The Occupational Health and Safety (Major Hazard Facilities) Regulations came into effect in the State of Victoria, Australia on 1st July 2000. Approximately 50 existing Major Hazard Facilities (MHFs) were granted a licence to operate on or before 30th June 2003. The Hazard Management Division has developed a number of regulatory activities for licence assurance over the licence term of up to 5 years.

This paper provides an insight into the continuing development and implementation of a Safety Case regulatory regime in Victoria. The paper provides an overview of the regulatory processes developed, and discusses observations in safety performance at Victorian MHFs. The information shared in this paper may be of value to other regulators, facility operators and safety professionals who have an interest in the implementation of performance based regulatory regimes for major or high-hazard industries.

KEYWORDS: safety case, major hazards, licensing, inspection, audits, major hazard facilities, Victoria, WorkSafe, Australia

INTRODUCTION
The Occupational Health and Safety (Major Hazard Facilities) Regulations came into effect in the State of Victoria, Australia on 1st July 2000, requiring Major Hazard Facilities (MHFs) to submit a Safety Case. A wide range of facilities submitted Safety Cases, which can be divided into the following industry groups:

1. Plastics and Chemicals (including mixed and specialty chemicals plants, explosives and some chlorine users),
2. Petroleum (including refineries and associated terminals),
3. Utilities (including LPG depots, industrial gases and water treatment), and
4. Logistics (including warehouses and terminal facilities).

The Victorian Health and Safety Regulator, WorkSafe, assessed the Safety Cases to determine if the regulatory requirements were satisfactorily addressed in order to grant a licence to operate. Approximately 50 existing MHFs started the Safety Case process in June 2000 and 42 MHFs submitted Safety Cases and licence applications between October 2001 and June 2002. Of those, 39 Safety Cases were fully assessed and verified by WorkSafe, whilst some facilities deregistered as MHFs through a reduction of inventory of hazardous materials.

As part of WorkSafe’s Compliance and Enforcement Policy, the Hazard Management Division (HMD) may use a number of regulatory activities for licence assurance
over the licence term. This paper provides an insight into the development and implementation of the Safety Case regulatory processes in Victoria, which may be of interest to other regulators, facility operators and safety professionals engaged in the continuing development, improvement and the practical implementation of performance based regulatory regimes for major or high-hazard industries. WorkSafe’s experience and observation from Safety Case preparation, assessment and licensing are discussed elsewhere.

POST LICENCE REGULATORY OVERSIGHT ACTIVITIES FOR MAJOR HAZARD FACILITIES
The Occupational Health and Safety (Major Hazard Facilities) Regulations provide for a maximum licence term of 5 years, however the regulations are silent on the role of the Regulator during the licence period. WorkSafe has developed and continues to refine oversight activities to monitor MHFs throughout their licence term. Oversight activities that have been developed include planned regulatory visits, as outlined in a Post Licensing Oversight Plan to review safety management systems and control measures, responding to events at MHFs, consultation with stakeholders, annual inspections and sector reviews. The post licence oversight activities are further discussed in this paper. The
licence term and oversight activities generate a cyclical approach to MHF oversight as shown in Figure 1.

POLICY, OBJECTIVES & STRATEGIES OF MHF OVERSIGHT
As there can be some years between MHF licence renewals with the accompanying assessment of revised Safety Cases, WorkSafe sought to develop a fair and transparent post licence oversight process to monitor, in a structured manner, the continued improvement of major incident prevention and mitigation, and compliance with general occupational health and safety (OH&S) legislation. The oversight policy objectives at each licensed MHF are to:

1. Systematically verify that operators of MHFs are controlling their OH&S and major incident risks, so far as is practicable (SFAP).
2. Ensure that the systems used by the operator, particularly the Safety Management System (SMS), are performing effectively to achieve the goals of safety legislation.
3. Ensure that all duty holders comply with the requirements of safety legislation.
4. Assure stakeholders that the first three objectives can be achieved into the future, which will generally include objective measurement, evaluation, consultation and reporting to stakeholders.
5. Provide a critical third party technical review.

To achieve the above objectives three complementary strategies were selected and implemented:

- Post Licensing Oversight Plans which are a series of planned visits to monitor progress at the sites on important activities needed to address major incident potential and other OH&S issues at the site.
- Annual Inspection (AI) at which the sites’ continuing implementation of their SMS and the controls identified in their Safety Cases are reviewed through a detailed inspection of a selected sample of control measures and SMS elements.
- Annual Review of individual MHF performance (micro level) and industry sector performance (macro level).

