EA - North West

March 1997

Environmental Compliance Audit of Glaxo Wellcome - Ulverston, Cumbria

ENVIRONMENT AGENCY

Executive Summary

In September 1996 a team of six inspectors from The Environment Agency carried out an audit over a full week at the Glaxo Wellcome Site in Ulverston, Cumbria. It was the first audit of its kind in the North West to involve representatives from all three organisations which formed the Agency in April 96 - Her Majesty's Inspectorate of Pollution, the National Rivers Authority, and the local Waste Regulation Authority.

The aim of the audit was to assess the Company's compliance with its environmental requirements as set out in its authorisations issued under Integrated Pollution Control, the registrations issued under the Radioactive Substances Act 1993, and the relevant Waste Management regulations.

Many aspects of the site's operations were examined in depth including its environmental policy and practice, plant design and maintenance, environmental and operational records, staff training and development, procedures and instructions, and its management structures. Inspectors also visited the site unannounced at night to assess the performance of staff in dealing with a site emergency - in this case an exercise simulating a spillage of solvent.

The report presents the findings of the team at the time of the audit. Part A covers the General and Site Wide Issues which were common throughout all areas of the site. Part B contains the detailed reports of the separate areas which were audited. The overall impression of the team was that Glaxo Wellcome showed a high level of understanding and commitment to environmental protection throughout the Ulverston site. The site performed better than average for the industry, based on the inspectors' judgment backed up by the revised Operator Performance Appraisal method, which is described in the report.

During the simulated spillage exercise all staff involved dealt with the situation in a competent and professional manner to ensure compliance with environmental requirements and minimise harm to the environment.

The Inspectors could not identify any significant areas where the Company were failing to comply with their environmental requirements but the report contains a number of recommendations which will further improve the Company's overall environmental performance. Some of these were brought to the Company's attention during the audit and there are examples where improvements had already been put in place by the end of the audit week.

In promoting environmental awareness the Company has developed a number of original environmental practices which are good examples for others to follow and these are outlined in the report.

Glaxo Wellcome have accepted the findings and recommendations in this report.

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Section 1 Overall Conclusions

Glaxo Wellcome's Environmental Performance

(a) There is a high level of understanding and commitment to environmental protection throughout the Ulverston site. It is a culture which is shared by staff at all levels in the organisation.

(b) There were no areas where the Company were failing to comply with their environmental requirements, but some aspects were identified which could benefit from improvements.

(c) Corporate and site environmental policies are targeted, and cascaded down to appropriate management and supervisory levels where actions can be put into practice. Extending this cascade further would offer even more benefits.

(d) The site comprises of a variety of small to medium sized plants, built to varying standards over the last thirty years. A range of complex processes are operated, and there is always the potential for unplanned incidents, but there is no reason to believe that the plants cannot be managed and operated safely to prevent pollution of the environment.

(e) In the event of an unplanned incident, the site has well thought out and fully documented procedures for dealing with most circumstances with the objectives ranked in order of protecting life, safeguarding the environment, and minimising the effects on the business. The procedures are rehearsed and staff are trained ready to implement them should the need arise.

(f) For most activities on site there is a profusion of well documented systems, procedures, and instructions, covering all routine operations and most foreseeable eventualities. There is a need to ensure that reviews are carried out at the Company's stated frequency so that they are always up to date, well focused, and easy to understand. The system of internal auditing, which is currently carried out, should ensure that the procedures are being followed.

(g) The introduction of IPC has raised the environmental profile and standards for ancillary support plant to the same as that required for pharmaceutical production plants.

(h) The Company's environmental performance, and staff awareness, has been improved in preparing for this audit, and as a result of comments made by inspectors during the course of the audit.

(i) In promoting environmental awareness the Company has developed a number of original environmental practices which are good examples for others to follow. Of particular note in this respect are:-

(i) The Spillage and Release Index for classifying releases to the environment and determining whether an incident is to be notified to the Environment Agency. (See Section 25 and Appendix 5)

(ii) The pocket sized IPC Awareness Cards carried by all process operators and shift managers, to emphasise the main pollutants, the key abatement systems, and reporting requirements of the IPC authorisations. (See Section 12 and Appendices 3 & 4)

(iii) The Unusual Incident Reporting (UIR) system of encouraging every member of the site to look for and report anything that could lead to a hazard to health or a release to the environment. (See Section 11)

(j) The need to continue with operator training to improve understanding of environmental effects of the processes and materials handled has been identified.

Conclusions on the Audit Itself

(a) The audit has provided a useful method for the Environment Agency to establish a collective view of the environmental performance of Glaxo Wellcome's Ulverston site.

(b) The benefits of integration of the Agency's three core functional groups working together yet maintaining individual specialist knowledge, has been demonstrated throughout this audit.

(c) Due to the complexity of many of the site's operations it is only possible in an audit of this type to gain an overall impression of the Company's environmental performance, and its compliance with environmental regulations, at the time of the audit.

Section 2 Overall Recommendations

Overall Recommendations

(a) Glaxo Wellcome are advised to read, take notice of, and implement the recommendations listed throughout the main sections of this report and collated in Appendix 7.

(b) The Environment Agency should implement the three recommendations advised in the main part of the report and in Appendix 7.

(b) Subject to any future Environment Agency policy on the frequency of these audits, a major audit of this kind should not be repeated within the next three years at the Ulverston Site unless there are any significant changes. In the meantime frequent, routine inspections by Environment Agency inspectors will aim to ensure that the site maintains the standards observed, and continues to comply with appropriate environmental requirements.

Section 3 Preface

3.1 The Environment Agency

The Environment Agency was formed on 1 April 1996 and is responsible under the Environment Act 1995 for the regulatory controls previously exercised by Her Majesty's Inspectorate of Pollution (HMIP), the National Rivers Authority (NRA), and the local authority Waste Regulation Authorities (WRA). Under the former structure, HMIP were responsible for implementing and enforcing the system of Integrated Pollution Control (IPC) for the larger, more technically complex industries in England and Wales as set out in the Environmental Protection Act 1990. HMIP were also responsible for regulating the control of radioactive substances (RAS) under the Radioactive Substances Act 1993.

The Glaxo Wellcome site at Ulverston, Cumbria, came fully under HMIP regulation with the issue of the IPC authorisation for the manufacture of Cephalosporin on 1 April 1994. HMIP were then responsible for regulating all releases to air and controlled waters from the site. Prior to the implementation of IPC, the NRA were responsible for issuing consents for discharges of effluent from the site into controlled waters, and were statutory consultees to advise HMIP on conditions to be included in the IPC authorisations.

The removal and disposal of solid and other wastes from the Ulverston site to landfill or for other treatment remained under the control of the Waste Regulatory Authority of Cumbria County Council until 1 April 1996 when this function transferred to the Environment Agency.

3.2 Large Scale Audits

The methodology for "Large Scale Audits" was developed by the former HMIP as a means of concentrating the efforts of a team of inspectors to examine an operator's compliance with environmental regulations. In 1995 HMIP carried out two trials of large scale audits, at the BP Chemicals site in Hull and at ICI Chemicals & Polymers site in Runcorn, Cheshire. These audits were limited to the IPC and RAS functions regulated by HMIP.

This latest audit of the Glaxo Wellcome site in Ulverston has extended this methodology, for the first time, to include inspectors from the Water Quality and Waste Functions as well as the IPC/RAS functions of the Environment Agency. This gave the Agency the opportunity of reaching a unified impression on the way that Glaxo Wellcome are meeting their environmental responsibilities.

3.3 The Glaxo Wellcome Site at Ulverston

Following the merger of Wellcome with Glaxo in 1995, the Glaxo Wellcome Group became the world's largest pharmaceutical company, with products targeting a wide range of therapeutic areas. The group headquarters are in the UK and there is a manufacturing or sales presence in most parts of the world.

The Glaxo Wellcome site at Ulverston is one of seven manufacturing sites in the UK, and is mainly concerned with the bulk manufacture of primary (active) antibiotics which are formulated into final sales preparations elsewhere. The site was opened in 1948 for the production of penicillin and streptomycin on the site of a former iron and steel works. It is located on the edge of the town of Ulverston in an area of exceptional environmental importance just outside The Lake District National Park, and along the edge of Morecambe Bay which is designated by English Nature as a "Site of Special Scientific Interest (SSSI)". The Ulverston Canal runs along one side of the site.

Over the years the site has developed and expanded, and now covers an area of approximately 65 acres and employs 1200 people. Although generally modern, there is a variety of chemical plant and buildings representing the changing standards since the site opened. A few of the buildings and one of the boilerhouse chimneys date from the iron and steel works period. Replacement value of the assets is estimated at £500M. Production capacity is less than 1000 tonnes per annum of primary pharmaceutical products, supporting a group business of around £1 billion.

The first generation of the more modern antibiotics known as cephalosporins were introduced in 1964, using the site's experience in fermentation technology. Manufacture of the earlier antibiotic products has been phased out over the years and the latest cephalosporin range now accounts for 90% of production activity at the site. The "bacterial infections" range of products, of which the Ulverston site is a major contributor, represents around 13% of Glaxo Wellcome's worldwide business.

The other main product made at the site is Griseofulvin which, in its final formulation, is a preparation used for the treatment of fungal infections. As with cephalosporin, the first stage of manufacture is the fermentation of a specially developed strain of a naturally occurring organism.

The site also has a strategically important development and pilot plant used for process development and scale up, and for the small scale production of material used in clinical trials of new products.

As a large scale manufacturer of organic chemicals, the use of organic solvents plays an important role in many of the chemical processes carried out. Solvent recovery and recycling is therefore an important part of the site operations. Around 95% of the site's solvent usage is recycled, representing a saving of £110M a year, half of which would be the cost of fresh solvent and half the cost which would otherwise be incurred for disposing of spent solvents.

Services provided on site include a steam raising boilerhouse and a waste solvent incinerator, both of which have separate authorisations under IPC.

3.4 Authorisations, Registrations, and Regulations to be Audited

IPC authorisation AK5687/AN5128/AU0368

Cephalosporin Production (antibiotic), main product range for the site. Authorisation includes solvent recovery and discharges to water for the whole site.

IPC authorisation AK5954/AU0376

Development Plant including stages for Lamivudine production (used in treatment of AIDS).

IPC authorisation AO1420

Griseofulvin (anti fungal) product range.

IPC authorisation AG7423/AT8193

Waste solvent and aqueous waste incinerator.

IPC authorisation AA2003/AT9092

Boilerhouse (Large Combustion Plant).

Radioactive substances, RSA registration AG7849

Six closed sources.

Radioactive substances, RSA registration AC8312

Open sources.

Waste Management Regulations Including :-

(i) The Duty of Care Regulations introduced in the Environmental Protection Act 1990.

(ii) The Control of Pollution (Special Waste) Regulations 1980, and The Special Waste Regulations 1996

(iii) The Registration of Carriers introduced under the Control of Pollution (Amendment) Act 1989 and the Controlled Waste (Registration of Carriers and Seizure of Vehicles) Regulations 1991

(iv) Waste Management Licensing Regulations 1994 .

Section 4 Audit Methodology

4.1 Audit Methodology

In preparing for the audit, reference was made to the methodology used by HMIP in the trial large scale audit of ICI Chemicals & Polymers at Runcorn in October/November 1995.

The audit was carried out by a team of six inspectors from the Environment Agency, four from the IPC/RAS functions, and one each from the Water Quality and Waste functions. Overall planning was the responsibility of the Audit Team Leader who, in this case, was the IPC/RAS site inspector for the Glaxo Wellcome Ulverston site. Only one other member of the team had any previous significant dealings with the site, whilst three members had no previous knowledge of the site.

The specific objectives were decided by the team prior to commencing the audit. Teams of two IPC/RAS inspectors were set up to cover the five IPC authorisations and the RAS registrations such that no inspector worked with the same inspector on more than one authorisation. The Water Quality and Waste inspectors carried out inspections independently in order to focus their expertise on the relevant areas of the site.

4.2 Audit Preparation

The site was given three months notice of the Agency's intention of carrying out a major audit. The reasons for the audit were discussed and the Company were given a copy of the report on the ICI Runcorn audit. Glaxo Wellcome confirmed their full co-operation with the audit, but sought clarification of the timing and the input expected from the Company.

The dates for the audit week were finalised about two months in advance. The Company were advised that some of the inspectors who were not familiar with the site would require a one day introductory visit beforehand. In view of the size and complexity of the site the Company proposed two introductory visits separated by an interval of a few days. A programme of presentations interspaced with visits to various parts of the site was prepared. Dates for the introductory visits were set for 5 & 10 September prior to the main audit week beginning on 16 September.

The audit team leader arranged a programme for the audit week which was shown to Glaxo Wellcome in order to arrange staff availability. The four IPC/RAS inspectors would be involved for the full week but less time would be required for the Water Quality and Waste inspectors. The Company was also informed that members of the team would wish to visit the site at night although the selected night and purpose of the night visit was not disclosed to the Company.

The Health and Safety Executive (HSE), Ministry of Agriculture Fisheries and Foods (MAFF), and South Lakeland District Council were notified of the audit and invited to comment. Only MAFF replied, stating that they had no comments but requesting a copy of the final report.

Before the two introductory days the audit team met to discuss the strategy and objectives for the audit. It was agreed that, within the constraints of the audit, the work should be carried out in a non-confrontational manner, but if anything was found needing immediate enforcement action by the Agency, it would be brought to the attention of the team leader and the Company in order to proceed with the appropriate action. A set of the relevant enforcement documents would be available for this purpose should the need arise.

Glaxo Wellcome offered the team the use of a lockable meeting room as a base for the whole of the audit week, enabling the team to meet in private at the start and end of each day to compare notes, share experience, and check on progress.

4.3 The Two Introductory Visits

The Company had clearly gone to considerable effort in preparing a well focused programme for the two introduction days, specifically aimed at regulators with little direct knowledge of the site and its operations.

