inspection, audit, performance indicators, learning from experience, and sharing of information, are major component parts of the of the overall risk equation); but to devote significant effort to these core issues would have disturbed the focus of both the Workshop and this Discussion Document. Nevertheless, some aspects of the issues examined at the Workshop can only be considered constructively in this wider context, a context which of course continues to be the focus of intense international debate. Appendix 1 to this Document provides a brief exposition of the above principles, to set this wider context; but the wider issues will only be considered further in this narrative insofar as they affect, or are affected by, the specific subjects considered in detail during the Workshop.

1.3 Roles of Stakeholders, and of Audits and Inspection, in Risk Management and Risk Control

There are many stakeholders involved, directly or indirectly, in the control of hazards and risks from chemicals and the installations which manufacture and process them. Such stakeholders range from multi-national, megalith corporations, through small and medium-sized enterprises and organisations, to the individual. Major or important groupings include:

- international bodies and organisations of various kinds;
- industrial operators and associations, multi-national, national and local;
- regulators/other public authorities, at national, regional and local levels;
- non-governmental public bodies;
- professional associations, and academia;
- pressure groups, local, national or international (e.g., FoE, Greenpeace, etc.);
- trade unions, worker protection societies (e.g., the *Berufsgennoschenschaften*), worker compensation organisations, 'User' Inspectorates, etc., with or without regulatory or quasi-regulatory powers;
- the public (in its many and varied manifestations); and
- others, such as certifiers and accreditors, consultants and consultancies, the insurance world in all its guises, the media, and so on.

In the realm of chemical accident prevention, preparedness and response, all of these stakeholders will share the same, or very similar, headline objectives - the prevention of incidents with the potential for human or environmental harm, and the operation of associated industrial activities at a tolerable level of residual risk. But within those overall ambitions there will be many differences of approach and motivation, and a wide range of nuances of interpretation and action. The active and reactive relationships, interplays and interactions in this social web are very complex. They form part of the social, economic and cultural scene described in Appendix 1. It is therefore imperative that the outputs of audits and inspections (at all levels), and the derivation and use of performance measures and indicators, are both relevant and responsive to them.

1.4 International Co-operation and Associated Issues

There is a great deal of international cooperative activity concerned with chemical accident prevention, preparedness and response, and in which many of the stakeholder interests identified above are closely involved; (some important examples are identified variously later in this Document). Some such initiatives are progressed on the basis of ongoing collaboration between the various parties; others on a sectional basis, but designed to fit in to the overall pattern. Appendix 2 of this Document briefly outlines the locus of the *OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response* (OECD 1992) in this wider international context.

1.5 Terminology and Definitions

There is currently no overall consensus on the definition and meaning of many of the terms used by stakeholders in the risk management process; and the core subjects considered by this Workshop - audit, inspection, associated performance indicators, learning from experience, and sharing of information - are no exception. However, it was agreed that to seek such consensus, even for a limited number of terms, would shift the intended focus of the Workshop; and divert much if not all of the time available away from these core issues. The original Discussion Document defined certain terms *for the purposes of the Workshop only*; and at the request of the Organising Committee, participants in the Workshop adopted the definitions without debate. Workshop discussions clearly demonstrated the problems inherent in and arising from differences in understanding of core terms.

The terms so defined were as follows:

Audit - an examination performed either by or on behalf of an industrial operator (**self** or **internal audit**) or by an independent third party (**external audit**). The definition includes the resultant report(s) but not subsequent follow-up activities.

Inspection - a control performed by public authorities (or by (an)other party/ies on behalf of public authorities). The definition includes the resultant report(s) but not subsequent follow-up activities.

Review - an examination to determine whether (1) a company's safety (and/or environmental) management system is consistent with its objectives and policies; and (2) its objectives and policies are appropriate.

A further brief discussion on the meaning and definition of relevant terms, and on some current international concerns and initiatives (including some relevant OECD projects), is at Appendix 3; along with a few other terms used in and defined for the purposes of this Discussion Document.

2. AUDITS AND AUDITING

2.1. Safety Management Systems; and the Causes of Failures Leading to Major Accidents

During the latter part of the 20th century there were many high consequence incidents (often involving many members of the public) the subsequent investigation and analysis of which highlighted failures, fundamental or otherwise, both in technical systems and in associated (safety) management systems. Indeed, there has been, in the last two decades, something of a sea change in the focus of such incident investigations, which has shifted from technical issues *per se* (although these clearly remain important) to the management systems in which the technical issues were embedded. (Of course, only a proportion of such incidents occurred in the chemical and process industries; others, such as *Herald of Free Enterprise*, the *Challenger* space shuttle, the escalator fire at *Kings Cross* all exhibiting nevertheless the same types of management system failings). This change in focus has gone hand in hand with the development of investigative and other approaches which have looked beyond immediate causation, to address the underlying or 'root' causes of incidents, accidents, and other deviations and violations. (Root causation is discussed in more detail in Section 2.7 *post*). The result has been the development and implementation of more formal appraisal methods of management systems, initially based on extrapolation of existing engineering approaches, but later bedded in socio-technical concepts (e.g., API 1990; CCPS 1989, 1992; CMA 1990; CONCAWE 1989, OSHA 1992, BSI 1994, IMO 1994, EU 1994).

A general consensus has emerged, about the typical architecture, structure and content of such systems (although it is recognised that many differences of detail, and in terminology remain). This overall consensus is encapsulated, typically, in the acronym POPMAR (HSE 1991, 1995) - indicating Policy, Organising, Planning and implementation, Measuring performance, Auditing, and Review of performance. Such an approach is of course equally applicable to environmental and quality activities (and indeed to a wide range of other organisational activities), and on that basis implies a further indicator of its robustness. Such systems and procedures are now widely endorsed, in principle (e.g., JRC 1993, EPSC 1994, EFCE 1996, JRC 1998); and there have been several comparative studies (e.g., JLP 1999). However, various studies have identified limitations (some of which are outlined later in this Document) as well as merits in the outputs of such approaches. Similarly, major incidents have sometimes occurred where apparently adequate safety management systems were believed to be in place, and where ongoing audit and associated procedures had led the operator to believe that adequate precautions were being followed (e.g., GV1999) (although in this-and other-case(s), and with hindsight it was found that there were several problem areas, including missed opportunities to discover gaps during audits and reviews). (01). There are substantial implications here for reliance on audit approaches, without wider safeguards also being in place.

Indeed, this potential problem introduces a further dimension. Many of the question sets used in most current audit methods were developed some time ago, since when several aspects of the industrial scene have fundamentally changed, with for example 'just-in-time' approaches to many parts of operational and managerial procedures, and widespread demanning at all levels. All of these have led to certain efficiencies, but at a cost of increased vulnerability to disturbance, and with less time for pre-critical intervention. (Q2) Clearly, appropriate safeguards are necessary to ensure 'fitness for purpose'.

2.2. Audits and their Benefits

There is a general consensus that audit approaches can provide a powerful tool in the analysis of industrial safety and environmental performance; and that when properly applied, the benefits of audits are perceived to be five-fold:

- as an effectiveness evaluation tool:
- as an identification tool for corrective action;
- as a monitoring tool, especially as an indicator of change;
- as a reinforcement tool for aspects of company 'culture'; and
- as a (re)assurance tool, particularly for third party interest.

However, while substantial work has been done on accident costs *per se* (e.g., HSE 1997), the cost effectiveness/benefit and the associated opportunity costs of the components of the 'POPMAR' taxonomy, and indeed of audit procedures themselves, have received less attention by regulators, and (at least openly) by operators. Costs, both normal and opportunity, are nevertheless an important element of the overall risk management package. (*Q3*) Furthermore, despite the above apparent benefits, the use of audits is not without reported problems. These include problems of local ownership and engagement (generally less prevalent where internal and reactive work is involved); the trade-offs of effort against benefits, both real and perceived; the loss of the big picture where the speciality audit dominates; failure to prioritise critically audit findings and recommendations; overlap and duplication; and the quality and independence of auditors. (*Q4*) These are real problems that must be carefully managed.

2.3. Structure and Design of Audits; Important Elements of Audits

CCPS (1989, 1993) defined the following audit types:

- Process safety management system audits;
- Process safety audits:
- Product audits:
- Compliance reviews; and
- Corrective actions

in which must now be included all relevant *environmental* dimensions. Many systems that protect people may well also protect the environment; but this is by no means universal, especially where safety/environmental trade-offs may be involved. (Q5)

2.4. (Safety) Audit Design.

Audits are typically based on either a check/action list or a points system, usually resulting in a list of recommendations for action, sometimes graded. The points system facilitates, at least in principle, the measurement of change (ideally improvement); but can tend to bias findings towards areas of good performance. (Q6) Careful focusing is essential.

Such audits tend to fall into 2 main categories:

- *technical*, in which the audit concentrates on undesired events or hazards, hardware issues (location, design features, reliability and availability, maintenance and protection), operating rules and safety critical procedures (including any relevant task analysis). Such technical audit question sets tend to be very specific.
- *management systems* (either of a general kind, addressing the generic systems which may be in place; or more specific, addressing system performance, operating incidents, company procedures, and 'human factors' issues, including organisational culture).

Clearly there will be areas of overlap, which need to be effectively managed; and the dangers of specificity in audit question sets must be recognised. (Q7) Also, a great deal of effort has more recently been deployed on the co-ordination of audit approaches, or the development of integrated models, sometimes combined with other aspects of performance, such as quality. This may result in further demand for adequate management of critical interfaces. There may be stored problems here.

The implications of these issues are discussed further in Section 5 post.

2.5. Summary of Audit Methodologies and Models

In recent years, the number of available (safety) management system audit models has increased substantially, encouraged perhaps by the repeated concentration of Reports of Inquiry (often in public) into the failures - leading to catastrophe (actual or potential) - of such management systems. Whilst there are many common elements in available models, there is also wide diversity, of application, content, coverage and approach. Of course, some diversity is a prerequisite of focus on specific industry characteristics; and where a more comprehensive question set or other approach is available, some selectivity is essential. (Q8) Safeguards will therefore be necessary to ensure that appropriate models are chosen, and their application correctly managed.

Some of the more common (or more documented) - and a couple of less familiar - models include the following (but it should be clearly understood that the list below is indicative only, and far from exhaustive. It is however representative of the types and range of models currently in use):

- ISRS (International Safety Rating System)
- AUDIT-PC
- SHARP (Safety and Health Audit Reporting Package)
- MANAGER (Management Safety Systems Assessment guidelines in the Evaluation of Risk)
- COURSAFE
- CHASE (Complete Health and Safety Evaluation)
- PRISM (and Safety Audit Manager)
- 5 STAR RATING SCHEME (nb. There are more than one of these!!)

- STOP (Safety Training Observation Program)
- C-MORT
- *M.E.S.* (*Metatechnical Evaluation System*)
- ARAMI (Accidental Risk As Methodology for Industries)
- LETSA (Loss Exposure Technical Training Scheme)
- AVRIM (and AVRIM2)(Occupational Safety Report Assessment and Inspection Method)
- STATAS (Structured Audit Technique for the Assessment of Safety Management Systems)
- PRIMA (Process Risk Management Audit)
- OIMS (Operations Integrity Management System)
- PARTNERSHIPS
- REALM (1&2) (Resource Efficient Auditing for Line Management)

There are wide variations in the content and approach of the above, and other schemes. In the examples given, there is a range of core management elements from three to over twenty, and sets of questions which range in number from a couple of hundred to several thousand. The methods and criteria by which the question sets are or have been validated is variable, and the majority of systems are based in the incidence assumptions which underpin the accident pyramids produced by Heinrich, Bird, Tye *et al*; but these may not necessarily reflect the rather different assumptions which should underlie the very low probability, high consequence events which are typical of chemical accidents, especially major accidents. (*Q9*) Again, it is important to ensure that any audit approach chosen is appropriate, and 'fit for purpose', and its application and use adequately managed.

Some systems incorporate elements of others. Most if not all incorporate some element of measurement, often dimensioned but rarely quantified, and some involve weighting of various elements of the outputs. The derivation and validity of such weighting is not always transparent. Outputs tend to be relative, and only locally comparative (Cassidy K in CCPS 1993a). (Q10) Such shortcomings may introduce significant problems, particularly in the wider application and use of audit approaches.

Furthermore, many such models contain elements developed in, or further developed from, collaborative research programmes such as the EU's Framework Programmes of Science and Technology for Environmental Protection (STEP) (e.g., CEC 1994), and it is important to acknowledge, in practical applications, the common-mode failure implications of any such common sourcing. There is also the problem of relevance, applicability and comparative validity. This is perhaps best illustrated by example. For the past two decades, many of the component models in the methodology of quantified hazard and risk assessment - essentially the mathematical approximations of the chemical and physical phenomenology associated with loss of containment - have been comparatively analysed, 'war gamed' and benchmarked. There now exists substantial knowledge of their validity and application, in the public domain. Currently, the availability of similar knowledge for audit approaches is much more limited. (*Q11*) Transparent benchmarking would add substantial robustness to current models, and result in increased confidence in their application and use

Most of the audit systems described above are proprietary, or at least company developed models (and some approaches blend in-house activity with external inputs); but most interestingly, three of the above models have been developed for use by, primarily or exclusively, first line regulators as inspection aids or assessment tools. (Q12) This remains the exception rather than the rule, however; although there could be many advantages in development and wider use of common(ly based) models by both regulator and regulated.

2.6. Important Elements of (Safety Management) Audits

Inevitably, the areas covered by such audits are very wide-ranging; but the main elements can be categorised into three general groups:

General factors, including health and safety culture, policy, and management structure, physical aspects of the plant environment, health appraisal and control, management (including transport) of hazardous substances, and energy source control;

Hardware issues, covering plant items and systems affecting safety, process equipment integrity (most of these items are better located in technical safety audits); and

Software (or peopleware) elements, including most procedures and methods, knowledge skills and training, and documented standards and methods. Also included here are quality assurance systems, task analysis and management, operating and maintenance procedures, purchasing controls, project engineering and change management, incident and accident investigation and analysis, and emergency response management.

This is a substantial shopping list (Q13) and there may be difficult decisions to be made between width and focus of coverage, any choice of targets for 'deep drilling', and the safeguarding of operational practicality and cost effective use of resources.