WorkSafe’s adopted oversight strategy is consistent with the European ‘Seveso’ series directives, which require in Article 18 that the Competent Authority conduct at least an annual inspection of each MHF.

POST LICENSING OVERSIGHT PLANS FOR MHFs
Following the completion of licensing of Victoria’s existing MHFs, by mid 2003, HMD undertook to develop a plan of activities known as post-licence oversight plans. These plans outline regulatory activities that review the adequacy and conformance with the requirements of the Safety Case and observe progress with the implementation of performance improvement action plans, to further reduce risks.
A specific Post Licence Oversight Plan was developed for each licensed MHF in 2003 by an oversight team consisting of a Field Officer and a Safety Case Officer. The plans drew heavily on the findings of the Safety Case assessment and other observations during visits and response activities.

The plans incorporated input from stakeholders such as other government agencies and were prepared in consultation with MHF managers and employee representatives. As the process involved significant consultation and group activity, about 8 weeks were needed to complete the process for an approved plan. Figure 2 provides a simplified representation of the process and the information sources.

A report template was developed to record summary information about the facility. It describes the oversight priorities and objectives at that site, the rationale for arriving at the objectives and the frequency of site visits to achieve the objectives. The first round of post licensing oversight plans set a visit frequency ranging from monthly visits to three-monthly visits.

The oversight report is effectively a ‘top down’ appraisal by the regulator of the high level safety performance of the facility. Attached to the oversight report is a plan given to the operator listing the topics to be addressed during the visit and the month that the visit is planned to take place. The chronological plan is currently generated from a spreadsheet that collates and maintains any relevant information that may require closure or follow-up during oversight. This process also assists HMD in retaining specific knowledge of site issues. The oversight report and spreadsheet tool will continue to be developed and improved as WorkSafe becomes more proficient in the implementation of regulatory oversight of MHFs.

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**Figure 2.** Post licensing oversight plan development process
Licence oversight is a complex cyclic process, as illustrated by Figure 1, that primarily relies on the skills of the oversight team in its effective implementation. The oversight plan prepared by the team is an aid to that process and should not restrict the flexibility of regulatory strategies and interventions at the facility.

The implementation and effectiveness of oversight plans at individual MHFs are reviewed annually to set regulatory direction for the following year. This is discussed under ‘Annual Reviews’.

ANNUAL INSPECTIONS AT MAJOR HAZARD FACILITIES
The annual inspection of MHFs is another oversight activity. The objectives of the Annual Inspection process are to:

- Assess whether or not an operator is continuing, since its licensing, to provide a satisfactory level of Safety Management;
- Support the continuation or amendment of an MHF’s licence term and/or condition;
- Support the continuation or amendment of the oversight visit frequency; and
- Identify areas where strategic intervention is required.

PLANNING AND IMPLEMENTING THE INSPECTIONS
To allow a comparison of observed findings from the inspections across similar facilities and to facilitate timely feedback to industry, WorkSafe decided to conduct annual inspections for each of the four industry sectors in separate yearly quarters. The first cycle of the annual inspections commenced with the Petroleum Sector in quarter 4 of 2003 and ends with the Logistics Sector in quarter 3 of 2004. It is intended that the annual inspection will be repeated during the post licensing cycle of the MHF as shown in Figure 1. For those MHFs granted a five year licence, there will be about 4 annual inspections between licence renewals.

A representative sample of the major incident scenarios were selected from the Safety Case and analysed to select control measures and safety management system elements for inspection. Information from Safety Case assessments, verification and post licensing oversight was also taken into account. A final list of 10 control measures was selected for inspection, the majority of which were deemed important or critical by the facility. The SMS elements to be included in the inspection were selected from SMS elements that support the specific controls selected, and from those SMS elements that were considered to be particularly relevant to that industry sector. For example, the SMS elements that were of particular interest to the first AI of the Petroleum Sector were asset integrity, management of change, permits to work, and control of third party services.

The annual inspection activities include:

- Planning and selection of the control measures and SMS elements for inspection, conducted by the Safety Case Officer and Field Officer assigned to the MHF.
- ‘Kick-off’ meeting about a week before the inspection advising the facility operator, in broad terms, of the topics for inspection. The purpose of this meeting is to
assist the operator in planning for the inspection and making available relevant site personnel.

- On-site activity by a team of inspectors that includes:
  - Interviews with site personnel, inspection of site records, physical observations
    and verification of the functionality of specific control measures,
  - Daily feedback to the operator on emerging issues, and
  - A close out meeting on the final day to provide interim findings from the inspection.
- Preparation of a formal report and issuing of a draft report to the operator for comment,
- Receiving feedback from the operator on the report and any actions that the operator has taken or proposes to take to address any matters raised by the inspection,
- Revision of the report to incorporate comments from the operator, and
- Monitoring the completion of improvements and actions arising from the inspection.