The introductory visits were regarded as an integral part of the audit, not only forming the basis for the later inspections, but also the subject of the team's enquiries on such matters as the site's environmental policies, waste minimisation, and management structures.

4.4 The Audit Week

The week commenced at 9.00 am on Monday 16 September with the target of completing the site work by lunchtime on the following Friday, ready for a feedback session with the Company on the last afternoon.

Glaxo Wellcome personnel accompanied the inspectors at all times while they were on site other than during the private meetings in the inspectors base at the start and end of each day and at lunch time. This was in accordance with site policy for health and safety of visitors and for security reasons, but inspectors were not restricted in any way in the choice of areas they wished to visit.

Each audit usually started with a discussion with the senior managers of the area, followed by an inspection of the plant. As well as considering whether the plant was suitable for the process the Inspectors examined process records, monitoring records, plant operating instructions, and maintenance records. There were also extensive interviews with staff at all levels, and training records were examined. At the end of each session a review meeting was held to record initial observations and clarify whether any further information was required. In some cases Glaxo Wellcome were able to supply the required information by the next day and in other cases written details have been forwarded to the team leader after the audit.

On the Wednesday evening, without giving any notice to the Company, one inspector undertook to observe the 7pm shift handover procedures in the Solvent Recovery Area. On the same evening, shortly after that inspector had left the site, other inspectors arrived for an unannounced night time visit to test the site emergency response procedures. The aim was to observe the Company's response, out of normal hours, to a serious spillage which could have environmental implications. One of the inspectors had earlier been

given the task of devising a realistic scenario for the simulated spillage in the Solvent Recovery Area, whilst carrying out the audit of that section.

On the last afternoon the team gave a two hour feedback of the audit to the site environmental managers. This included the preliminary observations and findings of each member of the team, covering the site wide issues and each of the specific areas that the inspection teams had covered. Glaxo Wellcome were also invited to comment on their observations of the audit.

Part A

General and Site Wide Issues

Introduction

In planning the audit it became apparent that there are a number of issues that do not fit any one particular authorised process, or are common throughout all areas being audited. These site wide issues have a direct impact on the Company's culture, policy and practice and can determine a Company's ability to comply with its obligations under the relevant Environmental legislation. These issues have been brought together in Part A of this report.

Section 5 Site Management Structures

5.1 Objective:

To determine whether the Ulverston site has an effective management structure in place to run the site in a safe way, to minimise unauthorised releases to the environment, and to satisfy all statutory environmental requirements.

5.2 Discussions:

The Company has undergone major structural changes in recent months as a result of the merger of the Wellcome Organisation with Glaxo early in 1995. All business areas have come under scrutiny and even the future of long established sites such as Ulverston has been questioned.

Organisational changes have been cascaded down to local production sites, and over the last twelve months a new management structure has been introduced at the Ulverston site. This has affected virtually all of the production staff.

The site has been re-organised along product-stream lines together with a site services group, all with separate but identical management structures which include responsibilities for processing, operations support, and engineering. The position of a single senior person responsible for the site has been replaced with a Site Management Committee (SMC) chaired by the Director of Operations - International Actives Supply, and attended by the heads of the various product streams, Site Services, Engineering, Quality Assurance, Finance, and other site functional groups. As well as production related matters, the SMC has overall responsibility for the site Safety, Health and Environment (SHE) standards.

The SHE Manager for the site is a member of the SMC, but does not report to a senior member of the site. Such is the regard for SHE matters that he reports directly to the Director of Quality and Compliance, who has responsibility for SHE matters of the whole group. The SHE Manager is therefore never compromised by conflicting interests of production at the site. He leads a small Site SHE group which provides technical advice to all production areas, carries out safety and environmental monitoring, and acts as the main contact for external regulatory authorities.

Processing and engineering have been largely integrated within each of the production areas which are headed by a Manufacturing Operations Manager. Reporting to the Operations Manager are four shift Team Managers, one Operations Support Manager (Days), and an Engineering Team Manager.

The Operations Manager and Team Managers are usually graduate chemists or engineers or former supervisors with extensive site experience. Each production shift team is headed by one of the four shift Team Managers. They are assisted by Team Support Managers who deputise for them when necessary.

The engineering team reports to the Engineering Team Manager, who is supported by an Engineering Team Support Manager.

A recent change to the site structure has been to abolish the system of having senior members of staff on a rota for call-out as the "Duty Officer" in case of an incident out of normal office hours. The weakness of the system was that the Duty Officer may not have sufficient detailed knowledge of the area in which there was a problem, and there would be time lost whilst he was called in. The role of Duty Officer has been replaced by a Shift Manager selected from the Shift Team Managers. The Shift Managers have been given additional training, and are more able to respond and take charge of any unusual occurrences. If necessary they can call on the most appropriate senior manager or environmental managers for more specialist advice.

5.3 Conclusions:

(a) The site has recently undergone radical changes in its management structure to create a more product oriented organisation. Most of the site's functions are now directly accountable to a business area.

(b) Engineering and process operations appear to have been satisfactorily integrated in their respective production teams headed by the Operations Managers.

(c) The Shift Team Managers provide a core of highly trained staff in charge of each of the shift teams at all times. The new role of Shift Manager provides a central focus for taking charge of unusual occurrences and incidents.

(d) Overall the site management structure provides highly trained staff at all key levels within the organisation and should enable the site to be run in an efficient way to satisfy production requirements and meet the management requirements stated in the IPC authorisations.

5.4 Recommendations:

There are no recommendations since the management structure appears to function satisfactorily.

Section 6 Corporate and Site Environment Policy

6.1 Objective:

To identify whether there is a corporate environmental policy and to determine if these policies are implemented at the Ulverston site.

6.2 Discussions:

In common with many organisations Glaxo Wellcome have closely linked their responsibilities for the Environment with those of Safety and Health in deciding their overall Safety, Health and Environment (SHE) policies.

The corporate policy, which is endorsed by the Company's Deputy Chairman and Chief Executive, applies to every Company within the group throughout the world. A copy of the policy is shown for reference in Appendix 1.

At Ulverston the corporate policy is embodied in a comprehensive document "Implementing the Safety, Health and Environment Policy at Ulverston", which is shown in Appendix 2. The first part lists the general responsibilities of all staff, the SMC, Operations Managers, and the Team and Support Managers. The second part shows a list of actions the site will carry out to ensure the corporate SHE policy is met. These actions are detailed under the following headings :-

Leadership and Discipline
Communications and Consultation
Monitoring
Sources of Information
Techniques used for Selection & Design of Equipment Process and Facilities
Written Safe Systems of Working
Permits to Work and Other Safety Certificates
Emergency Procedures
Accident and Incident Procedures
Information, Instructions and Training
Planning, Target Setting and Performance Appraisal
Audits of Area Safety, Health & Environment Management Performance

In addition to the Corporate Policy and the Ulverston Site Implementation Policy, the site operates a Waste Minimisation Policy which is examined separately in the next section.

6.3 Conclusions:

(a) Glaxo Wellcome have a corporate environmental policy at least equal to those expected from a multinational organisation of this type. The corporate policy sets the overall environmental aims of the Company but has few details of how the aims are to be achieved. Its purpose is to provide a basic framework for the local operating companies to follow in developing their own strategies.

(b) A cascade system has been developed to transfer corporate environmental policies into site policies.

(c) The implementation document for the Ulverston site clearly specifies individual and managerial responsibilities, and details the way the site focuses attention on SHE matters in all activities. This is not a one-off policy but a developing culture with target setting, improvement plans, progress reviews and built in self auditing programmes.

6.4 Recommendations:

The only recommendation is that the Corporate and Site Environmental Policies are maintained, reviewed, and updated as appropriate.

Section 7 Waste Minimisation Policy

7.1 Objective:

To determine the level of commitment given to waste minimisation at source to reduce releases to all environmental media.

7.2 Discussions:

Waste minimisation was the subject of a presentation to the audit team during the introductory visits.

The site claims to have operated a waste minimisation policy for many years in the fact that over 95% of the solvent used on site is recycled. In other areas wherever possible, the site operates a policy that it is better to try to avoid producing waste in the first place than having to dispose of it. There is a hierarchial approach to materials which considers eliminating, substituting, reducing, re-use, recover/recycling, abatement, and disposal only if all other efforts are unsuitable. However, the site is a medium sized organic chemical plant and by the very nature of its products there is a wide range and significant quantities of hazardous materials which are in regular use.

Waste Minimisation Project

The introduction of IPC and the prospect of new EU environmental legislation has given a new impetus to waste minimisation for the site. Faced with the prospect of more restrictive emission limits in the future the site has had to consider the options available. A programme of fitting end-of-pipe abatement techniques has been rejected on economic and environmental grounds, and the alternative of developing waste minimisation techniques is being pursued.

The Company has set itself the overall target of reducing emissions to air and water by 50% over a five year period. To achieve this the site has developed a list of objectives to be met within the period, based on the site's expectations of possible downward trends in emission limits likely to be required by regulatory authorities.

About a year ago a Waste Minimisation Project Team was set up to investigate and develop ways of achieving the site's target. The project is led by a core team who are able to bring in other expertise from each of the process areas as necessary. Initially meetings were set up to consider the individual process operations for each process and to draw up a list of every possible means of introducing waste minimisation, including reducing energy usage. A means of ranking the possibilities in terms of chance of success, costs, and benefits has been used to reduce the numbers and introduce a priority listing.

A number of promising projects have resulted from this exercise and are now being explored. Some are reaching an advanced stage and could soon be implemented.

Other Site Wide Waste Minimisation Initiatives

The culture of waste minimisation is not limited to processing activities but has spread to all activities on site. Facilities have been introduced to collect and recycle everything from waste paper, metal and plastic containers through to polystyrene chips, fluorescent light tubes, and plastic drink cups.

7.3 Conclusions:

The site is clearly committed to the concept of waste minimisation at every level. It is now part of the culture of the site. The Waste Minimisation Project has great potential for reducing the environmental impact of the processes carried out at the site and could lead to potential savings for the Company.

7.4 Recommendations:

The waste minimisation culture introduced at the site is to be welcomed. The Waste Minimisation Project for process activities offers substantial environmental benefits and is preferred to end of pipe solutions whenever possible. There may however be situations where end of pipe treatment is the only solution in a reasonable timescale. The Environment Agency recommends that the Company should continue to support the waste minimisation activities.

Section 8 Site Energy Policy

8.1 Objective:

To determine if the site has an Energy Policy as part of the considerations for reducing its environmental impact.

8.2 Discussions:

The Company were questioned about the site energy policies during the introductory visits and during the formal audit of the boiler plant. Although they were unable to provide full answers at the time, a more considered response was made following these sessions.

Energy Production On Site

Process steam raising capacity is provided on site by four steam boilers with a combined net thermal input of 160 MW, but the average normal demand is only around 60 MW. The boilers are approaching the end of their anticipated life and there are provisions for capital expenditure in the five year plans for a replacement boiler, but there were no definite proposals at the time of this audit.

Electrical power is normally supplied by the National Grid but there are standby provisions to supply the 10 MW electrical needs of the site. There are no plans for the site to routinely produce its own electricity and become a net exporter.

Energy Saving Policies

There have been site energy reduction targets in the past, for example in 1990 the aim was to reduce energy usage by 3% a year over a five year period. A number of projects implemented over that period either directly or indirectly resulted in an overall energy reduction of around 12%.

The Glaxo Wellcome Operations Business Plan introduced in 1996 to cover the next five year period does not have a direct energy reduction target but it does set an environmental target of reducing releases to the environment by 50% over the period. Indirect contributions could be made by energy saving, as the gases produced in power generation on-site contribute to the total environmental load, but it does not take into account the environmental effects of electrical power generated off-site.

A corporate target aimed at reducing energy consumption by 10% over the period 1996 to 2000, with 1996 as the baseline, has recently been introduced, and will be translated into a specific target for the Ulverston site.

8.3 Conclusions:

(a) The site's steam and power raising facilities are approaching the age when decisions will need to be taken about replacing older plant. Modern plant operating to BATNEEC would have less of an environmental impact.

(b) As yet there does not appear to be a current site policy aimed specifically at reducing energy usage. Savings in energy could offer financial benefits but more importantly would contribute to reducing the environmental impacts from both on-site and off-site generation of energy.

8.4 Recommendations:

(a) The site should re-evaluate the current and future needs for steam and power and examine how these are to be provided in the future, taking economic and global environmental aspects into account.

(b) The management should do more to encourage and emphasise energy saving measures, possibly by the re-introduction of specific targets for reducing energy consumption on the site.

Section 9 Site Operating Procedures and Instruction

9.1 Objective:

To examine a representative number of written site operating procedures and instructions to determine if they are relevant and up to date, and whether the general principles behind them are understood and followed by staff.

9.2 Discussions:

For any large, complex organisation there have to be written systems in place to ensure that both the routine operations and the more unusual events are carried out effectively to achieve the intended objectives. At the Ulverston site there are a variety of written procedures and instructions to ensure that products are manufactured safely and consistently and follow recognised standards of Good Manufacturing Practice (GMP) for the pharmaceutical industry. Many of these procedures are regularly inspected by health and pharmaceutical authorities from around the world to satisfy the requirements of countries to which the Company exports.

Site Wide Procedures

There are a large number of site wide procedures, however, for the purposes of this audit it was felt to be more appropriate to concentrate on the specific process related procedures which could directly affect releases from the site.

Operating Procedures

In all areas audited inspections were carried out on a range of batch sheets, Plant Operating Procedures (POPs), and Plant Operating Instructions (POIs).

Plant Operating Procedures describe how a process is carried out. It is site policy that they are reviewed by the Operations Manager every 24 months or whenever changes are introduced. Plant Operating Instructions provide the written instructions for how part of the plant, or a specific item of equipment, is to be operated. They only need reviewing at five year intervals unless there are any changes to the plant.