2.7. Audits and 'Root Causes' of Incidents and Accidents

In recent years it has become increasingly common to focus on the 'root cause' of incidents and accidents rather than 'higher level' causation. Such root causes are essentially patent or latent preconditions for failure (the so-called 'organisational pathogens'), and cover core areas such as:

- External systems, such as the regulatory, political, commercial, physical or geographical constraints which impose strong forces on the system yet are outside it;
- *System climate*, including business and economic factors, focus, corporate culture, safety culture, and technical competence and know-how;
- Organisation and management, covering such things as commitment to safety, decision making hierarchy, interaction with internal/external systems, resource provision and production resources;
- Site and plant facilities, including site layout and engineering and process design, commissioning, decommissioning etc.;
- Engineering integrity, both reliability and availability;
- *Management control*, in such areas as resource allocation and development, monitoring, quality control and development, management of change, competence/ies, responsibility and accountability, supervision and control etc., in both normality and emergencies;
- *Communication and information*, including information selection and quality and the dynamics of information processing;

- *Procedures and practices*, including both normality working and excursion and emergency situations. Training, quality control and incident reporting/investigation are also relevant here:
- Working environment, which also involves some aspects of safety culture, welfare and
 aspects of immediate supervision and support, as well as the more typical indicators of this
 category; and
- *Operator performance*, including recruitment, personnel capabilities, training, working discipline and safety and operating margins.

Such a list is, of course, indicative only, and in no way comprehensive; but it does serve to illustrate the extensive area which any audit system designed to address root causation needs to cover; the main aim being to identify the major variances in organisation and management and other root causes which affect the system under scrutiny. The intention is to build upon engineering solutions to technical problems and ergonomic or similar solutions to human error or man/machine interface problems (which tend to address more immediate causation) to facilitate the identification and placement of system defences throughout the 'socio-technical' context of an operating environment. The question sets in several of the audit systems identified above are designed, at least in part, on this 'Lines of Defence' principle, more usually applied to technical systems. (Q14) The assurance of robustness, the identification of critical elements, and the focusing of resultant actions are important issues in this context.

2.8. Internal and External Audits; Active and Reactive Systems

As the definitions adopted for the Workshop indicate, audits (of whatever kind) may be internal (that is to say, carried out by personnel belonging to the undertaking or company involved, but in principle independent of the activity being audited); or external, carried out by a third party, often totally independent. In practice, there is often a mix of the internal and external, as each approach is considered appropriate for a specific context. Many independent auditing bodies also carry out functions such as accreditation, certification, etc., not only for safety and environmental issues, but also for other organisational attributes (such as quality). There are both advantages and disadvantages here, which need to be managed.

In many cases, audits will form a proactive part of an ongoing programme of assessment activity; in others audits will be reactively triggered by an occurrence, or other manifestation or perception of performance inadequacy. (Q15) An appropriate general balance is essential.

2.9. Roles and Responsibilities, Qualifications and Experience, of Those Involved in Audits

Clearly, the primary qualities necessary for auditors must include independence from the effects of local influence(s), objectivity in analysis, and familiarity with the (technical or other) system under audit, and with the audit system being applied. (Q16) But this must be achieved with due regard for both cost and effectiveness, as shortfall may not only damage or invalidate the immediate audit, but might also have wider effects.

2.10. Audits and Process Safety Reviews

The effects of audits when used as part of process safety reviews is even more dependent on appropriate tailoring to both the specific issue to be examined, and to the characteristics of the organisation (or part) being considered. All relevant aspects need to be covered, by auditors familiar with both the company and the technology involved. Scope must be clearly defined, within any appropriate wider context; and quality review, preferably in some way independent, is a prerequisite (e.g., VTT 1990). (Q17) This is unlikely to be achieved without some formal structuring of both immediate and wider programmes.

A structured approach is clearly facilitated when audit and risk assessment approaches are deployed as complementary tools, in the pursuit of S, H&E management. Risk assessment then can identify which aspects of SMSs are S,H&E critical, audits thereafter checking that appropriate and adequate arrangements are in place, and operating with appropriate integrity. (For instance, one of the important (and powerful) capabilities of some of the techniques of risk assessment (in, for example, event and fault trees) is the capacity to identify - often using Booleian logic and algebra - the combinations of events or failures which may or will lead to the 'top event', and thereby those lines or nodes of defence which are critical to prevention. Currently, there are few, if any, parallel techniques for producing such 'minimum cut sets' for the elements analysed by audit question sets and other approaches. (Q18) Clearly, a great deal of developmental work remains to be carried out in this important area.

A great deal of research effort is currently being deployed in investigating the nature of, and the critical interactions of, massive and complex engineering and social systems, and some of this work may have lessons of significance for the identification of critical elements of management audit systems set in a wider risk management context. But (Q)RA techniques may already identify the critical areas of activity for auditing a particular operation; and such focussing might well be appropriate at each of the three general levels of application: management, specialist/technical, and people; but perhaps more particularly at plant or establishment level.

2.11. Audit Performance Indicators

It was the express intention of the Organising Committee that consideration of performance indicators be limited to those indicators which are relevant to the primary Workshop subjects (that is to say audit and inspection). (A definition of audit performance indicators, for the purposes of the Workshop only, is at Appendix 3). Audits are concerned with assessing (and dimensioning or measuring in some way) individual or multiple aspects of organisational culture, plant and equipment, systems and procedures, and people. Such assessment will involve observing and analysing activities, which will result in outturns or outputs of various types and varying levels. Essentially, activities identify what is (or isn't!) being done, and perhaps the level of performance or quality; while outputs and outturns measure the effects (including perhaps aspects such as quality), of such activities. Indicators and measures will be mixtures of the qualitative, the semi quantitative, and the fully quantified, at a specified or more general level, and expressed in either relative/comparative or 'absolute' terms. All such measures are not only specific to those subjects or concepts which they directly address, but some of them are also liable to be interpreted and judged in the wider risk management context outlined in Appendix 1. And such indicators may be used, especially in a correction or improvement regime, in conjunction with so-called 'SMART'-(Specific, Measureable, Achievable, Realistic, Time-limited)- objectives. (Q19) This complicates considerably any judgements about 'fitness for purpose'; a problem greatly exacerbated by the current lack of any consensus on appropriate benchmarking of any such indicators.

These issues, with examples, are discussed in greater detail, in Section 4 and Appendix 4 post.

2.12. Risk Based Auditing

Industry has in recent years been moving from more 'traditional' technical plant equipment inspection, monitoring and maintenance regimes (which are normally based on time and/or usage parameters) to approaches which are grounded in the concepts and concomitant procedures of risk analysis. Such risk based inspection (RBI) can provide a systematic method to guide the user in the selection of those options judged most likely to optimise a technical plant inspection programme for the purpose of reducing risk. Such approaches dovetail well with industry technical inspection codes and standards, and are increasingly being recognised within them (e.g., API 510 (pressure vessel inspection) and API 570 (process piping inspection) in 1998). Further work is still required on various aspects of these applications, including their useability and universality, the vexed question of auditor training and judgement, relevant standards and their anchor points, and the problem of verification. However, the vision for the future is acceptance of 'technical' RBI (coupled perhaps with reliability centered maintenance) by operators, jurisdictions and insurers, as a sound basis for controlling (and perhaps reducing) risk levels by applying the appropriate level of surveillance and control activity, depending on risk level.

Similar risk based approaches are now being applied in the financial world; and there is the potential for the application of such risk based approaches to auditing of safety and environmental management systems (and, indeed, for regulatory and other inspection, discussed in Section 3 post). But currently there has been only preliminary development work in the field of audit, where they may be substantial practical difficulties, some of which have been described earlier. (Q20) The advantages and disadvantages of adopting such approaches have yet to be fully determined, but the potential benefits may well warrant further development work. It is not clear, however, who is best placed (or indeed suited) to carry out such work.

2.13. The Environmental Dimension

All the above, as applied to audits and to related safety performance indicators, should be equally applicable <u>in principle</u> to an environmental context: it may be only the detail of the audit questions, of the indicators and/or of the benchmarks which differ (but problems may exist where consolidation or integration is attempted, as described earlier); and of course judgements as to acceptability or tolerability of environmental harm or risk tend to be at least as subjective, and as contentious, as those relating to the human dimension. (*Q21*) Currently, there is little consensus; although it appears to be the majority view that where there is unavoidable choice to be made between human and (at least at the local level) environmental protection, then the former prevails. Interestingly (EU 1996), in its definition of a major accident notifiable to the Commission, outlines some environmental criteria; but any implication that there is equivalence with the 'human' criteria also outlined is, at best, inferred. (*Q22*) It is difficult to identify the critical trade-offs; and they are rarely identified in audit procedures and protocols.

2.14. Audit Follow-up: Reports and Follow-up Activities, Successes and Failures, Improvement Potential

Several commentators (e.g., CCPS 1989) highlight the essential need for corrective actions, to address those deficiencies, weaknesses or vulnerabilities identified by audit. Prerequisites of this process are preparation and distribution of the audit report(s), the development of action plans (perhaps involving multiple time scales, including immediacies), review of action plans and ongoing implementation, and verification of action completion. Although optimal outturns are likely only where the corrective actions are owned by those they are intended to affect, resultant ongoing change will involve, at least in part, a

focussed tracking regime, and some independence of the corrective process from the mainstream operational process overall. The impression is that this element of the overall process is less successful, and provides one explanation for less than ideal audit results. (Q23) The reasons for this are not at all clear, or well understood; but until there is greater understanding and clarity it will be difficult to identify and monitor real improvements in the process.

2.15. Audits and Reviews

An audit, even when self contained, contains a number of progressive elements, operating over time; and because systems tend to degrade over time (the phenomenon known as 'corrosion') any audit, unless part of a wider set of initiatives, is essentially time-limited. (Q24) Many audit techniques (including most of those identified in Section 2.5 ante) are not designed to deal, at least fully, with the 'corrosion' phenomenon and its effects (although some recent developments in modelling are encouraging) and additional measures are normally necessary.

As a minimum consequence audits need to be repeated, either singly, or as part of a wider pattern of similar activity, again over time. However, this extended activity should itself be part of a wider review, with the type of characteristics outlined in, for example, Section B6 of the *Guiding Principles* (including setting and upgrading goals, at and for various levels). (A definition of '*Review*', in this context and for the purposes of the Workshop, is to be found at Section 1.5 and in Appendix 3). Indeed, in principle at least, this review component is a critical element in the overall auditing process. In practice however, a major organisational and operational fault line is often located, or develops at this interface (*Q25*); and managing the consequential problems is fraught with difficulties.

2.16. Commonalities with Inspection Activities

Comments in the above narrative (and on the issue of definition and meaning of terms) have already identified many (and often substantial) areas of interface and commonality between audits applied for various purposes, and between audit and inspection activity. Such areas are currently often regarded (particularly by industry) as areas of inefficient overlap; but they do offer the promise of substantial efficiency (and perhaps effectiveness) gains if properly managed. (Q26) It should prove possible to work towards harnessing the potential gains in this area; but there may be practical problems, particularly associated with the wider context outlined in Appendix 1, which militate against any optimal gain which the extent of commonalities may promise, or at least imply.

These and associated issues are discussed in more detail in Sections 3, 4 and 5 and Appendix 4 post.

2.17. Implications for SMEs, and for Emerging or Developing States

The 1995 Toronto Workshop (OECD 1995) considered the implications for Small and Medium-sized Enterprises (SMEs) of Chemical Accident Prevention, Preparedness and Response. The substantial value of auditing approaches was endorsed by the Workshop participants, who also acknowledged the specific and often substantial difficulties of SMEs in this area of activity. Such difficulties were recognised as a function of (lack of) size, resource, specialist personnel, and so on - indeed the very problems which are endemic, almost by definition, in such enterprises. Furthermore, there have been major changes in the structure of industry since the basis of audit approaches was first developed, with a major - often majority - proportion of national industrial labour forces now working in such SMEs. Many

audit approaches are relatively inflexible (indeed in some cases inapplicable) at the micro level. (Q27) This industrial population shift is widely perceived to have major implications for management and control of chemical accident risks; but it is a problem which has currently been recognised rather than solved. The suggestion that major companies, industry associations, and public authorities have a significant role in transfer of expertise is at best only a partial answer to the problem. Nevertheless there are excellent examples of the provision of such assistance, which could provide a blueprint for further initiatives.

EPSC has recently published (EPSC 2000) guidance on SMSs for SMEs, and EU JRC Ispra is currently developing guidance for SMEs on appropriate safety performance indicators (SPIs)). Furthermore, any moves to hazard or risk based inspection (discussed in Section 3 *post*) may increasingly override any allowances which might otherwise be admissible on the grounds of size or resource limitation, and exacerbate any 'fitness for purpose' constraints on audit limitation which might already exist. Solutions to such difficulties are unlikely to be easily identified or implemented.

Difficulties of a similar nature may exist for the application of standard audit approaches in 'emerging' states (for example those of the former 'Eastern Bloc'), where there may be significant and urgent technical or resource shortfalls or where different management cultures may have long prevailed; or in states in the process of industrialisation, where complex plant may be provided on a 'turnkey' basis. (These comments are, of course, an oversimplification of the reality of the situation, but do illustrate the additional attendant difficulties). (Q28) Again, it is much easier to recognise the problems than to identify, let alone implement solutions; but they are problems of great, and perhaps increasing, immediacy.

2.18. Community and Other Stakeholder Involvement

The wide range of stakeholders involved in the risk management process is summarised in section 1.3 ante. This involvement, particularly at 'community' level, has been further legitimised and strengthened by a variety of legal and similar imperatives based in 'Freedom of Information' or 'Right-to-Know' concepts. To date, such involvement has only rarely incorporated community or other stakeholder access to the outputs of audits, and even less frequently has allowed direct involvement in their conduct. Most examples currently in the public domain are from North America. (Q29) The North American experience shows that the potential for progress is great, and there are emerging examples of progress in such involvements elsewhere, but the time frame for such 'cultural' change is unlikely to be short, and there are many concomitant problems.

2.19. Summary of core questions

Representative questions raised in the Workshop version of the Discussion Document are itemised in the supplement. The core questions and issues raised in this Section on *Audits and Auditing* are summarised below. They involved questions and issues on:

- The design, applicability, validation and robustness of audits;
- The value of audits, as a practical preventative tool;
- The cost efficiency/effectiveness of audits;
- The potential for further development and use of audit applications;
- Internal and external synergies in audit approaches; and
- Stakeholder and wider community involvement.