Templates and spreadsheets have been developed to assist in the planning and reporting of the inspections. These templates will continue to be improved as WorkSafe gains more experience in AI. The current inspection report presents a summary of the findings from the inspection, assesses the implementation and effectiveness of the specific control measures and SMS elements inspected. From this the report draws conclusions on the overall level of safety management at the facility.

INSPECTION RESOURCES
The inspection activities described above required the coordination of a large component of HMD’s resources. For example the inspection of the Petroleum Sector, eight facilities including two refineries, required a total of 1300 person hours spent at site, and a similar on-site resource was required for the Plastics and Chemical Sector comprising 12 facilities of various size and complexity. A total of 4,000 person hours of on-site time is planned for the inspection of all four industry sectors. The size and complexity of the facility and its operations governed the number of inspection teams and time spent on site. This varied from one team of two inspectors over two days, to two teams of two inspectors and a lead inspector over 5 days. In addition to the site time, considerable effort is required for planning and reporting findings as well as close out and follow-up of any actions arising from the annual inspection which currently equates to a similar number of person hours as the on-site time.

ANNUAL REVIEWS
To gauge the effectiveness of HMD’s oversight activities at MHFs and to set the future regulatory direction, reviews are conducted annually. The annual review consists of two steps:

1. Annual MHF Review, followed by the
2. Annual Sector Review.
INDIVIDUAL MHF REVIEW
The Annual MHF Review occurs after the individual MHF annual inspection is conducted and the report finalised. The objectives of the MHF Review are to:

1. Identify if the MHFs’ safety performance has improved since licensing. Identify the OH&S and major incident potential performance of the MHF since the licence was issued, with particular emphasis on the past year’s performance. The information considered includes incidents, licence history, claims information, complaints, enforcement action, MHF action plan progress, annual inspection results, observed changes at the site and the MHF’s own information such as audits and KPIs.
2. Address specific issues to ensure the oversight objectives are met.
3. Encourage continuous improvement at the MHF.
4. Make appropriate suggestions for changes to the frequency of visits for the MHF.

SECTOR REVIEW
The Industry Sector Review is an analysis of individual MHF reviews described above. The objectives of the Sector Review are to:

1. Identify the OH&S and major incident potential performance of the sector since licensing, with particular emphasis on the past year’s performance.
2. Identify specific issues for the sector as a whole and propose methods to address them such as an education plan or sector specific projects.
3. Recommend HMD resource changes.
4. Inform the direction for future regulatory activity in that sector.
5. Ensure consistency between oversight teams and site strategies.

FINDINGS AND OBSERVATIONS FROM OVERSIGHT OF MHFs
HMD has completed a cycle of post licensing oversight activities for the Petroleum and Plastics and Chemical Sectors. Logistics and Utilities Sectors will be completed by the end of Q3 2004.

Results to date and feedback from industry have been supportive of HMD continuing to apply the post licensing oversight activities. With each complete sector cycle, HMD is generating improvements to the oversight process. Initial findings suggest safety indicators may be derived from the oversight activities. In addition to lagging indicators, such as the number of incidents, proactive activities by the operator or regulator, may provide a leading indicator of the safety performance of the MHF from which strategic regulatory decisions can be made. Future oversight cycles will provide further information from which trends in safety performance may be observed.

Initial observations and perceived trends from records of reported incidents, licence decisions, preparation and review of oversight plans, and annual inspections are discussed below.
INCIDENTS AT MHFs
All workplaces are required by law to report certain types of incidents and injury to the regulator. In addition to the incidents being recorded in WorkSafe’s incident system, HMD separately records certain details of incidents that occur at MHFs in a spreadsheet which allows more flexibility in the reporting and analysis the incident data. HMD classifies incidents reported by MHFs as serious, significant or minor. A serious incident is an incident that has the potential for a major incident through the release of Schedule 1 hazardous materials or the failure of major incident controls and has the potential for a fatality. A significant incident is one that involves quantities of Dangerous Goods in excess of 10,000 litres or failure of major incident controls that did not have the potential for a fatality or an injury requiring admission to hospital.

In 2003 there were 16 serious and significant incidents from the 143 incidents reported by MHFs and during 2002 there were 11 serious and significant incidents from the 168 incidents reported. WorkSafe publishes on the internet annual reports that describe the serious and significant incidents that occurred at MHFs in Victoria (www.workcover.vic.gov.au). Reports for 2002 and 2003 are currently available. The intention of these reports is to prevent further incidents by informing industry and the community. The first section of the web report describes the incident and the regulatory action completed by WorkSafe. The second section describes the action taken by the operator and general lessons for prevention which is completed by the operator of the facility.