Both POPs and POIs are essential reference manuals kept on plant for use by the operators or during operator training, but it is not usually necessary to refer to them during routine operation of the plant.

Specific comments on the standards found during the separate audits are set out later in the report. When inspectors asked to be shown copies of procedures they were always readily obtained by the operators. The procedures appear to have been well prepared, covering all technical aspects, and are understood by the relevant operators.

There were instances, particularly in the Solvent Recovery Area and the Waste Solvent Incinerator, where unauthorised (ie. unsigned) copies of procedures were found to be in use. The reasons given were that the original official copy had possibly been removed during operator training.

A few examples were also found where the review dates had been long exceeded, but in all of these cases the inspectors believed that the procedures were still relevant and there had been no detriment to plant operations.

An example was also found in the list of procedures for the Utilities area which dates back several years and includes duties which are now the responsibilities of other departments.

9.3 Conclusions:

(a) The site has well documented procedures. They are readily available to all staff who may have cause to refer to them in carrying out their duties.

(b) Staff are familiar with the procedures and understand their requirements.

(c) There are a few instances where the site instructions for reviewing and updating procedures have not always been followed.

9.4 Recommendations:

Some attention should be given to ensuring that all working copies of procedures are the official copies signed by the appropriate level of management, and that reviews are carried out at the frequency specified in the site instructions.

Section 10 Shift Handover Arrangements

10.1 Objectives:

To consider the adequacy of the shift handover arrangements on one of the process plants.

10.2 Discussions:

The flow of information from one shift team to the next in the form of a shift handover is a critical operation which needs to be carried out in a structured manner, with sufficient time being devoted to it so that the information handed on is complete and has been understood fully.

Shift Handover in Solvent Recovery Area

Solvent Recovery was chosen for the study for two reasons: it has a central role involving interaction with all other process plants, and, because of the large volumes of solvent handled, it has the capacity to have a serious impact on the environment.

Solvent Recovery covers four separate units on the site and as it would not be possible to cover all of these handovers, the audit concentrated on the handover for No.1 Site, and the subsequent Team Manager's handover for the four solvent recovery sites, the site incinerator, and the effluent discharge tanks.

The control room covering solvent recovery Sites 1-3 was visited half an hour before the shift change over time. The lead operator covering No.1 plant had already commenced filling in the required plant readings on the plant status sheet. The sheet provides a record of the state of the plant at the time of handover and has space for other commments such as maintenance work being carried out. Three additional copies are made using carbon paper but it is the final copy which is retained on plant for the incoming shift. An inspection of a sample of these carbon copies showed that some were barely legible.

The lead operator explained the plant status issues to the outgoing Team Manager who signed the logsheets and took the original plant status sheet together with two additional carbon copies, before moving on to other areas in the control room.

The lead operator briefed the incoming lead operator on the state of the plant using the retained copy of the plant status sheet, and made a tour of the plant with him. Both verbal handovers were communicated clearly and given at a reasonable pace to allow the issues to be understood.

The handover between the two team managers was witnessed in the Team Manager's Office as they discussed the plant status sheets and the written handover report prepared by the outgoing Team Manager. This was carried out in a structured manner.

An Unusual Incident Report (UIR) was raised for one issue noted during the handover. This concerned the discovery of corroded studs on a flange leading into an acid storage tank on the plant. The UIR system allows for a structured follow up of a report of a plant problem including feedback to the originator on the actions taken.

On completion of the handover from the lead operator and the handover between the two team managers, a short period of time was spent with the incoming team members to check their understanding of the information they had been given in the handover. Both team members demonstrated a good understanding of the information and issues raised in the handover.

10.3 Conclusions:

(a) The shift handovers witnessed during the audit were carried out in a structured manner with sufficient time for the issues to be communicated properly to the incoming shift team. The incoming shift team members appeared to have a good understanding of the information and issues handed over to them.

(b) Appropriate records were made of the plant status (including any plant issues) at the end of the shift and passed on to the incoming shift.

(d) One potential weakness is the use of carbon paper for making additional copies of the plant status sheets. Some poor quality copies of these sheets were seen on plant.

10.4 Recommendations:

Glaxo Wellcome should ensure that legible copies of plant status sheets are retained on plant for the reference of the next shift.

Section 11 Internal SHE Audits

11.1 Objective:

To determine how the site checks that it complies with safety and environmental requirements.

11.2 Discussions:

One objective of the Company SHE policy is to regard external standards as a minimum, to be improved on where possible. A system of auditing has been introduced to ensure that this objective, and other SHE policies, are being met.

Inter-Site Auditing

It is part of Glaxo Wellcome's Group SHE policy that regular audits are carried out to assess and report on the application of the SHE policies in all companies of the Group. Throughout the "Actives" manufacturing sites, there is a system of regular formal site auditing which is carried out by SHE managers or other trained staff from different sites.

Self Auditing Systems (SAS) and SHAPE

At the Ulverston site a Self Auditing System (SAS) and a Safety and Health Action Planning and Evaluation (SHAPE) system have recently been introduced. These require Team Managers to carry out a documented review of procedures, plant systems, and process equipment which are included in a documented programme. It is written into the Site Policy that the Team Manager will carry out these audits, and is included as part of the Team Manager's annual performance objectives. Copies of the SAS and SHAPE reports were examined by the inspectors during the Agency audit.

Unusual Incident Reporting (UIRs)

The Company have developed a reporting system for unusual incidents and have encouraged staff to use this for even the smallest of incidents (eg weeping valves etc). This does not replace the duty of staff to deal directly with a potentially hazardous situation relating either to plant or personnel safety, or to the environment. The reports are known as Unusual Incident Reports (UIRs).

The UIR form allows a structured follow up of any incident and the team manager or team support manager receiving a report form will note any action taken at the time and forward the report form to the Operations Manager for the area concerned, so that a review of further implications can be made. If there are health and safety or environmental implications, the Operations Manager passes the form to the Safety and Environment Unit.

When all appropriate actions have been taken, the report form follows the reverse path to the Operations Manager and back down to the team manager/team support manager, who signs off the report form. The form is then shown to the originator. If the originator is not satisfied with the response to the initial report, a further UIR can be raised.

Copies of UIR forms for the Solvent Recovery Area were reviewed. Follow up of the UIRs is by the following mechanisms:

1) The Team Manager makes a weekly report including all UIRs;
2) The Operations Manager makes a monthly assessment of all UIRs;
3) Safety, Health and Environment section (SHE) produce a monthly report on UIRs;
4) Areas are required to undertake an annual review of UIRs as part of their SHAPE review.

The SHE Group used to have a database to analyse UIRs and generate trends but this has fallen into disuse. A new software package is being considered.

11.3 Conclusions:

(a) Glaxo Wellcome is committed to carrying out internal self auditing at all levels in the Company to ensure compliance with its own Safety Health and Environment standards which aim to be higher than legal minimum requirements.

(b) Although the site does not operate to any recognised externally audited standards, the Agency is satisfied that the comprehensive auditing by trained auditors from other sites within the group, together with the site's own self auditing system, is at least as good, and possibly more focused than if an external organisation was involved.

(c) The UIR scheme encourages early reporting of unusual occurrences and incidents. It provides the ability to formally record and follow them up in a structured manner, and to offer feedback to the originator of the report.

11.4 Recommendations:

(a) The Company should be encouraged to continue with the inter-site audits, and the Self Auditing Systems introduced at Ulverston.

(b) The use of the UIR system by other operators of processes regulated by the Environment Agency, should be encouraged.

(c) The Company should consider the re-introduction of a keyword database for assessing trends in the Unusual Incident Report (UIR) data.

Section 12 Training

12.1 Objective:

To determine if staff at all levels receive appropriate training as required by the IPC authorisations, to enable them to carry out their duties and to be aware of their responsibilities for safeguarding the environment.

12.2 Discussions:

It is a requirement in every IPC authorisation that the process is managed and operated by persons who are qualified, experienced, trained, and supervised in respect of duties to be undertaken in carrying on the authorised process. As part of this audit, the inspectors took the opportunity to examine the training records of a variety of staff in different roles in a number of the process areas inspected.

There is no central repository for staff training records. Instead, the site has introduced a system of plastic "Pizza-Box" folders for each individual's training records, which is held by the manager in the area in which the person is currently working. The records are easily updated and are transferred when the person is moved to a different area of the works. They hold details of the individual's qualifications and a summary of training before the new system was introduced, followed by very detailed records of all training courses attended, seminars, and relevant company briefings.

Operations Manager and Team Managers are usually graduate chemists or engineers or former supervisors with extensive site experience. Technical Support Managers are very experienced persons promoted from operators.

For process operators, the status of operator grade achieved is recorded along with the types of operations, or process units for which the operator has been trained. The site has three grades of operators. The lead or "O" grade operators have at least 5 years site experience and Plant Operators Qualifications. A Class 1 Operator may not have qualifications but is trained on the site and only works under the supervision of an O grade until signed off as competent for certain operations. Two years experience is suggested as minimum before they undertake unsupervised tasks. The grade of "Class 2" operators covers new starters or former craftsmen from the site undergoing training as operators.

The site runs its own internal environmental awareness course which all process staff should have attended, in which the implications of authorisations were explained. Additional training as required under the conditions of an enforcement notice should also have been given. Whilst most of the training records examined by the inspectors were complete, some of the records for process operators contained no details of having attended environmental or IPC awareness training.

Formal environmental awareness training has been supplemented on site by the issuing of laminated pocket sized IPC awareness cards to all process staff. Examples are shown in Appendices 4 and 5. The cards are a unique innovation developed at the site to simplify the requirements of each IPC authorisation for process staff, and identify the main

pollutants and key abatement systems for that particular process area. The actions to take in cases of any doubt or during an incident which may have environmental consequences are listed.

All operators were able to produce their IPC awareness cards when asked by the inspectors. However when asked to name significant pollutants from their process not all operators could name them with confidence and there seemed some uncertainty when further questioned about their environmental significance. Operator awareness of the potential for their processes to cause environmental harm is seen as an area in need of some improvement.

Nevertheless, the audit team were impressed with the way that the IPC awareness cards have been developed and used by the site as a way of introducing IPC requirements to the operators and providing them with a handy reference card. They are an excellent innovation which could well be copied by other companies.

During the audit many of the staff were questioned about their knowledge of Integrated Pollution Control and the purposes of IPC Authorisations. All staff knew of the existence of the authorisations and were able to show or direct inspectors to their nearest copy. The level of understanding of details in the authorisations was appropriate for each level of staff involved.

12.3 Conclusions:

(a) Glaxo Wellcome operates a good system for recording training of all staff at the Ulverston site. It meets the requirements of the IPC authorisations.

(b) Not all staff appear to have had formal environmental awareness training and where there are omissions, for whatever reason, these staff need to be included in a round-up training session.

(c) The "Pocket IPC Card" system, which has been developed by the site to remind process staff of their requirements under IPC, is an excellent example for others to follow.

(d) Some operating staff need to be further aware of the key pollutants from their processes and their potential for causing environmental harm.

12.4 Recommendations:

(a) The Company should ensure that all appropriate members of staff have attended a formal environmental awareness training session.

(b) A further level of environmental training is now needed to provide personnel with a more specific understanding of the potential environmental effects of the materials they are handling.

(c) The IPC pocket card system developed on site should be publicised for other companies to follow.

Section 13 Plant Maintenance

13.1 Objective:

To determine whether the procedures for maintenance satisfy the condition in the IPC authorisations which requires the operator "to maintain in good working order all plant, equipment and technical means used in carrying on the authorised process".

13.2 Discussions:

A common maintenance policy operates for all processes on the site. At present all of the planned maintenance schedules are being transferred from a manual (Cardex) system to a computerised (EPMS) system. The transfer is being implemented in stages and should be completed by the summer of 1997. The new system should improve work planning and the efficiency with which the system can be interrogated for information on maintenance carried out and verification that it is carried out at the specified frequency.

The category of maintenance which is recorded on the Cardex or EPMS systems defines the priority and frequency of planned or other maintenance is defined by the plant area in conjunction with the engineering team. Categories in use are GMP (Good Manufacturing Practice), General, PSE (Plant Safety and Environment) and Critical. The EPMS system allows for reporting of planned maintenance of high priority items (Critical and PSE) which has not been carried out within the specified time window.

The EPMS system generates a list of work to be done for each week which is allocated by the Engineering Team Manager. The computer also generates a weekly report of any outstanding routines, which the Team Manager can follow up - particularly those with PSE or GMP priority. Records of maintenance actions are kept for at least 7 years.

In both the Cardex and EPMS systems the details of maintenance required for each plant item are specified on Job Cards which contain brief job descriptions, a reference to the appropriate GMP procedure, and space for the job to be signed off when completed together with any comments.

The maintenance requirements and schedules for new plant items are agreed when the items are installed and are based on Good Manufacturing Practice and/or manufacturer's recommendations. However the site is increasingly moving to "Condition Monitoring" instead of intrusive maintenance where appropriate. This allows simple checks to be carried out on plant items at a much increased frequency and concentrates maintenance effort where it is needed. The risks of releases during or following intrusive maintenance for example on pump seals is therefore reduced, but the pump would be inspected at a greater frequency.

During maintenance, liaison between engineers and production staff is achieved mainly by the Permit to Work system. Production prepare the plant to be worked on and issue a permit (General Safety, Confined Spaces or Source of Ignition certificate). The tradesman signs off the permit when the work is completed, and production then cancel the permit. A handover log is used to highlight continuing work at shift changeover.

Examination of Maintenance Records

During the formal audit inspections of the authorised processes, inspectors examined the maintenance records of selected critical process plant items and instrumentation systems.

The inspectors were particulary concerned that the change in systems is managed such that maintenance regimes are not overlooked and fall between the control of the two systems. Checks were made on a number of randomly selected plant items and the records of transfer from the Cardex to EPMS were examined. No evidence was found of any failures during the transfer.