3. INSPECTION AND INSPECTING

3.1. Philosophy of Regulation and Inspection

At the risk of misquoting Voltaire: "If Regulation (and/or Inspection) did not exist, it would be necessary to invent it/them". It is the conventional wisdom, rarely nowadays challenged, that some form and measure of independent regulation, inspection and surveillance of hazardous activities which might put people or the environment at risk, is a prime public expectation. Every current regulatory control system, national or international, for such hazardous activities therefore includes this convention. (The concept of 'Self Regulation', and the attendant practical difficulties, are discussed in more detail in Section 3.9 below). In the EU, the requirements relating to inspections have been strongly reinforced in the move from Seveso I to its successor, along with greater prescriptive detail about the obligations of the Competent Authorities; a change designed to bring greater consistency in regulatory performance, thereby levelling the Community 'playing field'. (Interestingly, an EU Technical Working Group to discuss Inspection Systems substantially predated the tabling of the Commission's proposal for a replacement Directive; and its resultant guidance is indicative rather than prescriptive). (Q1) There are tensions between overall consistency and 'subsidiarity' which need to be effectively managed; but there are problems of sanctions and the level at which they may be applied. Any attempts to widen further the so-called 'level' playing field inevitably exacerbate existing difficulties.

3.2. Purpose, Objectives and Important Elements of Inspection

Inspections by a regulator (or other party acting on behalf of, or under regulatory control) may have many elements; and at the practical level are often combinations of such elements, which might include the following (major) components:

- *preventative(active)*, often as part of a planned programme of activity. Such inspection activity may well involve elements of 'regulatory audit' (e.g., *AVRIM*, *STATAS*);
- *reactive*, usually in the wake or aftermath of an incident, or triggered by an adverse trend in some other performance indicator. Again, 'regulatory audit' may be involved;
- *licensing, permissioning, approvals;* a major area of activity in the context of chemical accident prevention, preparedness and response, as most regulators operate licensing, permissioning, or other approval (often standards-based) control regimes;
- data collection and checking, both for direct regulatory, and also wider purposes;
- *emergency planning*, to verify and validate the basis for, and the interfaces with, aspects of emergency planning;
- *safety/environmental case/report content*, a process which involves both verification and validation;
- culture and systems, often as part of an audit or similar assessment process;
- *technical*, the checking of plant and equipment against standards, either regulatory or technical, prescriptive or goal-setting; once, but in many countries no longer, the most predominant form of the inspection activity;
- aspects of siting, in controlling incompatible land-use(s); and
- *public and other stakeholder information/interest/involvement*, triggered by many causes, both local or distant, direct or indirect.

(Q2) And, of course, important concomitants are inspection reports and follow-up - in some cases (e.g., in countries covered by the Seveso II Directive) both elements being on a statutory basis. There is also an increasing demand for transparency of process.

3.3. Examples of National Approaches to Inspection and Relationships Between Health, Labour, Environmental, and Other Authorities, and at Local, Regional and National Levels

3.3.1 Varieties of Approach

It is fair to say that the regulatory processes for industrial risk (including the inspection process) has been under scrutiny for as long as those processes have existed. Given the historically often piecemeal nature of the development and growth of controls, such scrutinies have often been occasioned by changes in the nature of the industrial process, by the manifestation of previously unknown or changes in the perception of hazards and risks, or most commonly, by public and/or political reaction to a major incident. (This latter is a standard social phenomenon, of course). Initially, most such studies were at local or national levels; but latterly wider international cooperation (for example, via OECD, ILO, WHO etc.) - but allowing some subsidiarity at national or local level - has become more common.

There have been several recent descriptions of the regulatory control of chemical hazards and risks (e.g., Campbell 1986, AIChE 1994, Davies et al. 1995, EC 1995, Augras 1995, Jones 1997, Cassidy in (CCPS 1998) and in JRC1998a, JHM 1999); and in some cases detail of such regulatory activity (e.g., US OSHA, EPA) is posted and readily available on the World Wide Similarly, a number of comparative studies of aspects of regulatory approach and performance have also been compiled (e.g., by JRC-Ispra, on issues such as land-use planning, safety report content, and public information in the Seveso Directive context). In addition, there has been a considerable number of analyses and critiques of national and other state inspection regimes and systems, as part of the investigation, often in public, of major incidents. Most studies of the differences in approach have concentrated on describing (and occasionally and sectionally championing) the differences, rather than analysing them, or comparing their effects however complex such an exercise might prove to be! What all these studies show, however, is that whilst there is considerable commonality at the level of overall philosophy and principle, there remains great diversity of approach internationally, with even greater divergence of detail at national and local levels. Such diversity, however explicable, brings problems. (As a somewhat cynical correspondent with this author observed, the real repository of information and knowledge about local, national, regional, and international variations in standards of regulation and enforcement currently rests overwhelmingly with industry, and particularly with the multinationals, who may tend to use such knowledge for their own purposes and agendas, (03) Wider availability of this valuable information and intelligence could have great preventative potential in the field of chemical accident prevention; and the main obstacles to wider dissemination appear to be historical, cultural and/or organisational. This issue is considered further in Section 6.

3.3.2. Types of diversity

There are, of course, many reasons for such diversity, from differences in national regulatory approaches and systems, through differences of 'culture', to manifold historical legacies. Indeed diversity can be a strength as well as a source of problems, so long as there is a wider consistency. Common areas of variance are to be found in

- the national 'lead' at international level;
- split regulatory and enforcement responsibility across separate activities, especially workplace, environment, fire and public (health) risk;
- the overall consistency of regulatory coverage (overlap, duplication, lacunae etc.,);
- the level and locus (national, regional, local etc.,) of regulatory control; and any 'override' mechanisms:
- variable approaches to licensing, 'permissioning' and similar activities;
- the use of goal setting as opposed to prescriptive legislation and standards;
- the blend of chemical accident control with other regulatory and inspection functions;
- the mix or blend of enforcement and advisory activity;
- the use of 'third parties' in the inspection process;
- the use of intermediates or intermediaries (sometimes other stakeholders, such as the insurance world, worker protection and compensation societies, 'User' inspectorates, etc., or other agencies e.g., TUVs in Germany, KOSHA and KSGC in Korea etc.);
- extent of public information, involvement and engagement, at various levels; and the extent of any 'right to know' philosophy;
- variable approaches to the regulatory use of risk assessment, especially QRA; as opposed to deterministic approaches;
- the exercise of regulatory discretion, active and passive;
- the degree of selectivity, or sampling, in inspection and other control activities; and
- variable attention to, and focus on, hardware versus 'peopleware' activities.

Put simply, although there is much commonality in the headline components of the mix, there is little real consistency at the level of detail. Virtually all industrialised (and most other) communities have overarching regulation at national level, with some also pursuing general enforcement at that level. But there are no real examples of a regulatory regime with a single national agency dedicated solely and exclusively to focussed chemical accident controls, even when there is no strong regionalised or local regulatory power; (although there are examples of initiatives, mainly recent, to consolidate the approaches of different enforcement agencies to seek efficiencies and/ or to reduce the risk of duplication of effort, etc). Some regulatory authorities have set up, within existing agencies, specialised groups for enforcement purposes or for technical or other specialised support - either generally or at national level - but this remains more the exception than the norm; and some are looking to consolidate the effort of different agencies. But many tensions are reported to remain, even where such attempts have been made. Where new agencies have been created they have tended to be additional rather than replacement, consolidating or integrating in effect and operational remit (e.g., the creation of the Chemical Safety and Accident Investigation Board in the USA although this is intended, inter alia, to bring more openness and transparency to the investigative process); or, in the case of a 'newly created' state, something of a mirror image of predecessors, pending solution to more pressing problems (e.g., 'Emercom'-for emergency planning and management- 'Gosgortechnadzor'-for technical safety inspection- and the fire authorities in the Russian Federation (although again this is something of an oversimplification)). Similarly, there are great divergencies - ranging from total to none - in the level or extent of regulatory delegation from the centre; and other than in

'extended' communities (e.g., the EU) there is little evidence of any drive towards trans-national harmonisation, unless via generalised, goal-setting approaches such as the *Guiding Principles* or the *ILO Convention*; even where there are trans-national risks. It is clear that any significant elimination of such regulatory and enforcement diversity, at either national or international level, would require major effort. (*Q4*) Approaches other than 'goal setting' are unlikely to be favoured, internationally. All such approaches appear likely to involve substantial costs for uncertain benefit, and bring with them the very considerable additional difficulties associated with the 'policing' of any such harmonisation,

3.4. International Regulatory Relationships

As it took Flixborough in the UK, and Beek, Manfredonia and Seveso in the (then) EC, to galvanise regulatory and other action on the European stage, so did Mexico City and very shortly thereafter the tragedy of Bhopal trigger a set of major international initiatives to meet the worldwide stakeholder reactions to those tragedies. As well as action at national level, for the first time international agencies (e.g., UN, OECD, ILO) combined to produce overarching strategies for the regulatory and operational control such major industrial risks. These initiatives brought together, on a formal basis, national regulatory bodies from many parts of the industrialised world. Some fora for international information exchange and regulatory cooperation predated the above events, of course (the International Association of Labour Inspectors is one such example); and there have always been international contacts at policy, technical and personal levels. But these international initiatives were the harbinger of a step change in such cooperation and collaboration, which has continued to increase to the present day. (A further recent example is the European Network for the Implementation and Enforcement of Environmental law -IMPEL). Perhaps the preponderance of such mutuality is to be found, currently, in and between European States and North America; but there has been substantial extension of that activity to the Middle East, to the Pacific Rim, including Australia, and via initiatives such as UNECE, PHARE and TACIS, to the emerging countries of Eastern Europe. (Q5) The effectiveness and value of this international effort is widely recognised, and is to be further encouraged; but much of it is likely to continue on the current 'goodwill' basis, as a more formal, let alone statutory approach may import many counterproductive elements.

The outputs of, for example, of the EU Committee of Competent Authorities (CCA) are *prima facie* testament to the merits of co-operative effort. The benefits - in terms of increasing mutual understanding, consensus, and coherence - are obvious. They are particularly valuable when the interests of other major stakeholders, particularly industry, are brigaded (indeed, many of the major industrial stakeholders are multi-national, with access to a wide overview of regulatory activity and standards). And such cooperation can be further facilitated by the involvement of other bodies (examples include the (major) outputs of CCPS - in the governing bodies of which there is substantial formal regulator involvement; and EPSC, where in contrast and for various reasons the regulatory involvement remains at the informal level). In general, such cooperation between stakeholders has the potential for much benefit, but in the wider risk management context, transparency of process is essential.

The types of relationships outlined above are - and this is of course a generalisation - essentially high level, and concerned more with policy initiatives than with enforcement or technical matters, where arrangements for cooperation tend more to be at the personal or similar levels. The point has already been made, that the major multi-nationals know considerably more about comparative national (or indeed local) regulatory and inspection standards than do the various regulators themselves. This is a particularly critical issue where the implementation of an international regulatory standard is involved; indeed in the EU the Seveso II Directive provides both for a Regulatory Committee - proceeding by qualified majority - to assist the Commission in certain tasks; and for a forum - the CCA - to assist coherent implementation

and consistent application of the Directive (subject always of course to valid issues of 'subsidiarity'). It is no secret that implementation of Seveso II (let alone Seveso I!) by EU member states has been variable, with only one country reporting coming in 'on time'. Indeed, the Commission warned 11 MS of possible infraction proceedings following the implementation deadline. However, there are other more positive aspects to the oversight exercised by the Commission, especially in the context of information exchange and mutual support towards consistency. One example is the facilitating of a series of 'Seveso II Inspections' mutual joint visits (MJVs) between member states, now well under way. (Similar programmes of MJVs operate within the EU Environment programme. Such MJVs may have varied main objectives, such as:

- help to a MS (e.g., Ireland, March 2000, re. a dust explosion risk);
- information gathering on the solution of a particular problem, or the development of a practical arrangement (e.g., The Netherlands, November 1999); and
- mutual familiarisation, learning and advisory visits (e.g., Germany March 2000), Finland (Aug 2000) and the UK (Nov 2000). The next MJV is planned for April 2001 (France), followed by Austria (Autumn 2001), and Italy (Spring 2002). Indeed it is likely that this mutuality approach will be the basis of the majority of MJVs in future.

Similar types of visits will also be appropriate, for example, for those countries (Accession States) such as Poland, Hungary, Cyprus, Slovenia and Slovakia which plan to join the EU.

Clearly, there is much evidence of mutual international cooperation and collaboration between and amongst (at least some) regulators. (Q6) But there remains considerable potential for further cooperation and collaboration.

3.5. Roles and Responsibilities, Qualifications and Experience of Inspectors

Any regulation is only as effective as the level of its observance; and major determinants of the latter are the effectiveness (and to a lesser extent the efficiency) of its enforcement. There is universal consensus that inspectors dealing with hazardous chemical industries should have appropriate qualifications and experience; but there is less consensus on how these should be defined. The studies of inspection systems referenced *ante* are typical of the wider picture and describe a complex and varied mix of qualification levels (postgraduate, graduate and non-graduate) and qualification areas (scientific, technical, legal, other) at whatever operational level, or enforcement locus (national, federal, state, regional, local, etc.). In some cases, pre-appointment experience of the regulated industrial sector is required; in others, appropriate post-appointment experience is career-managed. The strongly expressed industrial preference for regulator qualification and experience is for pre-appointment industrial sector familiarity (along with an appropriate level of technical competence)- and suggesting potential efficiency (and perhaps effectiveness) gains in both areas; whereas some regulators prefer a sector distancing policy, with the intention better to demonstrate regulatory independence. Most draw a distinction between prior qualifications and the development of further inspection competencies (which would include familiarity with audit techniques and perhaps their use)- which further on or off the job training would provide and develop; and most provide deep specialist back-up for 'general' inspectors. Such back up can be 'inhouse', or provided by a(n external) third party; and is not necessarily restricted to issues of science or technology. (Q7) More closely aligned supra-national standards suggest, at least superficially, some benefits, but these are difficult to quantify objectively; and any major commonality of this type would be difficult to structure and oversee.

3.6. Inspection Performance Indicators

As indicated earlier, the Workshop Organising Committee was concerned to limit discussion of performance indicators to those indicators that related to the primary subjects of the Workshop - audits and inspections. (A definition of *inspection performance indicators*, for the purposes of the Workshop only, is at Appendix 3).

The comments made in the context of *audit performance indicators* (in Section 2.11 *ante*) are equally relevant to *inspection performance indicators*, but different scales, weightings and perceptions might apply, particularly in the context of those socio-politico-economic issues outlined in Appendix 1. Indeed, the widespread lack of objective benchmarking of such indicators is considerably more marked, in the case of inspection performance indicators, even at national and sub-national levels. International benchmarking is the exception rather than the rule (although trans-national regulation would appear to call for it) (*Q8*) and it is clear that implementation of local action and solutions may need to precede wider consensus. This constraint should not preclude, however, the development of standards via international cooperation.