An analysis of all reported incidents involving Schedule 1 hazardous materials by industry sector, by consequence of incident and by prime cause of the incident is presented in Figures 3, 4 and 5 respectively. The Petroleum Sector had the highest number of incidents followed by the Plastics & Chemicals Sector. The majority of these incidents were due to a loss of containment of dangerous goods from pipework and vessels. The Logistics and Utilities Sectors had a lower number of incidents which may be in part attributed to the simplicity of the facilities when compared with the size and complexity of petroleum and chemical facilities.

For the Petroleum and Plastics & Chemicals Sectors the primary cause of incidents can often be attributed to gaps or failure of systems to control risks such as maintenance activities, process operations, asset integrity and human factors. At the facility level many operators are analysing incident trends in order to link such trends to the performance of their safety management systems. In some instances this initiative has been made a condition of the licence to operate the facility.

Operators of MHFs through their Safety Case processes have identified opportunities to improve safety systems such as improvements to their asset integrity programmes, monitoring and maintenance of equipment. It is expected that these improvements will reduce the potential for a major incident, and over time will show a reduction in the number of reportable incidents. However, to date such a reduction has not been observed by the regulator. This may be attributed to an increased awareness of the reporting requirements under the legislation. Other contributing factors may be that it is too early to see a reduction, or that safety improvements are targeted at reducing the potential for major
incidents, and as such do not specifically target the reduction of reportable incidents for example minor loss of containment.

Where there is a history of reportable incidents at a facility it is important that the trends of the incidents are linked to the performance of control measures and systems to protect against such events. In the absence of such linkages it is difficult for the operator or the regulator to take initiatives to reduce the frequency of reportable incidents. WorkSafe will continue to collect, analyse and share information on reportable incidents to promote a better understanding of causal factors and to improve the control of risks to health and safety at MHFs.

LICENCE OBSERVATIONS

In total thirty nine licence decisions were made on or before 30th June 2003. Thirty seven MHF licences were issued following payment of the required fee, and two facilities were refused a licence. A range of licence decisions were made during this round of Safety Case assessments. The vast majority of licence decisions were for a full term, unconditional licence and the shortest licence term was 1.5 years. Two facilities were deregistered following submission of the Safety Case. Figure 6 shows a breakdown of the licence decisions made by industry sector.

The trend of licence decisions were not evenly spread throughout the industry sectors as illustrated by Figure 6. The majority of short term licences were in the

![Figure 3. Incidents involving schedule 1 hazardous materials for all industry sectors in 2003](image-url)
Plastics & Chemicals Sector. The negative licence decision was from the Utilities Sector, while deregistration occurred in the Logistics and Plastics & Chemicals Sectors.

In general, a shorter licence period was granted when WorkSafe required an early review and revision of the Safety Case in order for the operator to demonstrate the continued adequacy of the safety management system and the control measures at the facility. A licence would usually include a condition when WorkSafe required a formal demonstration of the effectiveness of specific risk controls and systems in order to reduce the occurrence of reportable incidents, near misses, and other events that may be potential precursors to a major incident.

In conclusion the duration of the licence term and inclusion of conditions is an indicator of concerns relating to the maturity of the safety systems and the incident history at the time that the licence decision is made.

OBSERVATIONS FROM OVERSIGHT
In addition to the incident trends, the industry sector review recommends changes to future oversight activities such as visit frequency and resource planned for the next annual
The findings in terms of changes in safety performance and oversight activities are summarised below for each of the four industry sectors.

The judgement of any change in the overall safety is the qualitative judgement of the oversight team based on observations that may indicate a change in the safety performance.

**Figure 5.** Cause of incidents at all industry sectors in 2003

**Figure 6.** MHF licence decision by industry sector
## Table 1. Changes to oversight plans following the industry sector review

<table>
<thead>
<tr>
<th>Industry Sector</th>
<th>Overall safety</th>
<th>Visit frequency</th>
<th>Annual inspection resource</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Improve</td>
<td>No Change</td>
<td>Reduce</td>
</tr>
<tr>
<td>Petroleum</td>
<td>20%</td>
<td>80%</td>
<td>0%</td>
</tr>
<tr>
<td>Chemicals &amp; Plastics</td>
<td>50%</td>
<td>40%</td>
<td>10%</td>
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</tbody>
</table>

Information for the Utilities and Logistics sectors is not yet available.
or safety culture at the facility. Such observations may relate to reported incidents, inspections of the effectiveness of control measures and SMS elements, effectiveness of performance monitoring, cultural changes that inspire employees to ‘hunt for errors’ or to challenge the safety performance of past practices and control measures. About 20–50% of facilities were perceived to have improved their overall safety performance compared with observations during verification of the Safety Case. In general, when no change in safety performance was observed it was judged by the oversight team to be too early to observe any change in safety performance. In general, a perceived reduction in the overall safety performance from that observed at the time of licensing occurred where observation of newly developed or improved systems indicated that they had not fully delivered on commitments and expectations at the time of licensing.