Detailed examinations were also made of the maintenance schedules of a number of specifically selected plant items, and inspectors followed the work order generated by the EPMS system, through the job specification, to the signed off form showing any additional work required and carried out by the maintenance staff.

In one area of the site, the inspectors noted an apparent lack of a maintenance or calibration schedule for some of the instrumentation associated with wet scrubbers used to abate releases of solvent vapours to air. This is unsatisfactory and has been brought to the attention of the Company.

Maintenance on Effluent Discharge Systems

The routine for calibrating pH meters on one of the local process effluent pits was examined and it was confirmed that the routine is carried out twice per week, and as an identified Plant Safety and Environment (PSE) item it is given a high priority.

The maintenance regimes for the tidal effluent discharge tanks were reviewed. Reports included visual inspections of the structural integrity of the High BOD effluent tank. The discharge valves did not appear to be on the EPMS system.

Inspectors discussed the construction and testing of local process effluent pits on the site. These tend to use acid resistant tiles with an acid resistant cement and a backing membrane and are satisfactory for minimising leaching to groundwater.

There is no formal requirement or schedule for testing or maintaining the process effluent pits, but annual clean outs of these are carried out and would allow for some formal condition monitoring to be carried out at the same time. The need to keep formal records of inspections carried out, and any follow up actions, was noted.

13.3 Conclusions:

(a) Overall the maintenance regimes in use at the site are satisfactory and meet the requirements of the IPC authorisations.

(b) The transfer of the planned maintenance regimes from a manual Cardex system to a computerised EPMS system should improve the control and scheduling of all maintenance activities when it has been fully implemented across the site.

(c) Examination of maintenance records for plant items chosen at random showed that the transfer from the Cardex to the EPMS system was being satisfactorily achieved.

(d) For some of the wet scrubbers used as abatement systems for solvent vapours released to air there appeared to be little or no scheduled maintenance or calibration of instrumentation.

(e) All inspections carried out, and any follow up work, particularly on the tidal effluent tanks need to be recorded formally. The maintenance requirements for the discharge valves should be included in the EPMS system.

13.4 Recommendations:

(a) Glaxo Wellcome should Audit the transfer of maintenance/condition monitoring regimes from the manual to the computerised system, to ensure that maintenance/condition monitoring of all relevant plant items continues at the specified frequency.

(b) The requirements for maintaining and calibrating instrumentation on some abatement equipment for releases to air need to be reviewed.

(c) All maintenance and follow up work on the effluent tanks needs to be recorded formally. The maintenance requirements for the discharge valves should be included in the EPMS system.

Section 14 Compliance Monitoring

14.1 Objective:

To determine if the site has sufficient resources and appropriate laboratory facilities to enable monitoring of releases to the environment to be carried out as required in the IPC authorisations.

(Monitoring of effluent discharges to controlled waters is also discussed in Section 23 - Aqueous Effluent Systems.)

14.2 Discussions:

Compliance Monitoring Requirements

The five IPC authorisations issued to the Company all specify routine monitoring of releases to air and controlled waters, which must be carried out and the results forwarded to the Environment Agency for circulation to public registers. Monitoring may be continuous or intermittent, and in the latter case the type and frequency of monitoring is set so that the operator is able to demonstrate confidence in complying with authorised limits at all times, even when there is no monitoring being carried out.

Glaxo Wellcome are also required to carry out a programme of air quality monitoring for sulphur dioxide, nitrogen oxides, hydrogen chloride, and particulates, in three locations close to the site and at a control point some distance away.

Measurements from continuous monitors need interpreting to give summarised results for use by the Agency. Intermittent or occasional monitoring requires the use of a wide range of techniques and equipment including very simple tests through to complex methods requiring the use of the latest sampling and analytical laboratory equipment. For some specialised techniques, such as dioxin measurements, specialist consultants will be required, but a medium sized chemical works would be expected to provide its own in-house monitoring for the majority of compliance monitoring required.

The Environment Unit

The site's Environment Unit comprises of five staff including a Senior Environmental Adviser who respond to the site's Safety Health & Environment Manager. The SHE Manager in turn responds to the Director of Quality & Compliance.

The Unit provides a central environmental service to the whole site, offering a centre of environmental advice and expertise, and carrying out all compliance monitoring required for the site and providing the main day to day contact with external safety and environmental regulators. It is responsible for maintaining monitoring records and supplying these to the Environment Agency at the required frequency. The Unit also prepares a quarterly IPC compliance report for internal purposes which is circulated to members of the Site Management Committee. Another function is to investigate all external complaints about the site and record details of the findings, (see Section 15).

Resources and Facilities Available

The Environment Department has its own range of portable monitors and a well equipped laboratory capable of carrying out a range of laboratory based analytical techniques. The department is staffed during day time office hours Monday to Friday and by a call out system if required at any other times. The laboratory facilities may be supplemented by the main QC laboratory which is used for analyses which the Environment Laboratory is not equipped to carry out. Shift Team Managers and Team Support Managers in the Solvent Recovery Area have recently been trained to provide shift cover for monitoring a number of key parameters for the aqueous effluent systems.

During the audit, as well as examining monitoring records, the team discussed with the staff the procedures used for determining the appropriate monitoring techniques they use. A "Methods File" is used to list all sampling and analytical methods used by the group. It records the basis for the methods, and other information including applicability of the technique, equipment to be used, procedures, sample calculations, and validation. The methods used are often industry standards or methods developed by recognised organisations. Where a commercial instrument is used a copy of the operating instructions is kept in the methods book.

There is a separate Quality Manual to record the policy, responsibilities, procedures and useful references. It includes the operation, maintenance, and calibration of instruments, method preparation, validation, sample handling and record keeping. Separate log sheets are held in a calibration file to provide a record of any instrument calibrations carried out.

The training record of one member of the staff was selected at random for examination. In addition to the basic training and courses and seminars attended, the record also contained a list of the monitoring techniques that the individual had been trained to carry out.

Monitoring Schedules

The IPC authorisations only call for routine monitoring of a representative selection of the two hundred or more release points to air. Greater emphasis has been placed on secondary performance monitoring such as liquor flow on scrubbers, or temperature and flow indication on vapour condensers, to show that the abatement system is operating to its design specification. It was suggested by the inspectors that the formal monitoring schedule should be extended to cover a greater number of release points.

As required in the improvement programmes, the site has carried out a major programme of vent monitoring for some of the other release points to provide data to back up theoretical emissions values quoted in the Company's IPC applications. Actual monitoring often goes beyond the specified minimum required by the IPC authorisation, and in the case of scrubbers, only the maximum release concentrations are reported which, for cyclical batch operations, represents the worst case.

14.3 Conclusions:

(a) The site is fully able to carry out all the in-house monitoring that can reasonably be expected. There is a wide variety of modern analytical laboratory equipment, and there are sufficient well qualified and knowledgable staff capable of developing the sampling and analytical methods required.

(b) The staff were able to demonstrate the sources and origins of the monitoring techniques they were using and provide validation records for the methods selected and calibration records of equipment used.

(c) Monitoring records are well maintained and easily retrievable.

14.4 Recommendations:

(a) The formal routine schedule for monitoring releases to air should be extended to include a greater number of release points.

(b) The site should consider whether there would be any advantages gained by extending the cover provided by the Environment Unit from 5 days a week to 7 days a week, daily working.

Section 15 External Relations

15.1 Objectives:

To consider how the Glaxo Wellcome site at Ulverston relates to the local community, the media, and other external interest groups.

15.2 Discussions:

Glaxo Wellcome is the largest employer in Ulverston, located in an environmentally sensitive area at the southern edge of the Lake District National Park. Effluent from the site is discharged into the Leven Estuary which is part of the Morecambe Bay Site of Special Scientific Interest (SSSI). Local housing is built close to the site boundary and is only a few hundred yards from production buildings in at least two areas.

In this situation it is essential that the Company not only acts responsibly, but is seen to be responsible in order to earn the respect of the community as a good neighbour. It is also seen as vital to the Company's image as a leading healthcare organisation that it pays special regard to safeguarding the environment.

The Company is an active supporter of the Chemical Industry Association (CIA) Responsible Care initiative, and has taken every opportunity to promote this initiative.

Complaints

Over recent years the Environment Agency (and HMIP before then) has received very few complaints about the site. In the last twelve months there were only two complaints from members of the public. An examination of the site's external complaints records for this year (1996) indicated that up to now there had been 13 complaints from members of the public directly to the Company. Of these 11 were about noise, mostly but not all, concerning the works public address system. The other two complaints were about odours.

The works operates a procedure for receiving external complaints and sending a senior person immediately, if at all possible, to talk to the complainant and investigate the cause. There is a standard proforma for logging complaints to try to categorise the symptoms using simple terminology.

Local Liaison Committee Meetings

In 1992 the Company applied for planning permission to Cumbria County Council, to build a new waste solvent incinerator at the site. To counter public concern, one of the planning conditions set by the Council was that the Company must hold a local liaison meeting to discuss the incinerator during construction and commissioning, and annually thereafter. These meetings have proved to be a useful vehicle for discussing the Company's environmental performance in the presence of local representatives, local and county councillors, and environmental regulators. They have now been expanded to cover all the site's activities, not just the incinerator.

Local News Letter - "Environment Matters"

In the summer of 1995 the Ulverston Site published the first ever Glaxo Wellcome neighbourhood environmental newspaper and distributed it to every household in Ulverston. The publication has been judged to have been a success and a second edition was published in the spring of 1996. It is hoped to make this an annual event.

The contents of these newsletters and the initiative taken by the Company in launching them are welcomed as a positive means of reaching out to the local community.

15.3 Conclusions:

(a) The Company has occupied the site for five decades and grown to be a medium sized chemical plant in an environmentally sensitive area. There have been very few complaints by the public to the Company and any that have been made appear to have been promptly investigated by the Company.

(b) The Company have established good relationships with the local community and are taking every opportunity to build on this record. The launch of the publication "Environment Matters" and its widespread local distribution is helpful in this respect.

(c) The support given by the Company to the CIA Responsible Care Initiative and its own initiatives such as "Environment Matters" should help to improve the Company's image in the eyes of an increasingly concerned public.

15.4 Recommendations:

The Company should continue to make every effort to maintain the goodwill it has built up over the years.

Part B

Detailed Audit Inspections

Introduction

This section of the report contains the individual reports, conclusions, and recommendations of the detailed audit inspections carried out for each of the IPC Authorised Processes, the Radioactive Registrations, the Aqueous Effluent System, and Waste Management of the Site. It also includes the report on the Emergency Procedures Exercise, and comments on the Operator Pollution Risk Appraisal system which was used to assess the overall environmental performance of the authorised processes operated at the Ulverston Site.

Section 16 Cephalosporin Plants

16.1 Introduction

The Cephalosporin range of bulk active antibiotics accounts for over 90% of the site's output. The process is split into three distinct operations some of which are operated as independent processing plants with their own management and operating systems. The process stages are :-

Fermentation and Extraction
Chemical Conversion
Finishing.

Some of the operations themselves are further divided into different stages carried out in separate buildings across the site. Intermediate products are isolated at each stage to allow quality testing, and bulking of products which are used as raw materials in subsequent stages.

The first operation is the fermentation of a specially developed form of a naturally occurring organism using large scale fermentation vessels. The fermented broth is transferred to the extraction stage where the solids are filtered out and Cephalosporin is extracted from the filtrate.

Chemical conversion involves a complex chain of processes to convert the basic antibiotic molecule so that it has increased antibiotic properties. There are two basic reaction chains producing different products for the Cephalosporin range of antibiotics.

Finishing involves the final purification of the active materials ready for storage and transfer off-site for formulation into finished products at other factories.

All Cephalosporin related processes carried out at the Ulverston site are covered by the IPC authorisation AK5687 and variations AN5128 and AU0368.

16.2 Objectives

16.2.1 To consider the adequacy of the plant used for the authorised process.

16.2.2 To consider the procedures covering the processes carried out in the plants.

16.2.3 To consider the environmental awareness of staff who operate the process.

16.2.4 To check compliance with the IPC authorisation.

16.3 Discussions

16.3.1 Fermentation and Extraction

Management Structure

The management structure for the Fermentation and Extraction stages follows the new general site structure. At the shift level there are two teams, one for Fermentation and one for Extraction each having four Shift Team Managers and Shift Support Managers. The operations cover the primary manufacturing stages of Griseofulvin as well as the Cephalosporin process.

Environmental Implications Of the Process

Aqueous effluent from the Fermentation and Extraction plants is one of the main sources for the High BOD effluent system contributing about 30% of the site's COD load and more than 90% of the suspended solids load. It is the subject of one of the site's Waste Minimisation projects which has proposed the replacement of the rotary vacuum filter, used for filtering the fermentation broth during extraction, with an ultra-filtration system. Elimination of the need for filter aid will significantly reduce the solids discharged to effluent. The spent mycelium will still be discharged to effluent, but other alternatives are being considered.

Fermentation Area Plant Visit

The fermentation hall is relatively old, containing manually-operated plant which has been updated in the past to include computerised process monitoring. The largest fermentation vessels have a capacity of 120,000 litres, but there are a range of smaller vessels for developing the Cephalosporin culture. The vessels contain an aqueous "broth", with inputs of nutrients and compressed air, and release carbon dioxide as the fermentation progresses. Batch log sheets used for recording process operations were inspected and found to be satisfactory.

Batching of raw materials, in the form of dry powders, to the vessels is carried out under extraction to a water scrubber. This has no instrumentation but the water flow is visible when in operation. The unit was labelled as "HMIP release point A43" but is defined as A1 in the authorisation. It was later explained that A43 was an internal number which had been used to avoid confusion with a release point in the Griseofulvin authorisation also identified as A1. A second unit in the area, identified as release point A2 in the authorisation, has been taken out of service.

The bulk storage tanks for ammonia, which is used in the fermentation stage, are probably the only area in Fermentation with the potential for a significant off-site release to air. Only Team Managers, Team Support Managers and Technicians are authorised to operate these vessels.