The 'SMART' approach to objectives is also similarly applicable. Relevant types, or classes of indicator would include *Outturn*, *Output*, *Activity*, *Efficiency*, *Effectiveness*, *Success*, *Cost* (*benefit etc.*), amongst others (there is of course some potential overlap amongst some of these). And in recent years, the overall focus has moved significantly from the *activity* to the *output/outturn* type of indicator, at both micro and macro levels. These issues are discussed further in Section 4 and Appendix *post*.

3.7. Commonalities with Audit Systems

The comments made in Section 2 above on commonalities between audit and inspection approaches and systems are, *mutatis mutandis*, equally applicable here.

3.8. Risk Based Inspection

The techniques of 'Risk Based Inspection' (RBI) of plant and technical processes are briefly discussed in Section 2.12 *ante*, where any cost effectiveness potential is also acknowledged. Also discussed there is the current general lack of any formal methodology or techniques to extend such approaches to audit activities. However, this is not the case for regulatory or enforcement activity, where techniques do exist, and have been widely applied for some time, to prioritise such activity/ies on a risk basis. The associated protocols, for undertakings with a chemical accident potential, generally involve judgements and estimates (sometimes fairly simply quantified or at least graded) involving the following elements:

- the hazard potential of the activity;
- numbers likely to be affected, on or off site, by an incident;
- regulators' familiarity with the hazardous activity;
- operators' reputation and past performance;
- regulators' perceptions of management competence; and
- elapsed period since previous regulatory control

coupled with judgemental weighting(s) for 'dread' and other elements of public concern (as discussed in Appendix 1). The outputs from these judgements and estimates are then used to deploy regulatory

resources between industry sectors, companies, plants and activities. This approach, clearly defensible in principle on the basis of regulatory cost-effectiveness, introduces a complex mix of risk elements, combining overall aspects of risk associated with the plant, with those risks associated with the regulator 'getting it wrong', either from misdirected focus of activity, or from incomplete or inadequate inspection. This context is further complicated where the regulatory activity involves licensing, permissioning or other approval activity; and where aspects of risk perception, communication and tolerability are involved, especially in any absence of other stakeholder involvement. (Q9) Any benefits may be won only at significant cost.

3.9. Self Regulation

The issue of self-regulation has always been contentious. It has become a commonplace that the duty to control risks lies primarily with the creator of such risks (UK 1972); and indeed in the context of the issues discussed in Appendix 1 this duty is driven by an economic as well as a moral imperative. Furthermore, the operator is subject to controls (either voluntary or mandatory) which sit alongside, but which are not specifically, regulatory controls, such as external and company standards, internal and external quality protocols, insurance requirements, etc. Such protocols are designed to ensure, verify and validate the very technical, managerial and operational systems that are the prerequisites of risk (and indeed other organisational) control. In the great majority of undertakings (and in most accident/incident investigations) failure to control risk adequately is almost invariably found to be as a result of an act of omission rather than of commission. However, it is very unlikely that in any democratic system, public tolerance of any imposed risk (and especially where social amplification of risk is involved) would result without the presence of, and confidence in, an independent regulator. The 'trick' is to combine the processes of self and external regulation effectively and efficiently. Nevertheless, there may be many elements of the self-regulatory process with the potential for regulatory acceptance. (Q10) Appropriate and transparent safeguards, including the engagement of relevant stakeholders, would be a prerequisite to any such 'self - regulation'.

3.10. Regulatory and Enforcement Discretion

Regulatory and/or enforcement discretion is not simply a halfway house between slavish application of detailed regulatory standards and the self regulation referred to above. It is always an element for consideration, even in a regime which involves licensing (and therefore potential license excursions of one or other kind); and as the regulatory norm moves in the direction of a goal setting approach, such discretion becomes an essential part of the regulatory and inspection process per se, especially as the industrial process or the control measures will rarely be standard, or the risks be of a similar nature or order. Furthermore there is often inconsistency of detail in regulatory requirements themselves, either at national level (for example, the differences between RMP and PSM requirements in the US) or supra-nationally (such as the differences – despite great commonality – between EIA, IPPC, EMAS and 'Seveso II' in the EU). There is a tension here between the search (indeed need) for consistency (at many levels and of many types, e.g., between different inspectors, between different processes and activities, between different in-state regulatory agencies, and internationally) and the discretionary tolerances which goal setting approaches facilitate. (Q11) It requires a consensus and balance that may not be easily achievable, given the wide range of technical, legal, social, economic and cultural contexts in which such risks may be located. And the context is further complicated by the common operational mix, in the regulatory function, of enforcement and non-enforcement (compliance assistance) activities.

3.11. Involvement of Third Parties in the Inspection Process

As indicated earlier, there are often many layers and types of direct and indirect risk controls applied to an industrial undertaking. Many of these controls are to satisfy the regulator - a simple example would be the examination of steam generating or other pressure plant - about both regulatory and technical compliance: a process which is, as discussed above, becoming increasingly risk-based, and which has many commonalities with audits (especially technical audits). In such cases, the regulator tends to be concerned with the competence of the third party performing the control, as much as with that of the operator. A second example might involve the regulatory interface of a 'User Inspectorate', and indeed this might import other regulatory tensions (as, for example, with the 'Seveso II' Directive). Many countries license, or otherwise 'approve' aspects of hazardous installations; such licences/approvals often being in part dependent on inputs from third parties of various kinds. (Q12) There are efficiencies to be had here, but there are many attendant difficulties, particularly in the wider risk management arena.

Many quality and other organisational procedures call for accreditation, certification and similar *imprimatura*, almost invariably awarded by external or independent third parties. Again, it would be unusual - but there are exceptions - for the regulator to 'second-guess' such accreditation etc. (even if the regulator had such specific competence). Indeed, regulators will sometimes need to engage the assistance of third parties (and there are many examples of the practice), where it is necessary to complement existing inspection personnel, either where there are shortfalls in technical or other skills, or to augment scarce resources. Taking this latter approach one stage further, there is again no obstacle, in principle and indeed in practice (e.g., JRC 1998a, JHM 1999a), to using, indeed approving, such third parties as first line assessors in some mainline aspects of the regulatory function (for example the initial assessment of a Safety Report). Of course, appropriate safeguards would be necessary in such cases (for example, the September 2000 meeting of the EU CCA discussed possible rules for dealing with conflict(s) of interest), but experience to date indicates that such safeguards are practicable. Once again, the 'trick' is to combine regulatory transparency, with cost efficient and cost effective approaches.

3.12. Resource Implications of Inspection Systems, and Regulatory Cost Benefit and Effectiveness

All regulation involves the deployment of resources, of one or another kind. Such deployment may be direct or indirect, will inevitably come with opportunity costs, and will bear either directly or indirectly on most, if not all stakeholders. Many regulatory systems now require any additional regulation to be justified on a cost-benefit basis, although the 'ground rules' for this process are generally ill defined in both economic and social terms (particularly where 'multiplier' effects may impinge on issues such as 'value of life'). Most regulatory authorities publish annual or other reports, outlining their performance (usually in 'activity indicator' terms, alongside statistical compilations of accidents, incidents, ill-health incidence, complaints, for the same period. It is increasingly the practice for such reports to be trended. Such studies may distinguish relative outlays on different industrial sector risks. All this allows some consideration of regulatory cost-efficiency, again perhaps on a trended basis. But questions of regulatory cost effectiveness are both more difficult and more contentious, the latter again particularly where aspects of aversion, dread, etc., are involved. Indeed, it may be argued that it is this latter element of perception, perhaps coupled with the regulatory use of the 'precautionary principle', which may justify any skew in resource deployment in favour of the low probability/high consequence type of activity, typical of chemical accidents. (In practice it is entirely typical of regulatory regimes for, and regulation of, such activities). It is unusual to find any detailed, quantified cost justification (e.g., on cost-benefit grounds) for such resource deployment in the open literature, either from the regulator or the regulated (although the debate on value of life saved - however defined - is beginning to take off). (Q13) There are currently no

widely accepted general protocols for demonstrating these aspects of regulatory performance, even in those states where some form of 'business case' in advance of additional regulatory control has become obligatory. Indeed, most such 'business cases' are prepared only to a very basic level of content.

3.13. Implications of Charging for Elements of the Regulatory Process

Most regulatory inspection systems for hazardous chemical installations involve licensing or approval procedures, at national, regional or local level. Where licensing is not required, some other form of regulatory 'permissioning' is usually the norm. It is quite usual for such licensing and similar processes to attract a charge from, or on behalf of, the regulator (e.g., Jones 1997 for some EU examples). (Q14) This charging tends to be on either a (scaled) fee basis, or less commonly, on a cost basis; and such charges are tolerated, (albeit sometimes reluctantly), by those from whom they are levied. Indeed charging of this kind may be considered one manifestation of the 'Polluter Pays' principle. There has been occasional debate as to whether or how licensing or similar regulatory activity might compromise the regulator, and there has been criticism where operational and safety permits have a common regulatory source (e.g., Cullen 1990). But such charging is not generally perceived to be controversial, in principle. However, the current UK determination to levy charges not only for the assessment of Seveso II Safety Reports, but also for any associated - and other - validation, verification and other inspection activity, has resulted in fierce debate there, with much concern expressed, and only reluctant acquiescence on the part of industry; and the process is far from complete. Certainly such charging proposals continue to be resisted (at least in principle, if not thus far in practice) by those who are required to meet them. The nature and basis for them are being closely scrutinised; and the wider and longer-term implications for the regulator/industrial interface are still unclear.

3.14. Inspection Follow-up; Reports and Follow-up Activities, Successes and Failures, Improvement Potential

The narrative in Section 6 *post* will give a clear picture that there are very few new causes of accidents; and that investigation of such accidents continues to show the same failings, time and again, failures which continue to manifest themselves also in both audits and inspections. The essential need for adequate follow-up is well demonstrated - a need emphasised with regulatory force in for, example, Article 18 of Seveso II, which requires, as part of an Inspection System, an appropriate programme of inspections, the production of an Inspection Report, and regulatory 'follow-up' with the operator within a 'reasonable period' - particularly important where deficiencies have been identified. (Of course, in the same instrument, regulatory discretion is not permissible in the context of 'serious deficiency', where prohibition is the duty imposed on the regulator). (*Q15*) At least part of the potential for successful improvement lies in the persuasive presentation of inspection reports, and in appropriate follow-up; but it is a fine judgement how best, and at what level, this is most effectively done. Rigour, in follow-up, can be variable in nature and effect. Certainly, full engagement with the operator is a prerequisite; and follow-up as part of a planned programme of improvement is to be strongly recommended

3.15. Implications for SMEs, and for Emerging or Developing States

These issues were discussed, in the context of audits, in Section 2.17 *ante*, and similar overall considerations (as developed in that Section) apply here insofar as both SMEs and emerging or developing states are concerned. (Q16) Moreover, the trend is for the degree of inspection and oversight of facilities with chemical accident potential to be based on the degree of hazard or risk, real or perceived, presented by those facilities, regardless of the facility size or available resources; and this approach has further implications for both SMEs (in particular) and undertakings (of whatever size) in emerging or developing states.

3.16. Community and Other Stakeholder Involvement

Section 2.18 above briefly considers the implications of any community or other stakeholder involvement in the auditing process or its outputs. Few current examples are described. A comparable paucity of examples exists for such similar involvement in the inspection process (*per se*, although there are examples - as in the Seveso II Directive, or in US EPA requirements - of such involvement being required in emergency planning and land use planning; and Seveso II Safety Reports etc., are to be public documents (*cf*. the limited availability of the contents of the 'Safety Declaration' in C.I.S. states, where it is not statutorily available to even the Emergency Planning Authority). Notwithstanding this, direct Community or other wider Stakeholder involvement in the inspection process (and indeed some other elements of the risk control and risk mitigation matrix) is currently considered problematical - at technical, organisational, and (especially) at social levels. (*Q17*) However, there are many benefits potentially to be gained from wider involvement (if not some degree of participation) in the overall inspection process, especially in the wider context of risk management described in Appendix 1.

3.17. Summary of core questions

Representative questions posed in the Workshop version of the Discussion Document are itemised in the supplement at the end. The core questions and issues raised in this Section on *Inspection and Inspecting* are summarised below. They involve the following:

- Tensions between harmonisation and independence; in regulatory standards; and in approaches to inspection and enforcement;
- The need for increased mutuality and cooperation between regulators;
- Improvements in regulatory transparency;
- Benefits of the regulatory and inspection process (including resource implications, issues of cost efficiency and effectiveness, and the implications of the involvement of third parties in the process); and
- Stakeholder and Community Involvement.

4. PERFORMANCE INDICATORS AND THEIR RELATIONSHIP WITH AUDITS AND INSPECTIONS

4.1. General

This section of the Discussion Document considers the types of performance indicators that are available, and their relationships with audits and inspections. A more detailed description and analysis of the issues considered here is to be found in Appendix 4 *post*, along with greater detail and examples of a number of such approaches. Appendix 4 also considers aspects of performance benchmarking, the question of anchor points, and the complex question of criteria against which performance may be judged. A number of critical questions are posed as the narrative in Appendix 4 is developed.

4.2. Trends and Commonalities

The narrative in Sections 2 and 3 *ante* clearly illustrates that there is substantial commonality between the basic approaches to audit, and to inspection of industrial systems. This has been accompanied by a trend, in the development of both management systems audit techniques and regulatory approaches, towards some form of performance measurement. Indeed, it is a commonplace (although by no means a universal view) that: "If you want to manage something, you need to measure it". Given these inherent commonalities, it is hardly surprising that they tend to be echoed in the measures that are generally used to assess performance.

4.3. Types of Performance Indicators

Essentially, there are three core types (or groups) of performance indicators, in this context:

- *activity*, which measures what is being done;
- output (or outturn), which measures the effects of activity/ies; and
- success, which compares outputs or outturns to criteria.

Such indicators can be used free-standingly, comparatively, progressively, or as an absolute measure of performance, from micro to macro levels. And just as there is significant commonality between audit and inspection approaches, so the above types of indicators are appropriate for use, in principle, equally by regulator and regulated. They also have proxy value for other stakeholders, especially in third-party judgements about performance. The major differences lie at the level of detail in their application (and in the value judgements which underlie the use of performance criteria), in either a safety or an environmental context. This overall applicability is a major plus factor in any consolidated or integrated approach.

4.4. Sources and Availability of Performance Indicators

There are many examples of performance indicators openly available, and there is a great deal of commonality between them. Many have been developed within organisations (often initially for internal use), but have then been more widely released. Furthermore, a large proportion of such indicators (and the associated question sets) are closely allied to those used for other assessment etc., purposes, such as quality or environmental performance via ISO approaches. In general, use of such indicators appears more comfortable when activity rather than output or outturn is being measured, or when incidence rather than system condition is being monitored and assessed. Similarly, there is less difficulty apparent when 'positive' indicators are being monitored, as opposed to the measurement of 'negative' outputs and outturns. It comes as no surprise that there is much more openness about, and availability of, performance measures than about performance itself, or about performance criteria.