A reduction of resource was generally recommended when the oversight team believed sustained continuous improvement was occurring, or there were efficiency gains in combining the oversight of two or more separate facilities operated by the same operator.

OBSERVATIONS FROM ANNUAL INSPECTION
The results from the first round of annual inspections at Victorian MHFs are summarised below:

Common themes from the annual inspections include:

- Critical function testing of hardware controls is not always well defined by the operator. This is usually related to the definition of a failure observed during inspection and testing of the field device. (e.g. the instrument calibration value that is recorded as a failure)
- Contractor management, particularly when it interacts with the testing of control measures (e.g. fire systems, gas detectors) is an area where improvements can be made.
- Implementation of auditing programs of the effectiveness of SMS elements was another area for improvement.

The annual inspections reinforced that performance monitoring of control measures is very important. There is potential for the facilities to be more effective in the use of the monitoring information to identify safety deterioration.

The annual inspections were generally well received by industry, particularly the industry sector focus. The process supports the opinion that in-depth audits and inspections by the regulator or by industry can provide an early warning of gaps or deficiencies in control measures or systems that may otherwise reveal themselves as a serious or significant incident.

SUMMARY
In summary it is difficult to form a view on the safety performance of individual or industry sectors based on a single or part cycle of the Victorian MHF regulatory oversight
<table>
<thead>
<tr>
<th>Industry Sector</th>
<th>No. Sites</th>
<th>Timing</th>
<th>Yes</th>
<th>Part</th>
<th>No</th>
<th>Yes</th>
<th>Part</th>
<th>No</th>
<th>Yes</th>
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<td>8</td>
<td>Q4 '03</td>
<td>97</td>
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<td>1</td>
<td>81</td>
<td>16</td>
<td>3</td>
<td>93</td>
<td>0</td>
<td>7</td>
<td>77</td>
<td>23</td>
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<td></td>
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<tr>
<td>Plastics &amp; Chemicals</td>
<td>12</td>
<td>Q1 '04</td>
<td>85</td>
<td>8</td>
<td>7</td>
<td>67</td>
<td>23</td>
<td>10</td>
<td>81</td>
<td>14</td>
<td>5</td>
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</table>

*Information is not yet available.*

**Table 2.** Summary of the extent of implementation of control measures and SMS elements
cycle. The early stages of oversight have not shown a reduction in the number of reported incidents at MHFs, but observed changes in safety performance made by the oversight teams indicates improvement. HMD recognises that the ability to make objective judgements on safety performance will improve on further collection and analysis of information from future oversight cycles and the ability to link this information to the effectiveness, or deficiency, of safety management processes at the MHFs. It is believed that in-depth inspections or audits by industry or the regulator, such as the annual inspection, may provide an insight to such linkages.

CONCLUSIONS
The MHF licence term generates a cyclic approach to oversight, with a maximum period of five years. The expectation of HMD is that the safety management processes at the MHFs show an improvement with each cycle of oversight. It should be noted that the Victorian MHF regulations require the ongoing improvement of the SMS with resulting improvement in the effectiveness of control measures.

The Safety Case licence oversight cycle has made intervention more systematic for the regulator and more predictable for the operator. The development and implementation of HMD oversight activities is a complex process that relies heavily on the skill of the oversight team. The process involves significant regulatory resource and involves consultation and collaborative working with other government agencies and stakeholders.

The Annual Inspection is an important component of oversight. It provides the key insight into the safety performance of individual MHFs to enable informed decisions on regulatory strategies and interventions for that facility to be made.

The Industry Sector Review helps to inform regulatory direction and strategies to influence or promote an improvement in safety at MHFs.

The Safety Case process is new to Victoria and some early observations of safety performance at MHFs have emerged. Observations of safety performance will continue to improve as information becomes available from future cycles of licence oversight. The trending of future information from oversight will be of particular value if the trends or resulting performance indicator are linked to observed improvements or deficiencies in the risk management processes at MHFs.

REFERENCES