The two ammonia tanks (12 te and 15 te capacity) are checked once each shift and recordings are made of tank level, tank pressure, and vapour temperature, on a log sheet. Prior to filling the tanks from road tankers, the Operations team prepare the plant and issue a clearance certificate, but the actual filling is controlled by a Warehouseman.

The Inspectors questioned whether it would better if the plant operators were responsible for filling the tanks. However, it is site-wide practice for Warehouse staff to control tanker deliveries, and Glaxo Wellcome reasoned that it is better to have people who

frequently deal with off-loading operations, than to use operators who may only have to do the job once every few weeks.

The storage tanks have interlocked valves and high level trips and alarms which repeat to the Fermentation control room. During filling the tanks are back vented to the road tankers. The tanks are located in bunds with locked-off drain valves. Any liquor in the bund is tested for pH before discharge to the effluent system.

Environmental Awareness

All Team Managers and Operations Support Managers have copies of the IPC authorisation and are aware of the relevant authorised limits for their plant. All Operators have been issued with laminated, pocket-sized, IPC summary cards which identify emission points, types of abatement equipment, potential problems, and reporting requirements for unauthorised releases.

Procedures for plant operations and generic issues (eg spillages), were available in the Team Managers' office/control room. The "IPC file" is kept there and contains the application and authorisations, together with notes on the effluent systems. A randomly selected operator on the plant was able to find the file without any difficulty.

16.3.2 Extraction

This is also an older, manually operated plant, but it is technically more complex than the Fermentation Plant. The fermentation broth is filtered under vacuum, the solids (mycelium and filter aid) being discharged to the High BOD effluent system. The filtrate, containing the Cephalosprin, is passed to resin columns where it undergoes a 2-stage extraction. The extracted solution is concentrated by reverse osmosis and the product crystallised from acetone before being filtered, and dried. Vents from the crystallisers, driers, acetone tanks and product filter are extracted to a water scrubber. The scrubber liquors, and acetone from the product filtration stage are sent to solvent recovery.

A number of Operating Procedures, which have environmental implications, were examined and found to be satisfactory. They included the procedures for neutralising the local effluent pits, and the operating instruction for the scrubber which is a key abatement system to prevent the release of acetone to air. The vent from the scrubber is monitored quarterly for acetone over a 12-hour period. The recordings and monitoring were satisfactory.

A randomly selected operator showed a good understanding of the plant and the process operated. He was aware of the IPC authorisation and where it was kept. He was carrying an IPC summary card for the process, and although his knowledge of the authorisation was limited, it was adequate for his level of authority.

16.3.3 Chemical Conversion

Chemical conversion is by far the most technically complex part of the Cephalosporin process involving a range of reagents and solvents. The conversion is carried out in a chain of reactions each carried out in dedicated units with isolation of intermediate products at each stage. There are two operational groups involved, known as Building 14 and Unit 5.

Four conversion stages are carried out in Building 14, and seven in Unit 5. A "stage" includes batching, reaction, clean-up, crystallisation, filtration and drying. Operators are usually trained for 3 or 4 stages to allow flexibility of operations. There are between 2 and 7 operators for each stage, and there are 10 operators per shift in Building 14, and 25 operators per shift in Unit 5.

A number of waste minimisation projects are at the feasibility stage, arising from the site-wide initiative. They are aimed at minimising releases of solvent to the environment, and recovery of product from waste streams.

Building 14 - Plant Visit

This is a relatively new computer assisted plant. Operators work from logsheets which identify both the automated sequences and the manual steps. There are generally a number of logsheets for each complete process stage. Further details of the automated sequences are provided in flow charts which were available at the control panels.

A randomly selected operator was able to explain the process stage that he was operating on, and the contents of the batch log sheets. He was also able to explain what would happen in the event of loss of coolant to the condensers, and the actions he would need to take to minimise releases of solvents to air. There are two coolant circuits for the building (+5°C and -20°C), which are both monitored for flow (pressure) and temperature. The Operator was able to locate the main release points to air, and identified the significant contributors to liquid effluent.

Some Plant Operating Procedures were available on plant, but a full set is kept in the Data Room. They included operation of the effluent pit, and the coolant systems.

A shift log is kept for each of the 4 process stages. They record the state of the process/vessels at the end of the shift, and have space for comments on any problems, maintenance, etc, and include a printout of significant process alarms that have occurred during the shift. These records are retained for 12 months, but batch process sheets are archived for 30 years.

The selected operator's training records were examined. There was no record of any specific environmental awareness training, but the operator was carrying an IPC summary card, and the Team Manager confirmed that environmental briefing sessions had taken place.

Unit 5 - Plant Visit

There are six separate buildings within the Unit 5 complex but due to time limitations it was only possible to audit two.

Building 5M is used to carry out one complete process stage plus crystallisation and drying of two other stages. Inspectors observed the batch sheet for the work in progress. The batch sheet included an environmental note for the operator to check that the abatement scrubber was operating satisfactorily prior to commencing the reaction, and to stop the process if the scrubber fan or water-supply failed. The scrubber (release point A45), which was inspected, is used for the abatement of HCl, HBr and dust in releases to air. The scrubbing liquor is recirculating water which is drained to the effluent pit, and refilled every tenth batch. There are differential pressure and flow indicators on the unit. Emissions of HCl to air are monitored quarterly by the Environment Unit.

The enclosure for batching of acetoxy ethyl bromide was inspected. The room is extracted to a scrubber during batching, and the operator wears an air fed suit during the operation. There is an audible alarm and a visual indication to warn of scrubber failure, but it is located on the floor below. The inspectors expressed concern that the operator would not be aware of scrubber failure, and suggested there should be a repeat alarm in the batching room. There is a second operator outside the batching room ready to warn the first operator, but the situation is unsatisfactory mainly from a health and safety point of view, and there are environmental implications.

Distillation and crystallisation vessels are equipped with condensers operating on the +5°C or -30°C cooling water systems. The latter are adequately monitored and alarmed for temperature and flow.

Building 5A was visited primarily to inspect the scrubber (release point A44) which is used to remove HBr. Instrumentation includes water flow, differential pressure and pump pressure. The scrubber is located external to the building, but the instrumentation alarms internally, on the first floor. A recently revised Plant Operating Instruction (POI) for the scrubber was checked and found to be satisfactory. The building is equipped with an HBr alarm system. There are a number of detectors around the plant which automatically shut down the plant and alarm locally and in the site fire station, in the event of a leak.

A check was made on The Manufacturing Guide Amendments and Plant Modification Authorisations which are used to control small-scale changes to the plant or process. They include a statement that safety and environmental effects have to be considered. Plant Modification Authorisations require approval from the Factory Safety and Environment Adviser if there are any effects on safety or the environment, and are usually only approved by the Production Section Head.

16.3.4 Finishing Stages

These buildings were visited during the two day familiarisation visits but not during the main audit week. The finishing operations are not as complex as the chemical conversion stages and have less potential for an impact on the environment. In the limited time available for the audit, inspectors concentrated their efforts on auditing the earlier stages, and were satisfied that their impressions and conclusions would apply to all parts of the Cephalosporin operations.

16.4 Conclusions

(a) The overall impression was of well-run plants with appropriately trained operators. Critical items which may affect safety and releases to the environment (eg coolant circuits) are appropriately instrumented and alarmed. The plants are judged to be satisfactory for carrying out the authorised process.

(b) Clear guidance is provided to process operators in the form of batch record sheets which operators have to complete and initial whilst carrying out the process. The sheets contain special instructions relating to environmentally sensitive items. Additional information, for reference, is provided in the plant operating procedures and instructions which were comprehensive, and up to date.

(c) There is a commitment to training for all staff, and a system for keeping personal training records has been established. Additional comments on training have been made in Section 13 of this report.

(d) Subject to the recommendations shown below, in general the plants involved with the Cephalosporin process comply with the requirements of the IPC authorisation issued for the process.

16.5 Recommendations

(a) Some of the vessels in Fermentation with release points to air are no longer used, and a minor variation is required to update the authorisation to reflect the current situation.

(b) Some of the release points to air have incorrect or misleading identification labels. These need clarifying, and a site-wide system introduced to avoid confusion between release points on different authorisations.

(c) The Finishing Stages of the process which were not included in this audit should be subjected to an early routine inspection by the site inspector.

Section 17 Solvent Recovery Area

17.1 Introduction

Solvent Recovery plants are operated at three separate locations on the site and handle 130 million litres per year of waste solvent for recovery with a total value of £110M. This figure is made up of the cost of fresh solvents (£55M), and disposal costs if the waste solvents could not be recovered (£55M). Solvent recovery is therefore important to the economics of the site and greatly reduces quantities of waste solvent that would otherwise have to be sent for incineration or off-site disposal. Some 12 solvents are used in 20 closed circuits and a typical total inventory at any one time would be 3 million litres. The plant comprises 24 continuous stills, 9 batch stills, and around 170 storage tanks.

Waste solvents for recovery arise from the main production plants on the site. To comply with product licences covering the manufacture of pharmaceuticals, solvents can generally only be recycled within the same process. As over 90% of solvents for recovery are from the Cephalosporins range, the Solvent Recovery Operation is included within the scope of the Cephalosporin IPC authorisation. The authorisation reference is AK5687 and variations AN5128 and AU0368. The variations relate only to the Cephalosporin process and have no effect on Solvent Recovery.

17.2 Objectives

17.2.1 To consider the adequacy of the plants used for solvent recovery operations.

17.2.2 To consider the procedures available and used in carrying on solvent recovery operations.

17.2.3 To consider the effluent discharge systems, together with their control and monitoring arrangements.

17.2.4 To check compliance with the IPC authorisation.

17.3 Discussions

17.3.1 Management Structure

Solvent Recovery follows the general site pattern with an Operations Manager (who also covers Waste Management) over 4 Shift Team Managers, an Engineering Team Manager, and an Operations Support Manager. Each shift has a Team Support Manager and 12-14 operators. The team also includes 2 operators for the site's Waste Solvent Incinerator (which was audited separately). The Engineering Team has a Support Manager and 17 tradesmen, covering instrument, electrical, and mechanical maintenance.

17.3.2 Procedures

In the Solvent Recovery Area, plant procedures consist of Plant Operating Procedures (POPs) and Plant Operating Instructions (POIs), which cover individual columns and associated tanks, and explain how individual plant items are operated. Some procedures contain drawings of the systems they are intended to cover. Engineering Line Diagrams (ELDs) are kept in the site drawing office. Supporting logsheets are used on the plant to record actions taken and readings which need to be taken.

Formal reviews of procedures are carried out by Team Managers every five years, but prior to 1995 they were reviewed every 2 years. The POI index and some of the POIs were examined in detail. Some out-of-date procedures were found, and there was a case where a new version had been issued but the old version had not been destroyed and was still in use on the plant. Previously the site library used to collected old procedures when new were issued, but there is now no system for collecting superseded procedures. Recipients are responsible for ensuring they have the latest version.

An important procedure for the area is the one for dealing with spillages. A copy of this (UP/76/93), was seen and found to be in need of updating. The Company undertook to re-issue it before the end of the audit.

17.3.3 Plant Inspections

Site 1 and 2
Only Column 1 on Site 1 was in operation during the audit. It is used to recover acetone from a 15-20% acetone/water stream from the Griseofulvin finishing area, and returns recovered acetone only to that process. No contact is made with the Griseofulvin plant unless the acetone is found to be outside the specification during routine sampling.

The acetone water mixture is received into Tank 24 and is filtered to remove Griseofulvin solids on transfer to the recovery column feed tank. The recovered acetone leaves the top of the column via a water cooled condenser backed by a second chilled water cooled condenser, and is stored in Tank 23 for use on the Griseofulvin plant.

An operator was questioned about the process from column start up to continuous operation, and found to have adequate knowledge of the plant.

On inspecting the plant, a filter housing was found to be leaking slightly. Given the dry weather conditions, the amount of liquid on the floor in the vicinity of the filter housing indicated that it had been leaking for some time. The filter is opened every 2/3 days to remove the solids which build up. The last time the filter was cleaned was the previous night shift. The plant feed rate was immediately reduced, and the repair was in hand by the end of the inspection.

Copies of the sampling and analysis protocols from the QA manual and some recent analytical results on the acetone product were inspected and found to be satisfactory.

All of the process tanks associated with Column 1 are in a single bund. The tanks are fitted with adequate high level alarms to prevent overfilling into the bund under normal operating circumstances (ie an inordinate length of time would have to pass, over 2 shifts, in high level alarm before overflow would take place). Tank levels are recorded once per shift.

Waste water from the recovery process is removed from the base of the column and passes to a local effluent pit which pumps automatically between two levels (if the pH is within the acceptable range) to the high BOD effluent system. A sample of the water leaving the column base is taken every hour and bulked up in the sample bottle over 24 hours for acetone analysis. The temperature of the water is such that its acetone content will be negligible. A sample is also taken from the effluent pit once per shift and retained for a short period to allow investigations should there be a high COD result for the High BOD effluent tank.

The important controlling parameter to ensure that no significant quantities of acetone are discharged to drain is the column base temperature. The Site 1 control panel contained a mimic of the column, showing the overhead vapour temperature, the mid column temperature, and the column base temperature. A computer printer provides a hard copy of these parameters but they are also manually recorded on a log sheet. A slight discrepancy was noted between the column base temperatures recorded on the log sheet and that recorded by the computer. This had been corrected by the end of the visit.

The log sheet notes that the column base temperature (corrected for pressure) should be greater than 103°C. However it does not provide a conversion factor for converting the uncorrected column base temperature for pressure to allow a comparison with the control limit. An additional column on the logsheet would allow the corrected base temperature to be recorded.

Site 3

All stills are controlled by conventional instruments. Column 63 was examined against a POI dated 22.3.93 and appeared as documented in the flow diagrams.