4.5. Quantification, and Links Between Performance Measurement and Risk Assessment

The assessment of operational performance in S, H & E, and the associated risk(s) from the hazardous activity/ies are clearly closely linked. Many audit and inspection systems employ indicators that are qualitative, or at best semi-quantitative. However, indicator elements are being increasingly quantified, to provide inputs to the risk assessment process *per se*, so as to reflect explicitly the level of management performance in any risk output figure. And some performance assessment systems (including systems developed specifically for regulatory purposes) are now capable of generating combined and/or integrated output, at least at the local level. Some problems remain in the use of such integrated systems, currently; especially for regulatory purposes.

4.6. Benchmarking, Standards, Anchor Points and Criteria

Performance indicators are, of course, meaningless if applied in a vacuum. Such indicators are readily applied in comparative, or progressive contexts (although even here care is needed in both application and interpretation). More recently, performance indicators and outputs have been set against standards (either qualitative or quantitative) at all levels between local plant, and company or industry sector. Increasingly, similar concepts are being applied to assess regulatory performance, either in the production of effective regulation, or in its effective prosecution. Benchmarking in this context remains problematical; and the public development of and wider consensus on, anchor points and criteria remains contentious (especially where there is community or other stakeholder involvement, and most particularly where questions relating to the 'tolerability' of risk(s) are concerned); as does their integration into wider risk management approaches, and indeed into the more limited question of the co-ordination (and perhaps integration) of inspections and audits. Solutions to the current difficulties at this more local level may, however, provide some impetus to more general progress.

4.7. Critical Questions

As indicated above, more detailed exposition and analysis of the above issues is to be found in Appendix 4. This detail has been appendicised so as not to interrupt too greatly the progression of the general narrative, on audits and inspections, to the question of their co-ordination and/or integration. Nevertheless, the issues outlined above and detailed in Appendix 4 give raise a number of important questions, of practice or of principle, which need to be considered as part of the overall process of co-ordination and integration. Many of these questions are to be found in the "Supplement to Discussion Document (Workshop Version).

The core issues and questions are concerned with the following issues:

- the need to develop robust output and outturn indicators and measures to supplement activity measures;
- the problems of benchmarking, anchor points, criteria, etc.;
- the lack of consensus on types of, and on appropriate performance criteria;
- further coordination and greater transparency of outputs; and
- wider stakeholder and community involvement.

5. CO-ORDINATED AND INTEGRATED INSPECTIONS AND AUDITS

5.1. Co-ordinated and Integrated Approaches to Audits

Industrial and commercial operators have for some time been moving towards combining, consolidating, and indeed integrating safety, health and environmental management systems, to facilitate the meeting of a number of operating challenges, both internal and external. (It would be misleading, however, to suggest that this movement is unidirectional, even amongst the larger organisations; and of course, SMEs have their own typical difficulties here). Such integrated systems are designed to allow a consistent, balanced approach to addressing diverse - and sometimes potentially competing - business In principle, integrating management systems reduces any compartmentalisation in the organisation, allowing a single sweep of an integrated tool as opposed to the multiple sweeps otherwise necessary. Many elements of S, H & E management systems (e.g., organisational aspects, management of change, emergency procedures) have in fact substantial commonality. Indeed, it is sometimes possible to brigade other aspects - for example, hazard identification, or staff auditing, into the same audit processes. Furthermore, as illustrated earlier in this document, there can be substantial commonality between the question sets for S, H & E management and those of other assessment regimes (such as quality). (As one somewhat audit-weary risk manager put it to this author: "If you are ISO accredited, you can ignore the next few thousand audit questions"). Indeed, many larger companies have not only developed integrated SH&E management systems, but have combined them with regimes based in total quality management approaches. Others integrate them into the business decision-making process (CCPS 1998). The potential benefits can be substantial, not only for the operator in preventing or reducing internal duplication of effort, but also externally, if there is duplication of or from other stakeholders (including regulatory authorities) studying the same, or related, procedures. Additionally, there is great potential scope - again at least in principle - for improvements in consistency and coherence, at all levels of the process, for all those involved. And because the approaches focus on the core organisational or business processes - culture, organisation, technology, people - any Change Management or Business Process Re-engineering should thereby be greatly aided, and measurement of the scale and effects of change facilitated.

Such consolidation and/or integration allows for easier communication both internally and with a wide range of external stakeholders. Indeed wider interactions may be facilitated thereby, including at least in principle those between regulators and regulated. (In practice, however, regulators currently tend to regard outputs from the regulated (or associated third parties) only as indicative illustration of performance, rather than definitive demonstration of compliance.

At this stage, most consolidated systems are in-house (e.g., Bayer's BAIT), and/or proprietary (e.g., Det Norske Veritas' INTEGRA). Many of the early combined approaches were essentially developed via the simple process of aggregation of formerly separate systems, with any resultant duplication removed. In general, any validation or verification is assumed to flow from that associated with the contributing components, and again the applicability, effects and impacts are assumed to be similar or in some case identical. Later models are more purpose built, however; contain weightings; and are more objective oriented. A major further initiative is the development of tools such as ProSmart (Campbell et al, in CCPS 1998), which is designed to combine many elements of audit and PSM, with focussed benchmarking and improvement functions, and the capacity to interface with the inspection process. Views remain divided on the overall advantages and cost effectiveness of such systems, especially in the area of low probability, high consequence events and incidents; and how performance standards are best verified and validated, with appropriate transparency. (Q1) Many consider that there is a need for substantial further development before the full potential of such systems can be fully realised.

Furthermore, such integration of approach in an operator may not currently be matched by that of the regulator.

5.2. Co-ordinated and Integrated Approaches to Inspections

Aspects of this, with some examples, are discussed in some detail in Section 3 above. To summarise, there is widespread recognition of the potential for cost efficiency of regulatory co-ordination and integration in principle - and a strongly expressed desire, from the regulated, for a move in this direction - but substantially less evidence of it being put into practice on any scale. (Q2) The reasons for this are unclear, and probably complex; and will certainly involve elements of protectionism amongst those involved, at both national and international level.

Furthermore, there are currently few studies available which demonstrate the scale of any cost effectiveness of such co-ordinated etc. approaches, at whatever level may be appropriate (plant, company, industry; local, regional, national - or indeed international). (Q3) Again, why this should be the case is not immediately clear. Certainly, such studies would not be simple; but techniques exist which should be readily adaptable to this context. There is, however, and without doubt, the additional difficulty of the lack of availability of and consensus on appropriate output and outturn measures, which is discussed in Section 4 above, and in Appendix 4.

5.3. The Co-ordination and/or Integration of Audits and Inspections

The weight of such evidence as exists suggests that there is potential for both cost effectiveness and cost efficiency in moves to co-ordinate (or ultimately integrate):

- industry systems for auditing SH&E (and perhaps other) management processes; and
- regulator systems for inspection and enforcement

although accompanying difficulties are also anticipated. In this context, one might also anticipate, using similar arguments, that there is the potential for benefit (in both effectiveness and efficiency) at the interface between audits and inspections, if the commonalities can be managed and any synergies effectively harnessed. Indeed, such approaches should be at the heart of any serious move to integrated risk management overall. However, there remain many problems and obstacles, either of a practical, or perhaps more problematically (in the context of wider stakeholder involvement), of a philosophical and/or cultural nature. Many of these are discussed above and in Appendices 1 and 4. (*Q4*) Many of these problems are unlikely to be easily resolved.

5.4. Summary of Core questions

The questions raised in this section of the Discussion Document are to be found in the "Supplement to Discussion Document (Workshop Version)". The core issues arising may be summarised as follows:

- The need to overcome current difficulties in methodology, including
 - Overall coordination and/or integration of audit techniques
 - Overall coordination and/or integration of inspection techniques;
- The development of approaches to the coordination and/or integration of audit and inspection approaches;
- The further development of integrated risk management techniques;
- Analysis of the cost effectiveness and cost efficiency of the introduction and adoption of such techniques and approaches; and
- The problems of wider stakeholder and community involvement

6. LEARNING FROM EXPERIENCE(S), AND IMPROVED SHARING OF INFORMATION

6.1. The Process

As (Kletz 1993) indicates:

"It might seem to an outsider that industrial accidents occur because we do not know how to prevent them. In fact they occur because we do not use the knowledge that is available. Organisations do not learn from the past or, rather, individuals learn but leave the organisation, taking their knowledge with them, and the organisation as a whole forgets".

If hindsight is defined as wisdom after the event, learning lessons from accidents, incidents (and all other relevant data, including the many outputs of audit, inspection and other activities) is a process of turning hindsight into foresight. But availability of data is only the start of the process; quality data need to be structured and accessible to become a potent preventative tool.

6.2. Analysis of Lessons Learned

Information and data on past events, accidents, incidents (actual and potential) and other technical and operational malfunctions is, of itself, only potentially valuable, unless it is available in such a form that it can be used in preventative action. But, sufficiently open and available and adequately structured, such data then provides vital inputs to future risk management at all levels. Such information is critical to the design and content of audits, and to the competence of those who perform them. Equally, it informs improvement in the processes of inspection, including investigation. Repeatedly, investigations of major incidents have identified many common issues and causes, and of lessons learned, from the investigation of a selection of high profile incidents involving hazardous chemicals, of both a technical and a managerial or operational nature (IALI 1997). But as indicated earlier in this Discussion Document, many of the lessons identified appear not to have been learned, or the consequential improvements necessary have not been taken into effect, either in the domain of the operator (with increases in compliance, or reduction in incidence rate); or with the regulator, in his preventative and enforcement outputs. (Q1) But the problem persists, even though its nature and character has been recognised, described and analysed.

6.3. Types of Data

There are several types of relevant data. These include:

- information about accidents, especially, but not exclusively, investigation reports;
- information on system performance and malfunctions, leading to 'incidents' or 'near misses';
- event data the non trivial events of a technical or 'peopleware' system;
- technical performance and reliability data; and
- human performance data.

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In some case, such data will be in the public domain, for various reasons; and the effects of the move towards greater 'Freedom of Information' are ever widening. However, the great bulk of such data will be held privately in one way or another, because of such issues as ownership, legal or commercial confidentiality, risk of regulatory response, potential criminal and/or civil liability at law or elsewhere, or perhaps simply the resource or opportunity cost of freeing up the data; and in some circles (e.g., insurance), such data is perceived to have commercial value. These may be substantial obstacles to wider availability of such data, and all 'solutions' will come at a cost, of one kind or another.

6.4. Sources and Availability of Data

Obviously, the two major sources of S, H & E data are industry and the regulator(s). In the case of industry, some of the available information will come from auditing and similar activities; but this will only be a (possibly small) proportion of the mass of information which develops and accrues at all levels (a spectrum ranging across the individual, the plant, the company, the industry, etc.) throughout the lifetime of an activity. Recording systems (where they exist) for such information will vary greatly, in structure, type and quality. Regulatory data will accrue from information provided statutorily, collected during regulatory functions, and otherwise. Again, recording systems will be various and variable, in design, content, quality, accessibility, and recovery potential. Although some information exchange mechanisms exist (the mechanisms between operators tend on the whole to be more structured than those between regulatory bodies, even at local level), there is little coherence, with much reliance on goodwill and personal as opposed to organisational relationships. Other major sources include the insurance world, in its various forms and applications, certifying and accrediting organisations, and other relevant bodies. The databases of the insurance (and reinsurance) world would, if made available, form a significant increment to the fund of information, even though such databases are usually structured and deployed for different purposes. Indeed, more active engagement and cooperation, both from specific insurance companies and from organisations representing insurers specifically (e.g., Lloyds, J&L Marsh and McLennan, etc.) or more widely (e.g., L'Association Internationale pour l'Etude de l'Economie de l'Assurance - the Geneva Association), would be greatly beneficial. Recording systems (where they exist) for such information will, again, vary greatly, in structure, type and quality. In all the above cases, maintenance and updating can present significant cost and resource problems, and any solutions identified will need to be implemented on a cost-effective basis.

6.5. Data Collection

There are many vehicles for data collection. Most remain closed, in-house or industrial sector systems (as an example of the latter, the ICCA 'Responsible Care' subgroup on performance reporting collects data from all 45 currently participating countries), with limited if any access to other parties. However, some databanks are more widely available, as described below. Databanks include information on:

6.5.1. Accident Data

Here a great deal of data exists, of variable quality. There are various databanks, such as FACTS (ex TNO), WOAD (ex DNV), MHIDAS (ex HSE/AEAT), ARIA (ex BARPI). (It was agreed in the mid-90s (at a meeting in Lyons of the OECD Expert Group on chemical accidents) that ARIA would form the basis of an OECD accident database, and also cooperate in the UN/ECE convention on trans-boundary effects), and, of course MARS (ex EU, JRC-Ispra). Despite the relative paucity of incidents on this latter database, a substantial number of analytical studies have been made of the data it contains (e.g., Kirchsteiger 1999). Two good sources of descriptions of available databases are (CCPS 1989, 1998a) and (ESReDA 1997). The latter reference documents in some detail 39 databases, covering in excess of 500,000 reports and ranging in database content of incidents from low hundreds to around 80,000. Of these databases, only 7 are available without any restrictions, whilst only nine of those with restrictions can be purchased by end-users. ESReDA is also developing a framework for the design of accidentincident databases, including quality elements. A recent significant initiative has been the launch of the UK IChemE's 'The Accident Database' (TAD), in which a large proportion of the entries carry the all-important 'lessons learned' message. All such databases, with or without the valuable 'lessons learned' analysis, carry a wealth of information, the main problems being variability in data quality, accuracy and completeness of coding-up, depth of analysis, and lack of 'population' detail.

6.5.2. Incident Data

Usually in house, closed systems; but there exist several methods of making (semi- or) publicly available, often in anonymised form, both data and (sometimes) analysis, examples being the UK IChemE's 'Loss Prevention Bulletin', and CIA's Datasheets. TAD is unusual in that a large proportion of the entries are sourced from confidential in-company reports; whilst a further important recent initiative is the setting up in 1997 of the CCPS Process Safety Incident Database- PSID. (However, access to the PSID data is to be restricted to participating companies, currently). Also, industry or sector fora exist (e.g., The International Process Safety Group) to facilitate information exchange. The European Process Safety Centre (EPSC) has recently agreed an incident information exchange scheme, using easily accessed IT, but again this is restricted to its own membership.

6.5.3. Event and Reliability Data

There is a wealth of event and reliability data available in principle, from a whole range of sources; but often such data is confidential to the specific source, or component or industry specific. Information that is closely specific may be very sparse. And while data may exist in abundance for common components failing at high frequency, low frequency failure data is inevitably rarer; and the potential user is driven to the less specific. Indeed the problems associated with the use of generic data, or extrapolation of specific data (along with the difficulties of identifying relevant populations), are sufficiently well documented to require no

further description here. Examples include the databanks of the SRDA, the Offshore Reliability Database OREDA, and ERDS at JRC-Ispra. For the future, CCPS is currently collaborating with DNV, and building on OREDA, to produce PERD, the Process Equipment Reliability Database, the structure of which is now in place, but which is, as yet, essentially unpopulated by data.

Other major sources will include the following:

6.5.4. Regulatory Data

The regulatory function in the context of chemical accident prevention, preparedness and response is, as described in Section 3 above, multi-faceted. Such varied functions provide very many opportunities for the collection of data and other information, whether obtained as a result of statutory provision (e.g., the contents of a Safety Report or an Environmental Impact Assessment), or collected in passing during regulatory activity such as inspection or accident investigation. This means, of course, that there exists, albeit in an internationally fragmented state in the records of regulators, at various levels and locations, an enormous compendium of data relating to industrial plant design, construction, maintenance, operational and other standards (and indeed of operator performance); with the potential for a wide range and type of analyses (e.g., by company, industrial sector, industry, process, hazardous substance, precautionary elements etc.). Such regulatory data is rarely openly and freely available (despite progress in the 'freeing up' of information over recent years); is seldom managed effectively by those who hold it, even at local regulatory level; is rarely, if ever, kept in common format; and its potential for wider benefit is infrequently used and never maximised. International cooperation in its exchange, opening up its potential as an unparalleled intelligence source, and its wider preventative deployment is generally negligible, even between regulatory bodies, let alone other stakeholders. Nevertheless, some direct initiatives are developing; and there will be beneficial spin-off in this area from other mutual activities, such as the MJV programmes.

6.5.5. Insurance Data

This type of information mirrors much of the above, but potentially with two other important elements - cost (both prospective and retrospective), and population. However, a major current problem is the relative inaccessibility of such data to third parties; and the resource costs which would result from the implications of conditional release. An additional difficulty hangs on the commercial value that such information is perceived to have, by some stakeholders.

6.5.6. Other Data

There are, of course, many other sources of data, and many other organisations and systems intelligence involved, directly or indirectly, in data gathering, analysis, collation and dissemination (for example the various media, emergency services records, and so on). But most of the data held by such systems will generally be included, in one way or another, in the major compendia described earlier.

Clearly then, there is no shortage of incident data. The main problems appear to be variable quality, restricted availability and, to an extent, user friendliness of such data; and additional needs for more comprehensive population data. These are very important shortcomings, in the context of chemical accident prevention, preparedness and response, especially where they restrict the dissemination of lessons learned. (Q2) And there are further problems, of available resources.

6.6. Summary of core questions.

The core questions and issues raised by this Section can be summarised as follows:

- There is no real overall shortage of basic data (incident, accident, performance, regulatory, etc.);
- There is much evidence of a continuing failure of corporate memory;
- Clearer analysis of existing data is required, to incorporate 'lessons learned', which should then be shared;
- Quality and relevance of available data should be optimised;
- Wider and easier access to available data should be encouraged;
- Stakeholder and community involvement should be encouraged; and
- Information and data sharing should be cost effectively and efficiently managed.

7. SUMMARY OF MAIN ISSUES

7.1. Main issues

This Discussion Document has provided a wide (but necessarily selective) international overview, of some important aspects of *audit and inspection* (as defined), of *performance indicators* and their use, and of the potential advantages of more *consolidated or integrated approaches* in these areas. The value of *data sharing* has also been considered. Each of these issues contains areas of both strength and weakness, and the route to optimal cost-efficient and cost-effective risk management is not always clear. Many critical questions have been raised, with the intention of providing a stimulus (should such have been needed) to debate in the Workshop; to subsequent focus on any necessary revision of *The Guiding Principles*; to ongoing action from the Workshop participants, and those they represent; and most importantly, to cost effective solutions to the problems in chemicals risk management which this analysis has identified.

7.2. Core questions

The Workshop version of the Discussion Document raised over one hundred and thirty questions in the course of its narrative. The relevant core issues addressed by these questions are summarised at the end of each Section, *ante*; and representative questions from the Workshop version are listed at the end of the Discussion Document in the chapter entitled "Supplement to Discussion Document (Workshop Version) – Representative questions from main text narrative." As might be expected in a Discussion Document, and in subsequent Workshop discussions, about issues that are closely related, a substantial commonality of core issues and critical questions relating to them emerged in both the initial drafting and in subsequent debate. These were principally concerned with:

- validation, verification, and the robustness of models, methodologies and techniques;
- cost effectiveness and/or efficiency of approaches and methods;
- development of, and consensus on, performance indicators, measurement and criteria;
- transparency and openness; and open information sharing at all levels; and
- cooperation, collaboration, and wider stakeholder and community involvement

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APPENDIX 1

A Short Note on Aspects of Risk Control and Risk Management

Life inevitably brings with it the prospect, or the risk, of harm; and it is one of life's ironies that those branches of science and technology which have been prime movers in the improvement of many aspects of our lives - in particular the chemical and engineering industries - are held in greater disregard because of the hazards and risks of their products and artefacts, rather than for the benefits to life and its quality which these have brought.

The tensions that arise between the thrust for technological progress, and the concerns of those who might be affected by any adverse impact, are rarely easily resolved. In many cases the science or technology involved is far outside general public experience or understanding: and indeed public perception of the hazards and/or risks may well be driven by issues which are more in the domains of the social rather than the physical sciences. It is in this context that the approach of "risk management" has been developed and applied, to try to reach a consensus of "tolerability" around which the various stakeholders - regulators, industry, consumers, etc., can operate. The basic principles of risk assessment and management are central to international initiatives such as the EU 'Framework Directive' on health and safety, and to more focussed Directives such as the so-called 'Seveso' Directives on major industrial accident hazards, or the Directives associated with environmental protection. Similarly, they underpin the Risk Management Programs and Process Safety Management Programs of OSHA and EPA in the USA, and similar initiatives elsewhere (e.g., US 1997, A/NZ1999, 1999a, CSA 1997, BCC 1977). And they are at the core of regulatory criteria such as 'reasonable practicability', 'best environmental option', 'best practicable means' and so on (Sing 1998), which increasingly underpin goal-setting approaches to the control of such risks.

Not surprisingly, there is no agreed definition of the risk management process: the issues and interactions can be very complex, and much effort is going into defining how they can be characterised; but it is possible to sketch the overall process into a coherent architecture, based on the principles of:

- IDENTIFICATION the recognition and location of any problem;
- ASSESSMENT the bounding and dimensioning of any problem;
- CONTROL the limiting of the scale of any potential problem, by prevention or avoidance;
- MITIGATION the amelioration of the residual elements of any problem.

Measures used to parameterise, or to limit, the component elements may vary between different types of hazard or risk, between different elements of the overall environment, or between different economic and/or cultural systems; but the underpinning logic of the overall approach remains a transparent and potent taxonomy.

At the heart of the risk management approach lies an essentially simple set of critical questions. The core questions are: What If?, What Then?, Then What?, So What?

"What If?" requires a combination of technical expertise, experience, and a degree of imaginative insight. "What Then?" and "Then What?" are essentially the techniques and practices of risk assessment, usually quantified, at least in part. "So What?" is the area of objective judgement, informed but not constrained by the earlier inputs. It is a decision process, often rigorous, which involves:

- a) dimensioning of likely risk with an understanding of the uncertainties inherent in the assessment process (and answering the further question "How much of what kind of what risk to whom/what?");
- b) reference to the likely benefits generated and the associated political, social and economic considerations;
- c) judgements as to tolerability or acceptability for groups directly and indirectly involved, and for any other stakeholders; and
- d) sometimes, decisions as to further reductions in risk, taking cost (including effort, and available technology) into account.

It is, in short, a process which is essentially economic and political, and technically informed. And because the process relates to the human condition, or to the wellbeing of other parts of the environment, it is ethics-rich.

The models and methodologies that have been developed for the processes of risk assessment and risk management are many and varied. Risk assessment involves an interactive process which considers (using risk assessment jargon) the source, the source term, the dispersion, the dose and the impact; a process in which there are many common components, including:

- in IDENTIFICATION, the use of substance/threshold approaches (and the current search for a hazard or risk equivalence approach);
- in ASSESSMENT, the classical approaches to consequence and probabilistic assessment, including:
 - a) comparative methods (process/system checklists, safety etc audits and reviews (technical and people), relative ranking, indices, preliminary/process hazard analyses etc.);
 - b) fundamental methods (HAZOP, 'What if?' Analysis, Cause/Consequence Analysis, Failure Mode and Effects Analysis, Failure Mode, Effects and Criticality Analysis, Goal Oriented Failure Analysis etc.); and
 - c) logic diagram methods (HAZAN, Fault Tree Analysis, Event Tree Analysis, Human Reliability Analysis, System Success Trees, etc.);
- in CONTROL, conformity with regulatory, technical and operational standards, the use of justification packages (safety cases) and information packages (safety reports), and licensing and other permissioning and approval activities; and
- in MITIGATION, emergency and land use planning, and public information and involvement.

Risk assessment, and particularly quantified risk assessment, has the capability to dimension, to rank, to focus, and to test the interdependence and interactive responses of the various component elements. There have been significant developments over the last 20 or so years in modelling techniques for such hazard and risk assessment, as a result of an enormous international research effort, especially in the areas of chemical and physical phenomenology (although the assessment of direct environmental and indirect human hazard or risk is currently less well developed and therefore even more uncertain than that

of direct risk to man). Most of the scientific and technical bases for the techniques are described in the literature, and many computerised packages are becoming available for use. Generally, such packages use mathematical models to estimate the source term, the dispersion, the dose and the impact to estimate hazard ranges or dose concentrations, to which is added a frequency/probability figure to enable a risk figure to be derived. (A criterion for level of harm, or for probability or frequency of exposure, can then be added for the purposes of risk management). However, the effort in the field of reliability data has been less obvious, despite substantial progress in reliability modelling techniques. Such lack of progress seems to stem from the following areas of difficulty:

- decoupling the 'hardware and peopleware' elements of existing data;
- the paucity of specific data relating to low probability incidents;
- the tension between generic and specific data; and
- the 'in confidence' nature (and concomitant wider unavailability) of much of the data which does exist.

Similar difficulties arise in the 'peopleware' arena. For too long, 'Human Factors' was interpreted in the limited (but of course still very important) sense of operator error; and most research effort was deployed in the development and refinement of human error models based in ergonomics, cognitive behaviour, etc. These now sophisticated models are being further developed, but it is unlikely that such development will result in significantly more accuracy (as opposed to precision, which is not of course the same thing) of fairly wide uncertainty boundaries. More recently, much development of 'culture', 'management', and 'organisational' models has taken place, most of which are grounded in audit techniques of one kind or another. Substantial further developmental needs remain, but such models can offer significant benefits in identifying critical risk nodes, and in their quantification. How such outputs can be integrated into existing QRA approaches is still a matter of contention; and a further problem for the future is the question of how such models (a difficulty of philosophy rather than technology) can be robustly built into the decision making process (QRA based or not).

There remain, of course, many uncertainties in the technical (and indeed in the related socio/economic/political) components of this process; but their criticality can often be tested and demonstrated by the transparency of the process (a very important issue in its own right), and by elements such as sensitivity testing, which can be used to identify and examine critical areas of control (both hardware and peopleware) to add insight to the adequacy of control measures, to any debate on tolerability, or to validate the relevance of any criteria which may have been applied.

The risk management component brigades into the assessment process, directly or indirectly, openly or covertly, judgements as to acceptability or (otherwise) 'tolerability' of the associated risks. As indicated above, this is an area of extensive (and often heated) debate, and little objective consensus, especially when actual, or defined, levels of tolerability are suggested. Of course, in an ideal world, any hazardous activity would not impose risks which were disproportionate to the benefits (such benefits can cover a wide spectrum, and inevitably involve economic as well as other, often less tangible, social value parameters), and any such risks would be equitably distributed across society in proportion to the benefits received. In practice of course, such equitable distribution is rarely possible; and distributive principles of a more general kind are now suggested, involving tests to ensure:

- that when a risk is so great, or the hazard so unacceptable, a mechanism for prohibition exists:
- that there is a minimum level of risk, below which further precaution is unnecessary; and
- that if a risk falls between these two states, that it must be reduced to a level which recognises the benefits of (or from) the activity, taking account the costs of any further action to reduce the risk further.

These principles combine with other generally accepted tenets:

- that risk should never be imposed unnecessarily; and
- that no individual or community should bear an unfair proportion of any risk.

Such value judgements involve very complex social processes. Hazards and risks are viewed quite differently, depending on the origins of the hazards or the nature of the risks that they present. Natural hazards seem to be 'tolerated' more readily than those which are man-made; and hazards which presage catastrophe appear less 'acceptable' than those presenting a lower level, continuous risk. A relatively well-established hierarchy has emerged, which involves issues such as:

- Voluntary vs. involuntary exposure;
- 'Natural' vs. man-made risks;
- Perceptions of personal control;
- Familiarity;
- Perceptions of benefit or disbenefit;
- The nature of the hazard or consequence;
- The nature of the threat;
- The special vulnerability of 'sensitive' groups;
- Public and personal perception of the type and extent of the risk;
- Perceptions of comparators; and
- Effect reversibility.

It is a decision hierarchy which pivots on the confidence, of those exposed to the hazards and risks, in those authorities and bodies who create the hazards and control the risks - regulatory and public authorities, operators, 'experts' of one kind or another, and the emergency services. Priority questions include:

- Do the stakeholders believe that all relevant views and interests have been adequately considered?
- Do the stakeholders have confidence in the effectiveness and independence of the regulatory authorities?
- Is there a consistent and credible consensus of scientific and technical opinion, or is there disagreement amongst the 'experts'? (Note: public perception of what constitutes 'disagreement' amongst experts is rarely consistent with the perspective of any 'experts' involved).
- What is known about the quality of the project, plant, and company management?
- Are the emergency and other responding services able to cope with foreseeable events, in the short and long term?

It is, in effect, a combination of physical and social detriments, in which some major elements may not be quantifiable in any meaningful way; and integrating the concepts into the risk management process, to the satisfaction of all stakeholders, can present severe difficulties, both philosophical and practical.