Associated storage tanks were examined. They were all bunded and the bunds appeared effective, but had drain valves with no blank flanges. As the bund drainage is directed to the effluent pits the use of valves alone is acceptable.

A number of small glass sample bottles were seen about the plant which spoiled the otherwise excellent housekeeping aspect of the plant. All tanks examined had adequate high level alarms.

Site 3 has two effluent pits, one on-line and one being neutralised or pumping to high BOD. Neutralisation is by manual dosing with acid or caustic as appropriate. The pit is mixed by submerged jet pump and there is a continuously sampling pH meter. On discharge the effluent is pumped through another pH monitoring point and both pH systems are recorded. Control of pH is reliant on operator judgement but Glaxo Wellcome said that a control system is under consideration.

Sites 1 and 3 drain to an underground storage tank. The tank is covered and difficult to see into, and appeared to have some oily contents. There is no indication of tank level, and no high level alarm, but there is control of pH. Operators have to examine the tank frequently and pump the contents to the High BOD effluent when necessary. The tank would only be sampled if it was thought that the contents were not suitable for discharge. Some storage tanks have underground bund lines to the effluent tank with isolation valves at the tank.

Site 4

This is the newest of the solvent recovery sites and has computer controlled stills. Pocket IPC cards were carried by all operators on the plant, and copies of the IPC authorisation and variations were seen in the control room. Some of the sequence flow diagrams for the computer logistics were examined, and one was found to be incomplete.

The plant is constructed on a concrete slab which drains to a catch pit. The catch pit is emptied to one of two nearby effluent pits, depending on the contents, by manually operated pumps. There is a high level alarm in the catch pit but it is located too close to the top of the pit. A lower alarm, or continuous indication might provide better control and reduce the likelihood of an overflow. The two effluent pits are pH controlled and empty automatically if the pH is within the permitted range. However, a spillage of a water soluble solvent could go unnoticed, especially if it has been raining, and could be transferred from the effluent pits to the High BOD.effluent system.

It was noted that there was no POI for operating the catch pit. Glaxo Wellcome have confirmed that the POI for the effluent pits will be modified to include operation of the catch pit, and will include a requirement to check for solvents prior to discharge.

An inspection of Column 55, which separates isopropyl ether (IPE) from ethyl acetate, confirmed that it was as shown in the flow diagrams in the POI.

The still pot on Column 51 was the only vessel on the slab to have a bund. Some heavy black residues were leaking from a drain valve on the bottom of the pot leaving a viscous deposit on the bund floor of about 1 meter diameter. A blank flange was attached to the valve by one bolt but pushed to one side. Glaxo Wellcome arranged for this to be attended to during the visit.

Process records for the unit were examined. The computer control system records process data but operators are required to maintain a manual log of key data at 2 hourly intervals. The computer prints a shift handover log which has space for written comments, "Plant requiring attention", and operators can draw attention to notes written on the back of the form. There was some inconsistency in that some operators put "None" in the boxes while others left a blank. A whiteboard is also used to pass notes to the next shift.

17.4 Conclusions

(a) The process was as described in the application and the plant and equipment employed appeared adequate for the duty. Some minor plant deficiencies were found during inspection but the process was being operated within the conditions of the authorisation.

(b) The management structure, in particular at team level, functioned well and most staff appeared knowledgeable and competent. There were a number of new staff but supervision and training is good.

(c) Plant Operating Instructions and procedures are satisfactory, but document control needs improving.

(d) Effluent discharge systems seem to concentrate mainly on pH control and do not always consider the prevention of releases of organic material.

(e) Overall, the Solvent Recovery Area was complying with the requirements of the IPC authorisation.

17.5 Recommendations

(a) Document control for some procedures needs to be improved. In the short term, redundant procedures should be removed, and any which need reviewing should be identified and modified as a matter of priority.

(b) During Shift handover the notes should be completed fully with a "None" entered rather than blanks left. Use of a whiteboard to draw attention to important matters is good, but there should always be a written record as well.

(c) Better controls and alarms are needed to prevent overfilling of some local effluent pits.

Section 18 Griseofulvin Plant

18.1 Introduction

Griseofulvin, an anti-fungal agent, is the second main product made at the Ulverston site. The manufacturing process involves 3 stages:

(i) **Fermentation**
A fermentation process produces a broth containing Griseofulvin solids, which are removed by filtration.

(ii) **Extraction and Purification**
Griseofulvin is extracted from the solids into acetone. The extract is concentrated and Griseofulvin recovered by crystallisation and filtration. The recovered Griseofulvin is purified by washing with petrol and methanol and finally dried to give an intermediate product.

(iii) **Finishing**
The intermediate product is dissolved in acetone and the solution decolourised with charcoal. The Griseofulvin is crystallised out using water, recovered by filtration then washed and dried.

The process is covered by the IPC authorisation AO1420, and there have been no variations. The authorisation includes the recovery and recycling of acetone, petrol and methanol within the extraction stage. Recovery of other solvents used in the process is carried out by the Solvent Recovery Department.

18.2 Objectives

18.2.1 To consider the adequacy of the plants used for the various stages in the Griseofulvin process.

18.2.2 To consider the procedures available and used in carrying on fermentation and extraction operations.

18.2.3 To check compliance with the IPC authorisation.

18.3 Discussions

18.3.1 Management Structure

The Fermentation and Extraction stages of the Griseofulvin process are encompassed within the management structure responsible for the much larger Cephalosporin process. The management structure follows the general site pattern with an Operations Manager over 4 Shift Team Managers, an Engineering Team Manager, and an Operations Support Manager.

There is no particular segregation of responsibilities between the two products in fermentation, but in extraction three or four operators are dedicated to Griseofulvin extraction and finishing stages during production runs.

18.3.2 Procedures

There is a Manufacturing Guide for Griseofulvin fermentation process. The current one, dated 17.3.95, was examined and adequately cover the basic chemistry and processing operations.

There is a set of general Plant Operating Instructions for plant items and equipment. The index of these showed dates from 1992 to 1994, the review period being 5 years.

A number of Unusual Incident Reports (UIRs) were examined and generally dealt with minor issues that were quickly resolved. The inspectors were aware of a pump leak near the extraction plant on 18/8/96, and noted that the incident had been properly recorded.

18.3.3 Plant Inspections

Fermentation

The Griseofulvin authorisation was immediately available in the Team Manager's office. Fermentation was included in the audit of the Cephalosporin process (Section 16 of this audit). The inspectors therefore sought an operation unique to Griseofulvin, the filtration stage, which is undertaken in a dedicated facility at one end of the fermentation building.

The Plant Operating Instruction (POI) for filtration was obtained and the plant checked against the flow diagram. The diagrams were sufficiently accurate.

The fermentation broth is fed to a rotary vacuum filter and the felt (filtered fermentation solids) is transferred to the extraction stage. The vacuum is provided by a liquid ring vacuum pump and the seal liquor is directed to the Low BOD drain. The filtrate is discharged to High BOD effluent on completion. The area was clean and tidy but Inspectors queried that the filtrate vessel is not bunded. However, there is a drainage channel which led outside the building to the High BOD effluent system and would cope in the event of a vessel failure.

Extraction

The Manufacturing Guide for extraction was dated August 96 with a review set for Aug 98. Extraction is carried out in manufacturing campaigns, but there was none in progress at the time of this audit. The relevant POI was examined and the flowsheets found to adequately represent the plant.

Felt from the fermentation stage is charged to a vessel where the Griseofulvin is extracted into acetone, and transferred to other tanks for intermediate storage. The bottom drain valve on one of these tanks showed some signs of leaking, but the tanks are effectively bunded with padlocked drain valves

The dissolved Griseofulvin is transferred to an adjacent building to filter the spent felt using vacuum filtration. The spent felt is washed then transferred to a skip for off-site disposal at a licensed landfill site. Previously this was discharged to High BOD - as described in the IPC application - and there is still provision to do this. The vacuum pumps exhaust to air through a water scrubber which has a low flow alarm on the water circulation line.

The filtrate is concentrated in an evaporator. The condenser on the evaporator has temperature in/out indication but no alarms, and although the area is continuously manned, the inspectors advised that alarms should be considered.

Griseofulvin crystallises on cooling and the crystals are removed by centrifuge. The crystals are cleaned by washing with petrol followed by methanol, and dried in a steam oven. This releases methanol to air but there is a proposal to introduce a final water wash before drying, to reduce the quantity of methanol released. The change would need approval and a formal revision of the Manufacturing Guide.

Methanol and Petrol Recovery

Methanol and petrol washes from the extraction stages are collected in 2 storage tanks outside the extraction building. The tanks are effectively bunded with padlocked drain valves.

There are separate steam heated stills for methanol and petrol in the Extraction Building which has floor drains leading to the Low BOD drain. The exit drain is normally locked shut and spillages would be contained and dealt with within the building. Spillage equipment was available.

The condensers on each still are supplied with cooling water from a common supply. There are indicators for total flow, inlet coolant temperature, and exit vapour temperature on each condenser. The coolant outlet temperature is monitored and alarms on high temperature and isolates the steam supply to both stills. A high exit vapour temperature on either condenser will also shut off steam supply to both stills.

The stills vent to air with only the water cooled condensers to abate releases of solvent vapours. There is some potential to further reduce these emissions using chilled water condensers or back up adsorption, but it is recognised that other VOC release points on site are more significant and have greater priority.

The recovered solvents are stored in tanks outside the extraction building. The tanks are bunded with drain valves padlocked closed. Some of the bunds appeared to have cracks in the base which could indicate structural defects. The bunds are hydraulically tested every 5 years but these need to be re-examined.

The tank pumps are located outside the bunds and there are Low BOD drains close by. A seal failure on a pump would release solvents to drain. Glaxo Wellcome admitted that this had happened in August but it was quickly detected and the pump isolated. Bunding of the pumps with low kerbs would not give much additional protection. Glaxo Wellcome are considering installing drain isolation valve downstream of the extraction area which would enable spillages to be held and dealt with before getting too far into the drain system.

Finishing Stage

Griseofulvin from the extraction phase is dissolved in acetone in a steam heated vessel and recirculated through a carbon filter. The vessel has a high temperature alarm and is fitted with a water cooled condenser but there is no temperature or flow indication on the condenser. The relevant POI requires the operator to check that inlet and outlet cooling water valves are open and that cold water is flowing before operating the plant. The inspectors considered that fitting a flow indicator and temperature alarms would entail little cost and improve control of the plant.

The Griseofulvin is crystallised, centrifuged and washed with water. The vessels and centrifuges are vented to air via a water scrubber. The scrubber has water flow and differential pressure indication, but no alarms, and the operator is required to record flow and pressure drop every 2 hours. The batch log was inspected to confirm this takes place. Alarms could readily be fitted at low cost to give better fault detection.

The Griseofulvin from the centrifuges is dried in steam heated ovens, sifted, blended and packaged. The sifter and blender are extracted through a Dustmaster bagfilter unit. The exhaust of the unit is outside the area and not readily visible but there is no fault detection equipment.

18.4 Conclusions

(a) The process was as described in the IPC application, and the plant and equipment was generally satisfactory for the duty. The process was capable of being operated within the conditions of the authorisation at the time of the audit.

(b) The management structure is good, and all staff appeared knowledgeable and competent. Staff qualifications and experience were appropriate for the process, and additional specific plant training had been provided. Training records were documented.

(c) Plant Operating Instructions are up-to-date, and are comprehensive and well written.

18.5 Recommendations

(a) Glaxo Wellcome should consider the provision of additional simple alarms on a number of plant items indicated in this report, which would give early indication of faults and prevent releases to the environment.

(b) Measures should be considered to reduce releases to air from the petrol and methanol stills, and from the drying of the intermediate Griseofulvin product.

(c) Early inspection should be carried out of apparent cracks in the concrete bunds around the recovered solvent storage tanks.

Section 19 Development Plant

19.1 Introduction

The Development Plant comprises Unit 4 operations and the Pilot Plant. The IPC authorisation AK5954, covers the manufacture of organic chemicals in the Development Plant and is an envelope authorisation. The variation to this authorisation, AU0376, includes the Lamivudine process in the process description and an additional laboratory for further pharmaceutical development.

19.2 Objectives

19.2.1 To consider the adequacy of the plant used.

19.2.2 To consider the procedures used for the processes carried out.

19.2.3 To consider the effluent discharge systems, together with their control and monitoring arrangements.

19.2.4 To check compliance with the IPC authorisation.

19.3 Discussions

Management Structure

The management structure of the Unit 4 Operations followed the general site structure of Operations Manager (responsible for operational compliance with the authorisation) with process, engineering and operations support managers working to that person.

The Pilot Plant uses a similar, but smaller structure, which has a facilities manager as the equivalent of a team leader and a technicians group with a dedicated chemist and chemical engineer for each project.

Plant Operations

The types of activity carried out in the Development Plant, varies from process development through to manufacture of products for research and development purposes, for clinical trial and for pre-launch stock. The envelope authorisation allows a range of chemical reaction types to be carried out. Plant and equipment, including abatement equipment can be re-configured to suit individual processes operated within the plant.

Releases to atmosphere from each process operated in the Development Plant are required to meet any concentration limits specified within the authorisation. This may require the use of a number of scrubbers linked in series, each with a different capture medium.

Operations within the plant are controlled by the use of process guides, operating procedures/instructions and plant log sheets. Process flow diagrams are produced for each new process to be undertaken and authorised at an appropriate management level. Minor changes can be made to the plant, using the Plant Modification Authorisation

(PMA) site procedure, which is designed to ensure that staff of the appropriate level and disciplines are involved in the authorisation process.

The IPC authorisation requires a mass balance to be drawn up for each new process before it is operated, showing the releases to each environmental medium expressed in kg/te of product. The mass balances, combined with the associated process diagrams define the processes operated within the Development Plant.