APPENDIX 2

OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (See Discussion Document Section 1.4)

The OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (OECD 1992) (and now under review) is a guidance document intended for public authorities, industry, labour and other relevant stakeholders, to assist them in establishing policies and programmes related to the prevention and avoidance of, preparedness for, and response to accidents involving hazardous substances. The Guiding Principles are currently being revised and updated, and publication of the Second Edition is expected in 2002.

The *Guiding Principles* emerged from recommendations made in a series of OECD Workshops, held between 1989 and 1991, which addressed a range of issues associated with accidents involving hazardous substances. The Workshops considered the roles and responsibilities of such relevant stakeholder groups as government authorities at all levels, management and employees at hazardous installations, and the public potentially affected by such chemical accidents. The Workshops were sponsored by the OECD Working Group on Chemical Accidents, a policy body consisting of representatives of Member countries and other international organisations, with observers from industry, labour, and other non-governmental organisations. Since the publication of the *Guiding Principles* in 1992, the series of Workshops has continued to the present day, considering new issues, or further developing issues or topics that are included in the *Principles*. For example, two Workshops in the series have focused on transport issues, i.e., chemical safety in port areas; and transport of hazardous substances by pipelines. Two other recent Workshops elaborated subjects that are already addressed in the *Guiding Principles* - emergency preparedness and response, and human factors.

In general, the objectives of the *Guiding Principles* are "to set out general guidance for the safe planning, construction, management, operation, and review of safety performance of hazardous installations in order to prevent accidents involving hazardous substances and, recognising that such accidents may nonetheless occur, to mitigate adverse effects through effective land-use planning and emergency preparedness and response". The introduction to the *Guiding Principles* further states that within their context "the word 'safety' embraces health, safety and environmental protection, including protection of property, to the extent that they relate to the prevention of, preparedness for, and response to accidents involving hazardous substances".

The *Guiding Principles* are written in a broad way, setting out objectives in prevention, preparedness and response, rather than specific means and methods for achieving those objectives. They are intended for application worldwide, irrespective of location or size of facility, and their focus is predominantly, but not exclusively, on fixed installations of all types that produce, process, use, handle, store, transport or dispose of hazardous substances.

The *Principles* are intended to complement international, national, regional and local regulations and other guidance and advice. At the international level, they stand alongside initiatives such as those of UN (1998) and the ILO (1991, 1993); at the regional level, e.g., EU (1996); and at national levels, regulations enacting the above EU requirements, or stand alone, such as those of US (OSHA and EPA). These are paralleled by many sectional (mainly industrial) initiatives of various types and on varying scales, ranging from the very local, to major international initiatives (such as the chemical industry programmes under the 'Responsible Care' banner). Ideally, such initiatives should be based in consensus, and proceed with the agreement and involvement of all relevant stakeholders, through appropriate fora, national and international.

APPENDIX 3

Some Issues relating to Terminology and Definitions

(See Discussion Document Section 1.5)

There is currently no consensus on the definition of the various terms used by stakeholders in the risk management process, even when the barriers of different languages are discounted. Some recent and current initiatives to promote understanding and communication of the commonalities (and differences) between different risk cultures and languages are described, very briefly, later in this Section; but it is not the purpose of the Workshop to debate or pursue these issues except insofar as they impinge on the issues of *audit* and *inspection*. Yet even here the differences in meaning and understanding of terms can be clearly illustrated, by referring to the different meaning and understanding of these terms, even in a common language, on either side of the Atlantic Ocean. Similarly, there is no consensus within single bodies - for example, many regulators would consider the regulatory use of audits a component of the inspection process. Clearly, convergence (in meaning and understanding) must be a long-term goal; but progress is unlikely to be swift.

It is therefore intended that the Workshop adopts, to facilitate debate and as an aid to common understanding, definitions of some few terms which will be the common currency of the Workshop discussions. Where any term so defined is used in a different sense or meaning, the user should make this clear to the Workshop, unless it is already clear from the context of its use. It is not anticipated that the adoption of these definitions will be the subject of lengthy debate, *for these are definitions for the purposes of the Workshop only*, and are not intended for longer-term adoption.

The terms (and definitions) proposed for the purpose of this Discussion Document, and for use in the Workshop are:

Audit - an examination performed either by or on behalf of an industrial operator (**self** or **Internal Audit**) or by an independent third party (**external audit**). The definition includes the resultant report(s) but not subsequent follow-up activities.

Chemical Accident - any unplanned, sudden event which causes or is liable to cause injury to people or damage to buildings, plant, material or the environment.

Chemical Incident - any unplanned, sudden event which has the potential to become, or to escalate into, a chemical accident (q,v).

Inspection - a control performed by public authorities (or by another party/ies on behalf of public authorities). The definition includes the resultant report(s) but not subsequent follow-up activities.

Inspection Performance Indicator - any measure used by an internal or external assessor to assess or describe, comparatively or absolutely, the level or adequacy of performance of a regulator or other public authority in any element of their role in the regulation of safety. Similar measures may be applied to performance in environmental or other appropriate contexts.

Regulatory Audit - a part of the inspection (q,v) process, using audit (q,v) approaches.

Review - an examination to determine whether (1) a company's safety (and/or environmental) management system is consistent with its objectives and policies and (2) its objectives and policies are appropriate.

Safety Performance Indicator - any measure used by an internal or external assessor to assess or describe, comparatively or absolutely, the level or adequacy of performance of an industrial operator in any element of the management of safety. Similar measures may be applied to performance in environmental, quality, or other relevant contexts. Similar (or identical) measures may be applies to Inspection or Regulatory performance

The importance of defining risk management terms is well recognised, the immediate need usually being met by the use of a dedicated definitions section in International Instruments or in national legislation which embodies or enacts the content of such Instruments. There have been several attempts to suggest a wider basis for such definition of terms, usually at the national level (notably CCPS,1992; IAEA 1988; HSE1995) and with some international examples (e.g., CEFIC 1988, ILO 1991, ISO 2000), but whilst some of the definitions suggested have gained prominence and in some cases wider recognition, there has been little general consensus, even on the meaning of a limited number of the more common core terms. These problems were recognised in the debates at the 1995 OECD Paris Workshop on 'Risk Assessment and Risk Communication, in the Context of Accident Preparedness and Response', which subsequently led to the Expert Group on Chemical Accidents' project to design and develop the OECD Chemical Accident Risk Assessment Thesaurus ("CARAT"). The framework for this Thesaurus is now in place, with some initial entries; however, filling the pages will require major international effort. But even here the intention is to map and to inform, and not 'to direct, still less to prescribe' a particular approach or meaning. The parallel OECD Dictionary of Chemical Risk Assessment is another recent example of this informative, rather than deterministic or definitive approach. It may well be that such international activities will be a major instrument through which new insights into the analysis of the risk assessment process will be developed, and by which the comparison of risk management regulation and performance will be facilitated.

APPENDIX 4

Some further notes and questions on performance indicators and measurement, benchmarking, standards, anchor points, and performance criteria.

(See Discussion Document Section 4)

1. Overview

The trend in the development and implementation of safety management systems in manufacturing and other activities, and its mirroring in recent regulatory trends (for example the MAPP, SMS, audit etc., requirements in the 'Seveso II' Directive, and the requirements of the OSHA - PSM and EPA - RMP requirements) has now triggered a further move, from simple implementation of such systems to the inclusion of performance measurement, and with it the development of (safety) performance indicators. These trends, anticipated for example by (EPSC 1994, CCPS 1993a) have now led to the development of generic frameworks for such measurement, and latterly to emerging practices and practical systems amongst operators, and other relevant organisations (such as quality accreditation bodies). And whilst much of the emerging methodology remains proprietary, there is now sufficient information in the literature (normally Conference and Symposia, or other technical publications), for an objective, if early, view of the value of these initiatives to be taken.

Some of this information is now being consolidated (e.g., EPSC 1996). The OECD Expert Group on Safety Performance Indicators ((OECD 2000) - in which reference is to be found an extensive range of international responses to an earlier call for examples of SPIs) is currently developing an extensive, if indicative system of such approaches.

The concepts and principles underlying approaches to the development of performance indicators are relatively simple, but a major difficulty lies in the fact that most outturn and many output indicators involve what is essentially the measurement of negatives (few, or the absence of, injuries, illnesses, etc). This problem is exacerbated by two further limitations:

- good performance may not provide sufficient information for the safety management process; and
- where high consequence incidents are involved, a very low incidence, or complete absence, may not in itself be a sufficiently comprehensive (or even adequately illustrative) indicator.

Other proactive measures are, therefore, necessary. Such measures - sometimes surrogate in nature- are indicators of assurance that a systematic, preventative management approach will reduce or prevent incidents of significance. Such assurance stems firstly from adequate:

- safety /environmental management inputs plant and equipment which is fit for purpose, adequate operational and maintenance procedures, and competent, knowledgeable, trained personnel. However, to manage such inputs, they need to be measurable (and measured! although not necessarily quantified); so the second essential element is
- a framework for performance measurement a combination of inspections, assessments and audits.

General categories for such monitoring activities include:

- regular, often frequent inspections and audits, mainly carried out by staff at local level;
- periodic, in depth inspections, assessments or audits of some specific aspect or topic, usually carried out by a combination of local and more specialised staff, and with significant time intervals; and
- overview audits and assessments, carried out by independent assessors, typically at yearly or greater intervals. Such assessors may be either independent 'in house', or external, third party personnel. And the measurements or indicators obtained in these processes require a feedback loop to the management system, with action and follow-up.

There is a great variety in the detail of areas covered by such auditing and monitoring systems, but most produce a higher level commonality, embracing inspections of equipment and facilities, compliance audits, measures of management control inputs, behavioural observation and feedback, specialist audits, mechanical integrity assurance, hazard and risk assessments, system integrity audits, attitude surveys, and overarching management audits. Of course, this list may not be complete. (Q1) And as a further complication, many of these activities are complementary.

Performance in such activities cannot be expressed in terms of a single parameter or index, in terms which are useful for the management of improvement or other change (although a single - for example, risk - figure might serve as a high level indicator for other, including some regulatory, purposes). Indeed, the measures used to express, or in some cases to characterise, performance embrace a range of mostly qualitative, sometimes comparative, and occasionally quantitative indicators from each monitoring activity. There can be considerable difficulty in combining, or integrating such measures; and inherent uncertainties are almost always thereby increased. The separate measures can be expressed in a variety of ways, which will include:

- inferences based on, for example, non-compliance found, or recommendations made;
- qualitative assessments of performance (with all the problems of subjectivity);
- quantitative ratings such as percentage compliance; and
- ratings (either qualitative or quantitative, and again with subjectivity difficulties), about systems adequacy or implementation.

Benchmarking, set either against an objective standard of some kind, or using other relevant comparators, is also a valuable approach; and quality indicators such as timeliness, alignment, resourcing adequacy, and adequacy of outputs are equally important. (Q2) But currently available measures appear to be neither fully developed, nor sufficiently comprehensive.

2. Types of Performance Indicators

It is possible to categorise the indicators produced by the above approaches into the following general groups:

Outturn Output
Activity Success
Cost (benefit, efficiency, effectiveness, etc)
Other

Such indicative groupings are, at the general level, equally applicable to both the Regulator (see section 2 & 3 *ante*) and to the industrial operator (and in the latter case, many are at least as critical to the review process as to ongoing audit). They are applicable, subject to their close definition, at all operational

levels, and from macro to micro scales. What differences exist tend to be at the level of detail, and even there is considerable commonality of approach, even if benchmarks and criteria- for reasons which are usually not entirely transparent- diverge. Are any improvements necessary, or indeed practicable? (EPSC 1996) details a wide selection of examples from companies such as Hoechst, Bayer, BP, ICI, Dow, TUV-Sudwest, DNV, Borealis, Exxon, BASF, AEAT, Shell, Dupont, and Norsk Hydro; and there are many other examples in the literature. Whilst again they vary at the company or system level of detail, they contain a substantial measure of higher level commonality, within the above general groupings, and cover indicators for areas of 'activity' and 'output'. (It is perhaps significant that the developing work of the OECD Expert Group on SPIs appears much more comfortable, currently, with the identification of measures for 'activity' than for 'outturn' or 'output'. (Q3) At least some of the reasons for this are historical; but there may also be more fundamental difficulties, of definition, measurement, and meaning.

Furthermore, it may also be significant that in most systems, objective quantification is more prevalent where incidence (of whatever kind) rather than condition is being monitored and measured. Or, to put it another way, it seems that such objective quantification is more an attribute, currently, of 'lagging' rather than 'leading' indicators (as defined, for example, in OSHA's PSM programme. The *OECD Guiding Principles* use the terms 'reactive' and 'proactive/positive' with similar meaning). Typically, such numerically quantified 'lagging' indicators include:

- safety indicators such as fatal accident rate, lost time injury rate, lost time injury/severity rate, total recorded injury rate, number/cost of process related incidents etc.;
- safety and health indicators such as occupational diseases, occupational health absences, absenteeism, etc.:
- environmental indicators, such as releases, emissions, incidents/near misses etc. which of course a regulator could consolidate at other levels as well as company or plant related.

However, system condition monitoring (of whatever type) is usually qualitatively expressed, and where any dimensioning is attempted, it is typically either subjectively or relatively expressed. However, at the 'headline' level of output and outturn measures, there have been recent indications of substantial forward development and promise of further potential progress. In the UK offshore industry, for example, the post Piper Alpha regulatory control package was introduced- with the perhaps reluctant cooperation of the industrial stakeholders - alongside the ambition of a major (and monitored and measured) reduction in incident and accident rates; which has been, reportedly, realised. (Interestingly, MARS shows an essentially year on year steady state for reported major chemical accidents in the EU; and the basic assumptions about the accident reduction potential underlying novel elements in the introduction of 'Seveso II' are regarded by some commentators as little more than acts of faith, and by others as cost negative). Other examples include the Netherlands, which has produced a series of Environmental Plans, inter alia, against which industry and regulatory performance is monitored; equally, some 'voluntary' initiatives are similarly monitored (as in, for example, the Dutch Responsible Care Report 1999). And increasingly widely, there is an emerging drive to raise 'contracts', (or agreements described in similar terms), between regulator and regulated, at national, industry sector, or more local levels, based on performance increases in outturn or output indicators (that is to say, in incidence reduction and effect). Such joint targeting approaches might offer much promise, in principle and in practice, whatever the detailed practical difficulties (which could however be very great) - not only for a consensus partnership between principal stakeholders, but also as one agent for co-ordinated, consolidated, and ultimately integrated approaches to the control of chemical accident risk. (Q4) These are major initiatives, but it is yet early days; and there may be other, equally valid approaches to be developed.

3. Environmental Dimension

Everything in the foregoing section, as applied to safety performance indicators, is equally applicable *in principle* in an environmental context: it is only the detail of the indicators and/or the benchmarks which differ, with appropriate local distinction made between covenanted and uncovenanted components. Of course judgements as to acceptability or tolerability of environmental harm or risk tend to be at least as subjective, and as contentious, as those relating to the human dimension. Interestingly, 'Seveso II' (EU 1996), in its definition of a major accident notifiable to the Commission, outlines some environmental harm criteria; but any implication that there is any equivalence with the 'human' criteria also defined in the Directive is, at best, inferred. Overall consensus in this area, amongst all stakeholders, is a goal unlikely to be realised, at least in the short term; although as noted elsewhere in this Document, there appears to be an emerging majority feeling, among principal stakeholders, that where human and environmental protection measures conflict, then the immediate protection of people prevails.

4. Sources, Availability and Application of Performance Indicators

As discussed above, there is little difference in principle in the nature of performance indicators for the two major stakeholders - the regulator(s) and the regulated - and indeed, directly or indirectly, for some other stakeholders also. The complications (and indeed the major difficulties, and perhaps the Devil!) lie in the detail; but at least some of the associated problems can be addressed by adequate definition.

There are several source areas for such performance indicators. By far the greatest number have been developed in-house for internal use; and some of these have been developed not only for potentially wider application - subject to appropriate training of those who apply them - and for focussed use in the area of justification of activity, demonstration of adequacy, tolerability, etc. Others have been developed proprietarily, often by consultancies and other similar organisations, for commercial application and use. Such methods are often associated with accreditation or other certification procedures, and accompany or parallel other procedures; for example quality and environmental management, in the ISO 9000 and 14000 Series (ISO 1987, 1992). Recent developments have gone on to address indicators in areas of great complexity, such as sustainability (e.g., Delft 2000). There has also been considerable effort deployed in developing regulatory performance indicators, and indeed the (usually surrogate) bases of many such indicators, especially of the 'activity' type, are in the public domain, often associated with (sometimes selfdefensive) cost-efficiency presentations. Operators (and indeed some regulators) have also developed and sometimes applied, local or more global output and outturn indicators and measures - but as these tend to be closely associated with perhaps the more emotive cost-effectiveness issues (and often involve vexed ethics-rich questions of life and other valuations) the ready and public availability of such systems, and descriptions of performance against them, tends to be somewhat limited. Promising though these approaches seem to be, further development, and increased transparency seem essential.

5. Quantification and the Links Between Performance Indicators and Risk Assessment Outputs

It is conventional wisdom (although not universally accepted) that "If you want to manage something, you have to measure it." As indicated above, many indicators used in performance measurement are qualitative, or at best semi quantitative. However, there is evidence of a growing appreciation of the value of SMS reviews being combined with, or integrated in, quantified risk assessments; partly as an aid to judgements as to tolerability issues of one kind or another. Several techniques have now been developed to perform such quantification of elements of safety management

performance. These may be used to assist in improving such performance alongside a QRA, or to modify the QRA result(s) to reflect the level of safety management explicitly. However, it must be noted that this is currently an issue of some contention, in several areas of the regulatory process. Examples of such systems are ISRS, MANAGER, STATAS, PRIMA, SMART, IFAL, MES and AVRIM (see the indicative list of SMSs in section 2 above). It is important that where such techniques are applied, the risk causation model is transparent. And other models, whilst not adopting a fully quantified approach, incorporate weighted judgemental adjustment of standard assumptions such as failure rates, causation ratios etc. Here, transparency is equally important, and iterative testing of assumptions and sensitivities vital. This is, of course, but one facet of the issue of uncertainty in the risk assessment process, and which applies equally to other assessment and analysis regimes; but it is a facet which has been more overtly confronted at the QRA interface than elsewhere. There then remains the fundamental issue of the validity and robustness of the outputs, in regulatory and operational judgements, when set against enforcement, operational or tolerability criteria. (Q5) Early, or easy answers are unlikely here.

6. Criteria; Levels of Relevance; and Standards and Anchor Points

It is not the purpose of this *Discussion Document*, nor indeed of the Workshop to debate, or to consider at any length the issue of wider performance criteria (e.g. risk management and tolerability) against which any performance indicators (in whatever context) might be set. Nevertheless, these issues (which are outlined still briefly but in more detail in Appendix 1) are pivotal. Performance indicators in a vacuum are essentially meaningless. The detail of such criteria, especially the level(s) at which they are applied, is essentially a localised (that is to say, national, regional, local, company, or other - e.g., cultural) decision; and there is a wide range of such criteria, across a spectrum (often mixed) from deterministic to probabilistic in nature and from private to public in character. In the wider arena, the ALARA, ALARP, BPEO, etc concepts now appear to be generally accepted in principle, but their application in practice remains variable. Nevertheless, a hierarchy of such criteria has emerged, with benchmarks incorporating:

- prescriptive international Conventions, Directives, Regulations etc.;
- goal-setting international instruments as above;
- national (and sub national) regulation, prescriptive or goal- setting;
- approved regulatory guidance;
- international standards (technical or non-technical);
- national standards (ditto);
- industry (and similar occupational sector) standards (and advice) (ditto);
- company standards (and advice) (ditto);
- cost benefit (and similar) justification; and
- justification via use of (Quantified) Risk Assessment (Q)RA.

Of course, these benchmarks are also sensitive to the locus of the user. The character, nature and perhaps application level of the benchmark will reflect this. For example, some parts of industry are cautious about the incorporation of essentially voluntary initiatives in performance norms. Similarly the 'precautionary principle' (*Vorsorgeprinzip*) - the concept of acting to reduce risk in advance of a complete scientific understanding, by extension of evidence and in the exercise of reasonable foresight - may be taken up by the regulator and may consequently cause divergence in administrative application, from those standards which industry might otherwise wish to see applied. But such anchor points can, nevertheless, be of great value in the interpretation of performance and performance outputs and indicators, and impinge, directly or indirectly, on the more local operational indicators identified in (e.g., EPSC 1996). However, much research and developmental work is still continuing in these areas, and appropriate engagement of operators, regulators, and other primary stakeholders is essential.

7. Relationship of audits with safety performance indicators and other safety and environmental performance validation systems; and co-ordination of audit and inspection performance measures

Audit related activities, involving proactive performance indicators for monitoring compliance with standards or other benchmarks, are accepted as markers for the identification of weaknesses in the performance of SMSs. These relationships are generally considered to hold true for interfaces with the types of audit and assessment systems used to examine other aspects of organisational and management performance. However, recent work (JLP 1999) has confirmed that the preventative value of risk control via these activities is acutely sensitive to the number and type of elements taken into account as indicators; and that the value of quantifying performance using simple audit rating systems may be specifically local. This may be true where the activity is carried out singly, or where is partially or totally combined or integrated with other related assessment activities. Such shortcomings could significantly limit and localize the usefulness, and indeed the value of some audit outputs; and of any concomitant quantification. However, it might be argued that such difficulties do not arise to the same extent, or indeed at all, in the co-ordination or consolidation of performance output or outturn measures, locally or more widely, and for both regulator and regulated. In any event, these are crucially important issues, and substantial further effort will be required to resolve the problems.

8. Core Questions

The core issues and questions may be summarised as follows:

- the need to develop robust output and outturn indicators and measures to supplement activity measures;
- the problems of benchmarking, anchor points, criteria, etc.;
- the lack of consensus on types of, and appropriate performance criteria;
- further coordination and greater transparency of outputs; and
- wider stakeholder and community involvement.

KEYWORD INDEX

(Reference is to Section, Subsection, or Appendix Number in Discussion Document)

Accident

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Lessons learned. 6.2

Root causes. 2.7

Audit(s)

Active. 2.8

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Stakeholders. 1.3, 2.18, 3.16, 6.5. A1

Terminology. 1.5, A3

SUPPLEMENT TO DISCUSSION DOCUMENT (WORKSHOP VERSION) REPRESENTATIVE QUESTIONS FROM MAIN TEXT NARRATIVE

This Chapter (which is new to the revised version of the Discussion Document) contains representative questions from the text of the Workshop version of the Document. The locations of these questions in the Workshop version are indicated, in the revised version, by parenthesised references (e.g. (08)).

Such questions were posed in Sections 2-6, and in Appendix 4, of the Discussion Document.

Questions from Section 2: Audits and auditing.

- Q1. How common is this phenomenon? If it is not uncommon, what are the implications for the cost-effective use of audits in the context of chemical accident risks?
- *Q2.* How robust are audits and similar procedures, in this latter context?
- Q3. What is the position, in reality? How different are accounting and social 'bottom lines' in this context?
- Q4. How far might these problems affect the value of audits, specifically and overall?
- Q5. Could this lead to difficulties in developing robust consolidated or integrated audits? If so, what is/are the solution(s)?
- Q6. How serious a problem is this? How is it best managed?
- Q7. How is this done adequately? Does the fact that the technical audit question sets tend to be very specific obscure the 'big picture'?
- Q8. How may appropriate choice and application be effectively managed? What safeguards are needed?
- *Q9.* How significant is this? How may any resultant problems be adequately managed?
- Q10. How important are these shortcomings?
- Q11. How significant is this lack of benchmarking? What are the implications?
- *Q12.* What are the relative merits and demerits of common audit tools for regulators and regulated? Are there many examples of such common usage currently available?
- Q13. How can both width and focus of coverage be guaranteed, whilst at the same time safeguarding operational practicality?
- Q14. How robust is the assurance of such approaches? How is criticality identified? How is resultant action (best) focussed?
- Q15. How should the advantages be optimised? Is there an appropriate general balance, and if so, how is it best achieved and maintained?
- Q16. How is all this cost effectively achieved? What are the implications of shortfall?
- Q17. How are such safeguards ensured?
- Q18. Would such techniques be valuable, and if so, how should they be developed?
- Q19. What is 'fit for purpose' in these contexts? How significant is the current lack of subjective benchmarking of such indicators (referred to in section 2.5 above)?
- Q20. What would be the advantages and disadvantages of such (risk based) approaches? Is further development warranted? If so, how and by whom?
- *Q21.* How is this effectively, or best managed, in audits?

- Q22. What are the critical trade-offs? How are they, or should they be, highlighted, in audit?
- Q23. Why should this be? What might improve such shortfall?
- Q24. How many audit systems are designed to recognise and/or to compensate for the potential effects of (management system) 'corrosion'?
- Q25. How should this potential problem be managed, successfully?
- Q26. How practical is this? What are the major problems?
- Q27. What implications does this industrial population shift have for chemical accident prevention, preparedness and protection? How can (or indeed should) SMEs be helped, in this, or in wider operational contexts?
- Q28. What can, or should be done to alleviate such difficulties, and by whom?
- Q29. Are there other (than North American) examples? Do the benefits of such involvement outweigh the concomitant disadvantages and difficulties? If so, how may they be effectively overcome?

Questions from Section 3: *Inspection and Inspecting.*

- Q1. What are the tensions between consistency and 'subsidiarity'? Are they objectively manageable in a non-consensual situation, or indeed at all? If so, how? What sanctions are available, and how should they be applied? How can, or indeed should, any such 'level playing field' be further widened?
- Q2. What other major, or essential elements of inspection are there? Is this mix manageable? What are examples of best practice?
- Q3. This knowledge is valuable; should it be more widely available, and if so, how?
- Q4. Is goal-setting the only practicable approach? How could it best be done? Could the costs of such effort be justified? How? How could (or should) any implementation be overseen, and by whom?
- Q5. How effective has this co-operative effort been? Should further mutuality be encouraged? If so, how?
- Q6. Is the present, essentially ad-hoc system adequate? By what criteria should adequacy be judged? What improvements are indicated? How can other states become more involved? How might stakeholders other than regulators be better engaged?
- Q7. Given the wide diversity of inspection approaches described above, would it be worthwhile to seek more closely aligned standards in this area? And if so, what should they be? Who should police them?
- Q8. How should these situations be remedied? Should national convergence be the initial priority?
- Q9. How best are the potential efficiencies in such approaches to be harnessed? Is it possible to develop consensus approaches across different regulators, locally or more widely? How can other relevant stakeholders be engaged? How comfortably does this kind of 'RBI' sit with regulatory activities which involve licensing, permissioning, et al?
- Q10. What are these? What safeguards would be appropriate in such cases? How should other stakeholders be engaged?
- Q11. Is consistency, in a discretionary context, a reasonable aim? If so, how might it be achieved? How would it be overseen? Would any safeguards be necessary? If so, what would they entail?
- *Q12.* What are the implications of this?
- Q13. How is regulatory cost effectiveness and cost efficiency best demonstrated? How far should it be obligatory?

- Q14. What regulatory charging is legitimate, and what safeguards or other constraints can those on whom such charges are levied reasonably expect?
- Q15. What follow-up methods hold most potential for success? How can their use be encouraged?
- *Q16.* What, if any, allowances, can be made for such problems? What are the attendant difficulties? How should they be managed?
- Q17. Is this one of those cases where the practical organisational difficulties outweigh any more philosophical or other benefits? If so, how far should it be attempted to solve these difficulties?

Questions from Section 4: Performance Indicators and their Relationship with Audits and Inspections; and from Appendix 4: Some further notes and questions on performance indicators and measurement, benchmarking, standards, anchor points, and performance criteria.

- Q1. What other elements, if any, need to be addressed?
- Q2. Are the presently used systems of measurement adequate; and if not, how can they be improved?
- Q3. Why should this be?
- Q4. Are these promising ways forward? Are there others? How should they be further developed?
- Q5. How should such problems be managed, or overcome?

Questions from Section 5: Coordinated and integrated Inspections and Audits.

- Q1. Do the advantages and strengths of consolidation or integration outweigh the current problems? If so, how may the latter be overcome? Can an operator with consolidated or integrated systems reasonably expect consolidated or integrated regulation?
- Q2. Why should this be?
- Q3. Again, what are the reasons for this? Are they significant?
- Q4. What practicable solutions are there, currently, to such difficulties? Where are future solutions to current problem areas to be sought?

Questions from Section 6: Learning from experience, and Improved Sharing of Information.

- Q1. How can such repeated failings be explained? What can be improved?
- Q2. How can these difficulties be overcome, and by whom? How may the additional difficulties related to population data be eased, to strengthen the basis of risk management? What are the resource implications? How may the full range of stakeholders, given appropriate community involvement in the risk management process, be adequately and constructively involved in the freeing-up and sharing of such information?

ANNEX 2

OECD WORKSHOP ON AUDITS AND INSPECTIONS RELATED TO CHEMICAL ACCIDENT PREVENTION, PREPAREDNESS AND RESPONSE

Madrid, Spain 6 - 9 March, 2001

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