The Pilot Plant carries out smaller scale work which ranges from chemical conversion to drying operations. The control of processes and the process plant is carried out in the same way as in the Development Plant. Configurations are authorised in a similar manner to the larger scale plant and process flow diagrams are produced for the required plant layout using a computer register of the plant process vessels with inter-vessel links being made, where appropriate, using registered plant flexible couplings.

The manufacturing activities in the Development Plant during the audit were 3 intermediate stages of the manufacture of Lamivudine. The only process being carried out in the Pilot Plant at the time of the audit was a drying trial. The process flow diagrams for the second stage of the Lamivudine process were examined followed by an inspection of the plant. Inter-vessel transfers are made by pumps rather than nitrogen blowing to minimise the release of VOCs from the transfer operations.

There were two process scrubbers in use, with different capture media in each. The process scrubber for absorbing alkaline gases uses a dilute solution of phosphoric acid as the capture medium, which is changed when the pH reaches a specified level. The pH is checked before each batch is started to ensure that it will be efficient enough for that batch.

The process scrubber for absorbing acidic gases uses a dilute solution of caustic soda as the capture medium and this is renewed for each batch. The recycle tanks for the scrubber capture media are fitted with high level alarms but only one of the rotameters fitted in the recycle lines is fitted with a low flow alarm. Although the scrubber flowrates are recorded as part of the operational checks during each batch, a low flow alarm should be fitted to the recycle line rotameter on the second process scrubber.

Some of the spent scrubber liquor is disposed of by off-site incineration; the remaining spent liquor is discharged to the High BOD effluent system via the plant effluent pit. The discharge pumps for the pit are interlocked to prevent out of pH specification liquor from being discharged to the High BOD drain. Whilst checking the maintenance and calibration records, the pH meter was shown to have a significant pre-calibration error, but no action seemed to have been taken to identify the cause.

19.4 Conclusions

(a) The processes carried out within the Development Plant appear to be well documented and the process plant in use appears to be fit for purpose and complying with the requirements of the IPC authorisation for the Development Plant.

(b) The procedures and log sheets in use appeared to define the operation of the process adequately, together with the information that the operator was required to record for each batch.

(c) Records of planned maintenance and calibration operations were kept, but pre-calibration errors need to be highlighted so that action can be taken to identify faults.

(d) The liquid effluent management systems appeared to be fit for purpose.

19.5 Recommendations

(a) The process of fitting low flow alarms to the process scrubbers should be continued and should include those in the Pilot Plant.

(b) Ensure that pre-calibration tolerance errors for pH meters are recorded and reported for corrective action.

Section 20 Waste Solvent Incinerator

20.1 Introduction

The present waste solvent incinerator came on line in May 1993. It is used to destroy up to 650 litre per hour of organic solvents comprising of the residues from solvent recovery operations and organic waste solvent streams which cannot be recovered economically from some of the production or development plants. It is also used for the incineration of up to 1,000 litres per hour of aqueous waste which would otherwise be discharged to the Leven Estuary.

The unit is a modern, downward fired solvent incinerator, designed for a temperature in excess of 1100°C which is maintained for at least 2 seconds to ensure total destruction and minimise the release of products of incomplete combustion. The exhaust gases are continuously monitored for a range of parameters.

It is a condition of the IPC authorisation and planning consent that only waste arising at the Ulverston site is allowed to be incinerated. Not all waste streams are incinerated on site and some organic wastes are still tankered off-site for recovery elsewhere or for destruction by merchant waste incinerators.

The waste solvent incinerator is covered by the IPC authorisation AG7423 and the variation AT8193.

20.2 Objectives

20.2.1 To consider the adequacy of the plant used in the process.

20.2.2 To consider the procedures covering the process.

20.2.3 To consider the effluent discharge and monitoring systems.

20.2.4 To consider the feedstock control arrangements.

20.2.5 To check compliance with the IPC authorisation.

20.3 Discussions

20.3.1 Management Structure

The waste solvent incinerator is part of the Solvent Recovery and Waste Management area, and as such the management structure has been examined elsewhere during the audit.

The waste solvent incinerator nominally has two operators, a lead craftsman and one other, who is also responsible for activating the tidal discharges of aqueous effluent from the site into the Estuary.

20.3.2 Procedures

Some of the POIs in the control room were found to require updating, and the one for operating the incinerator was an uncontrolled copy. The fact that many procedures were out of date does not mean that the plant was operating unsafely, but the situation is unsatisfactory.

Management have accepted the need to establish a procedure and document control system for the area, and have set priorities for creating and updating procedures to cover issues identified during the audit.

20.3.3 Incinerator Plant Visit

Receipt of Waste Streams for Incineration

Routine streams for incineration are controlled by having a register of acceptable streams which at present lists 28 solvent and 3 aqueous streams. Inclusion on the list involves a pre-authorisation analysis together with a technical and environmental assessment, backed up by regular re-analysis. The register was examined and found to be satisfactory.

Non-routine streams can be incinerated and these are also covered by pre-authorisation analysis and a technical and environmental assessment. Streams are only accepted by the incinerator operators after checking that they are registered and cleared for incineration, and that there is sufficient capacity in the storage tanks.

There are two identical storage tanks, one used for receiving whilst one is feeding the incinerator. The receiving tank is jet mixed when the level in the tank is sufficient. When the tank is nominally full a sample is taken for analysis, and if this is acceptable the TM/TSM will authorise the batch to be incinerated. The tanks are situated in a suitable bund, and although there was some evidence of a small number of minor leaks in the past, in general the storage area was to a high standard.

The transfer pumps are located in a separate bunded area in front of the storage tank bunds. These are the main source of a trace of solvent odour in the area. The pump mechanical seals make use of the waste solvent stream which may lead to fugitive releases. The pumps are on an inspection rota during which the condition of the seals is monitored and action taken if the leak rate becomes significant. Alternative pumps could reduce or eliminate the fugitive emissions, and this could be considered as part of the waste minimisation programme.

Drum inputs can be made to the receiving tank via a small transfer tank situated next to Site 4 Solvent Recovery. The control of drums at the drum off-loading area could be improved. Access to the area is restricted but this was observed to lead to drums being left at the entrance. A trailer containing bulked miscellaneous waste solvents from laboratories was also left nearby and there was no indication how long it had been there. Glaxo Wellcome agreed that this was unsatisfactory and had implemented changes to the procedure by the end of the audit. The drum off-loading area drains to a dump tank and if the effluent is free from visible oil/grease, the contents are pumped to the low BOD effluent system. The need to record these observations was identified.

The Aqueous Waste storage tank, and the diesel support fuel tank were inspected. A disused bund drain line was noticed, leading from the Diesel tank bund, which appeared capable of draining the bund contents to the surrounding area. The management have confirmed that this line is effectively blanked, but it should be removed when convenient to prevent confusion.

Incinerator Control Room

The incinerator control room computer holds the control sequences for the incinerator and its associated effluent plant.

The analysis of the batch of waste solvent is used to calculate the required caustic feed rate to the quench pot at the base of the combustion chamber to neutralise the acid gases formed during combustion. The chloride content of the feed stream is limited by the IPC authorisation to 33% w/w as chlorine. The details of the two main chlorinated streams (dichloromethane and chloroform) are entered on a control sheet which contains a conversion factor which is used to ensure that the chloride limit is never exceeded. The basis for the calculation was questioned, and the inspector noted that it should be shown on the control sheet.

The record sheet for the batch of waste solvent being incinerated and the authorisation allowing it to be incinerated were inspected and found to be in order.

The shift handover log was examined. Whilst the factual and technical contents were to a high standard, the main problem raised was that the third carbon copy in the control room was often difficult to read. This problem has been raised elsewhere during this audit.

The Incinerator and Associated Equipment

The plant tour raised a number of minor points, many concerned with the lack of labelling at the burners, the scrubber tower de-mister area, and exhaust gas sampling points.

The operator is required to carry out a number of actions on the top floor of the incinerator during start up and it was felt it would be useful to have a copy of the POI in this area for reference.

A water dump tank is provided on the top floor to provide an emergency water quench to the bottom of the incinerator in case of loss of quench water supply, allowing the incinerator to be shut down safely. The unit cannot be run without a water head in the tank, but on examination it was found that due to isolation valves being installed on the tank pressure switches, it could be possible to hold pressure on the switches while the tank is in fact empty. The Company have agreed to review these valve arrangements.

A critical operation for the incinerator was the positioning of the manual damper on the combustion air supply. This should be recorded for setting up purposes.

Maintenance of the flow controllers for waste solvents and aqueous waste requires lines to be drained. To improve housekeeping in this area, drip trays should be provided for the drain valves in the vicinity of the aqueous waste flow controllers.

The materials of construction of the plant downstream of the combustion chamber are such that minor leaks may develop as a result of thermal cycling of the plant. Protective sleeving has been fitted at appropriate points.

The environmental analyser for the vent gases takes a sample from the duct between the condenser tower and the process stack. Critical items are duplicated to ensure continuity of sampling and analysis of the vent gases. The only issues raised were the need for improved labelling for the sampling points which are used for regular manual check monitoring by outside contractors, who may be acting on behalf of Glaxo Wellcome or the Environment Agency.

Aqueous Effluent From the Incinerator

The effluent stream from the incinerator is directed to one of two local effluent pits. Addition of sulphuric acid to the pit to lower the pH is under computer control and has been set to bring the effluent within the required pH value for discharge by the time the pit is half full. Effluent is then switched over to the second pit whilst the contents of the first pit are discharged to the Low BOD effluent system.

During the inspection, a set of circumstances was discovered which could lead to overfilling the effluent pits. The plant operator would normally react to this situation and take appropriate action, but it is possible that he could be involved with other actions away from the control room when the situation arises. The Company agreed to consider changes to the control system to give additional warning and prevent the situation arising.

20.4 Conclusions

(a) The waste solvent incinerator is a modern plant and is operated satisfactorily to minimise its impact on the environment.

(b) Management and process operators are fully trained and show an in depth knowledge and understanding of the plant they were operating and its environmental requirements.

(c) Some of the written procedures for operating the plant are in need of updating but this does not affect the way the plant is operated.

(d) The incinerator has an impressive continuous monitoring system for exhaust gas analysis.

(e) There are good systems in place for selecting and controlling waste streams suitable for incineration on the site incinerator.

(f) Operation of the incinerator complies with the requirements of the IPC authorisation.

20.5 Recommendations

(a) Glaxo Wellcome should establish a procedure and document control system for the Solvent Recovery and Waste Management Area, and set appropriate priorities for creating and updating procedures.

(b) In the drum off-loading area, a procedure should be established for recording all observations made on samples taken from the effluent pit prior to discharging to the site effluent system.

(c) Improved control is required for the receipt of drums and other containers of waste solvents.

(d) The use of sealed or low leak rate pumps for the transfer of waste solvents to the incinerator should be investigated as part of the site waste minimisation programme, to reduce or eliminate fugitive emissions.

(e) Improvements to labelling are needed in certain areas as indicated in this report.

(f) The emergency quench tank system should be re-examined to ensure that it can never be isolated when the incinerator is in use.

(g) Drip trays should be provided under the drain valves on the lines associated with the solvent and aqueous waste flow controllers.

(h) Consideration should be given to modifying the computer control system for the effluent pit to give early warning of pH problems, and prevent the effluent pits overfilling.

Section 21 Boiler House Large Combustion Plant

21.1 Introduction

The site boilerhouse comprises of 4 water tube boilers with a maximum aggregated thermal capacity of 174 MW net thermal input, but with a normal operating capacity of 60 MW (net Th input). It is used to supply all the process steam and steam heating requirements of the site and has the ability to provide standby electrical requirements in case of loss of outside supply. The boilerhouse has its own IPC authorisation AA2003 and variation AT9092, and is defined as a combustion plant rated at over 50 MW (net Th input). It is also a Large Combustion Plant as defined by the EU Directive (88/609/EEC) on The Limitation of Emissions of Certain Pollutants Into Air From Large Combustion Plants. The plant therefore has its own annual quota under the UK National Plan for reducing emissions of sulphur dioxide (SO2) and oxides of nitrogen (NOx) into air.

Three of the boilers all nominally rated at 30 MW (net Th input), were installed in the early 70's and boiler No4, nominally rated at 70 MW (net Th input), was installed in 1980. Boilers 2,3 and 4 can be fuelled by natural gas or Heavy Fuel Oil (HFO) but Boiler No1 can only use HFO. Natural gas is the site's preferred fuel with HFO retained mainly for standby and to give flexibility of supply. Boiler No4 provides the main load assisted by either boilers No2 or No3. Boiler No1 is rarely used.

Boilers 1,2 and 3 exhaust to a single 41m high steel chimney, and boiler No4 has a separate 43 m high steel lined, brick chimney.

The plant has its own water treatment facility to provide boiler feed water. Effluent from the water treatment plant and boiler blowdown water joins the site's Low BOD effluent system.

21.2 Objectives

21.2.1 To consider the adequacy of the boilerhouse, and its potential for releases to the environment.

21.2.2 To consider the procedures covering the processes carried out.

21.2.5 To consider releases to the environment and their monitoring arrangements.

21.5.2 To check compliance with the IPC authorisation.

21.3 Discussions

21.3.1 Management Structure

The Boilerhouse is the responsibility of the Site Services Department and until the recent reorganisation the department and its staff also ran the site effluent systems and the waste solvent incinerator. The management structure for the Boilerhouse is similar to that observed elsewhere on the site and no further comments are made here.

The question of whether there was a specific site energy policy was raised with the Boilerhouse Management. Although a number of energy saving measures are being taken there does not appear to be a specific energy policy as such. This is discussed more fully in Section 9 of this report. Some of the older boilers are now reaching the end of their anticipated life and there are allowances in the five year capital budget for a replacement boiler, but the type of replacement will very much depend on the future plans for the site at that time.

21.3.2 Procedures

The list of procedures for the boilerhouse staff was found to be out of date and contained references to duties no longer carried out by the staff. This needs to be brought into line to reflect the changed responsibilities of the Site Services Department. One of the POIs for operating the boilers was examined and again found to be out of date by several years. However the document appeared to be very comprehensive, and the fact that it had not been reviewed would not affect the way the plant is operated.

21.3.3 Boilerhouse Plant Inspection

HFO Storage Tanks

One of the improvement conditions in the IPC authorisation was to provide bunding for the three large HFO storage tanks which are located close to the Ulverston Canal. The HFO day service tank also required bunding.

Limitations on the space available, and the cost of providing tank bunds to the standards required for all three HFO storage tanks has forced the site to rethink its storage requirements. Since the application for IPC authorisation was made, the site's fuel policy has been revised. Now, with less emphasis on strategic storage, two of the three storage tanks have been taken out of service. The third tank, and the day storage tank, have been modified by the construction of a tank within a tank, resulting in the void between the outer tank wall and the new inner wall providing more than the minimum 110% bund capacity required. This has been a major engineering project but is a good example of how a solution has been found to a difficult problem of meeting an IPC condition to protect the environment.

A recent requirement of the IPC authorisation is for improvements to the HFO tanker off-loading facilities. These are progressing with improvements to the tanker delivery route completed, and hard standing in the delivery area still awaited.

Boilerhouse and its Control Room

Particular note was taken of the newly installed Codel smoke density meters for the two boilerhouse chimneys which supplement the CCTV monitors which constantly view the top of the two stacks. The new meters provide a permanent chart recording to confirm or deny any possible complaints about excessive emissions. A manual recording of visual sightings is still maintained in a logbook, and it was suggested that these manual records could now stop.

One of the operators in the boilerhouse control room was interviewed and his training records inspected. The operator showed a good understanding of the boilerhouse and was able to produce a copy of the IPC authorisation. Although he was also carrying a pocket IPC awareness card, on questioning about environmental consequences of releases from the plant his knowledge rapidly became sketchy.

Flue Gas Monitoring

Inspectors were shown the location of the sampling points for the routine flue gas analysis which is a requirement of the IPC authorisation. All are on exhaust ducts from the respective boilers before reaching the boiler chimneys. The sampling points are a reasonable compromise between ideal location and those physically available, and all were suitably labelled. An examination of the documentation for calibrating the portable Land Combustion Gas analyser was found to be completely satisfactory.

Waste Minimisation Projects

A number of waste minimisation projects have been implemented or are undergoing trials in the boilerhouse. The most direct has been the switch to low sulphur HFO, at a cost penalty, to lower emissions of sulphur dioxide when burning HFO.

Low NOx burner tips for burning HFO have been evaluated for Boiler No.4 in a joint trial with Powergen. The results indicate the possibility of lowering NOx emissions by up to 25%. Other Low NOx burners have been identified for use on Boilers 2 & 3 at a cost of around £50,000 per burner. These offer a way of meeting the future required NOx emission limits and extending the life of the boilers. The total cost of these modifications should be considered against the cost of a new replacement boiler.

A small energy saving measure has been the replacement of fixed speed motors with variable drive motors on the induced air fans for the boilers, which as well as conserving energy has significantly reduced noise levels and improved the working environment in the boilerhouse. The possibility of variable speed pumps for the site's cooling water systems is being considered.

21.4 Conclusions

(a) Although the boilerhouse is one of the older parts of the site, efforts have been made to improve its performance and reduce its environmental impact. The most significant improvement is the preferential use of gas as opposed to HFO, and the switch to HFO with a lower sulphur content as a backup fuel. Reduced HFO storage and the major effort to modify the remaining tanks to provide tank bunds have considerably reduced the potential for a release to the environment.

(b) The use of Low NOx burners offers a way of making significant reductions in NOx emissions.

(c) Some of the written operating procedures are in need of a formal review but this is not detrimental to the way the plant is operated.

(d) Monitoring of releases to the environment from the boilerhouse are satisfactory.

(e) Operation of the Boilerhouse generally complies with the requirements of the IPC authorisation.

21.5 Recommendations

In order to reduce emissions of NOx, the site should continue with the burner tip trial on Boiler No4, and consider fitting Low NOx burners on the remaining boilers, or other means, to meet tighter environmental standards.

Section 22 Radioactive Substances

22.1 Introduction

Radioactive materials are used on the site for industrial process control/level measurement, analytical determinations, and historically for research purposes.

At the time of the audit Glaxo Wellcome held the following registrations under the Radioactive Substances Act 1993:

a) A certificate of registration dated 1 March 1993 covering the use of radioactive materials in the form of closed sources for industrial process control and gas chromatography; and

b) A certificate of registration dated 25 May 1982 covering the use of radioactive materials in the form of unsealed sources for research purposes.

A certificate of authorisation used to be held for the disposal of radioactive wastes arising from the use of the unsealed radioactive materials, but this was revoked in 1993 following the cessation of this work. Following the transfer of all remaining unsealed radioactive materials off the site, the Company have requested the cancellation of the registration for these sources.

22.2 Objectives

To consider compliance with the extant certification under the Radioactive Substances Act 1993, and to consider the cancellation of the certificate of registration covering the unsealed sources.

22.3 Discussion

22.3.1 Control of Radioactive Materials on the Ulverston Site

The Company has a site wide procedure covering the handling of radioactive materials. This procedure details the site arrangements for the control of radioactive materials including those for radiographic sources brought onto the premises by contractors. The document also includes the local rules covering the use of sources for process control/level measurement on the site.

Although the local rules are a requirement of Regulation 11 of the Ionising Radiations Regulations 1985 (IRRs), they also include some information which is required by the certificate of registration under the Radioactive Substances Act 1993:

i) Information on source location on the premises, the radionuclide/s involved and the activities of the sources;

ii) Details of surveillance arrangements for the sources;

iii) Requirements for reporting the loss, theft or breakage of a source, or the escape of radioactive material; and

iv) Interim storage arrangements for sources.

In this respect, this procedure is an important control document for the use of radioactive materials on the site. The local rules for the Quality Assurance (QA) laboratory were not included in the site procedure and the document should be amended to include these. It also requires minor amendments to reflect the revised site management structure, the reporting arrangements to the Environment Agency, and to correct the revised certificate reference number.

22.3.2 Closed Radioactive Sources

Closed radioactive sources are used on the site in three locations. The first of these is the use of nickel 63 electron capture detection heads in gas chromatographs in the site QA laboratory. The activity contained in each of the two sources on the site is so low that the Company could claim exemption from registration under Section 7 of the Radioactive Substances Act 1993, if it could be shown that all the terms and conditions of The Radioactive Substances Act (Testing Instruments) Exemption Order 1985 No.1049, were complied with. The other two site locations where closed radioactive sources are used are plant locations and the sources are used for process control/level measurement purposes.

Compliance with certificate conditions

Copies of the certificate were displayed in all locations where radioactive sources were in use. The local rules include the job title of the person who is responsible for supervising the keeping and use of registered sources.

QA Laboratory

The only issue here was the need to amend the record of the receipt of the sources which indicated incorrectly that one of the nickel 63 source activities was 370 MBq, whereas the labelling on the gas chromatography machines identified both sources as 555 MBq.

Unit 5

This plant used two cobalt 60 sources in level detection units on separate vessels in an enclosed room. For the purposes of the IRRs, guards had been erected to prevent routine access to areas around the source containers which would require a supervised area to be declared.

The main issue here was that of labelling. Labels were placed on the guards in the vicinity of the sources for identification purposes. The remains of what appeared to be the source container labels were barely visible due to corrosion. It is not unusual for source container labels to become corroded in either external plant locations, due to weathering, or in corrosive atmospheres on chemical plants.

The source containers should be re-labelled with the full requirements of the certificate of registration. The labels should be capable of withstanding a reasonable fire and should not be capable of being removed easily. There were appropriate arrangements to check

that the sources were in place. Inspections of the sources should also include the need to check the integrity of the source container (and other) labelling and to report any defects for corrective action. Given the nature of the documents, it seems sensible to include these requirements in the local rules.

Record keeping for these sources was found to be acceptable.

Unit 4

This plant used two caesium 137 sources in level detection units on separate vessels in an enclosed room with restricted access. Labels giving details of the sources inside the room were placed on the windows of the room. However, source container labelling appeared to be an issue here as well.

The source container labels could not be identified, partly due to nature of the protective clothing required for access. The source containers should be labelled clearly with the full requirements of the certificate of registration and, as above, should be capable of withstanding a fire and should not be capable of being removed easily.

Appropriate arrangements were in place to check that the sources were in place on a suitable frequency. Inspections of the sources should also include the need to check the integrity of the source container (and other) labelling and to report any defects for corrective action. Again, it seems sensible to include these requirements in the local rules.

No issues were raised in respect of the record keeping for these sources.

Temporary source storage

The Company has given adequate thought to the need to provide appropriate temporary storage arrangements for sources during extended maintenance periods and prior to transfer off site.

22.3.3 Unsealed Radioactive Materials

Small quantities of unsealed radioactive materials have been used historically on the Ulverston site for research purposes in a dedicated laboratory. Radioactive wastes produced as a result of the keeping and use of the unsealed radioactive materials were disposed of under a certificate of authorisation, the conditions of which ensured that the impact of the disposals was not significant.

In 1993, research work with unsealed radioactive materials ceased on the site and the authorisation was revoked at the request of the Company. Some unsealed radioactive materials were stored on the site until their transfer off-site in mid-1996, when the Company then requested the cancellation of the certificate of registration covering them.

Records in respect of the keeping and use of unsealed radioactive materials, disposals of radioactive wastes and contamination surveys were reviewed. No issues were raised and this supports the Company's statement that there are no unsealed radioactive materials or wastes, on the premises and the extant certificate can now be cancelled.

The Environment Agency intends to issue a cancellation notice in respect of this certificate, together with a notice under Section 20 of the Radioactive Substances Act 1993 to keep the records associated with the certificate for a prescribed period.

22.4 Conclusions

(a) Some record keeping and source control documentation amendments or suggested inclusions were identified.

(b) Labelling on source containers needs to be brought up to the standard required by the certificate of registration and inspected by the user on a regular basis.

(c) All unsealed radioactive materials appear to have been removed from the site and the certificate of registration covering their keeping and use may now be cancelled.

(d) The certificate of registration covering the keeping and use of closed radioactive materials needs to be re-issued to reflect recent changes in the name of the Company.

22.5 Recommendations

Glaxo Wellcome should:

(a) Include a copy of the QA department local rules in the site procedure covering the use of radioactive materials on the Ulverston site, and should amend the document to reflect the reporting requirements to the Environment Agency, the latest management structure and to correct the specified certificate reference number.

(b) Amend the QA department source records to reflect the actual source activities.

(c) Bring the source container labelling requirements for the level gauges up to the standard required by the certificate of registration.

(d) Make regular checks on the integrity of source container labelling and report any defects for corrective action and consider including these requirements in the appropriate local rules.

The Environment Agency should:

(e) Issue a cancellation notice including a notice to keep records in respect of the certificate of registration covering the keeping and use of unsealed radioactive materials.

(f) Re-issue the certificate of registration covering the keeping and use of closed radioactive sources to reflect the recent change of user name.

Section 23 Aqueous Effluent Systems

23.1 Introduction

There are two effluent systems at the Ulverston site which discharge into controlled waters of the Leven Estuary in Morecambe Bay. The first is known as the High BOD system which discharges a relatively small volume of aqueous effluent with a high organic waste content comprising mainly of process effluent. The second is the Low BOD system with a larger volume but a much lower organic loading, comprising mainly surface water drainage, domestic effluent, and some low strength process effluent.

Effluent from both systems is collected in tidal tanks and is discharged on the ebb tide, over a period of about twenty to thirty minutes, commencing half an hour after high water. The High BOD system has a single tidal tank, but the Low BOD system has two identical tanks which are usually operated separately.

The Low BOD tanks and discharge line are located adjacent to an identical arrangement for Ulverston town sewage works operated by North West Water. The Low BOD and NWW systems discharge close together into a deep water channel in the Leven Estuary, about 10m away from the discharge line from the High BOD system.

Conditions relating to discharges of the High BOD and Low BOD effluents are set out in the IPC authorisation for the Cephalosporin process, reference AK5687/AU0368.

23.2 Objectives

23.2.1 To assess the operation and monitoring of discharges to controlled waters to determine if the systems are adequate.

23.2.2 To determine what measures the Company are taking to protect bathing water quality in the area.

23.2.3 To examine and comment on any physical characteristics which may influence the effects of the effluent discharges on the environment.

23.2.4 To assess the environmental awareness and preparedness of the Site Fire Service in safeguarding the effluent systems whilst coping with site emergencies.

23.3 Discussions

<u>Operation & Monitoring of the High BOD and Low BOD Effluent Systems</u>
Throughout the site there are a multiplicity of logging procedures to record the condition of effluent discharged into the site effluent system. They record a large variety of information and provide an essential audit trail, but some of the records are not always fully completed.

There are a mixture of audible and visible alarms on a variety of systems. Some divert to 24 hour control rooms, some are dependant on security staff in the main gatehouse observing the alarm and informing relevant personnel.

Although the current tidal discharge systems appear to work, they are convoluted and unnecessarily complex involving manual operations at remote locations. The High BOD system requires a manual operation of the valve to discharge. The High BOD system is protected by continuous pH and Total Carbon (TC) meters. The Low BOD system which serves the site drainage systems and can potentially be subjected to spillages, only has continuous pH and does not have a TC meter.

Routine samples are taken of the Low BOD and High BOD systems by trained staff. It was observed that bottles were not always labelled prior to filling. Secondly, it appears to be the practice to write details on sample bottle lids which can lead to mistakes. Retained (Compliance) samples of the final discharge are obtained by staff from the Environment Unit using a pre-designated schedule. These samples were correctly labelled. The sampling scheduled is for weekdays only.

In addition to the routine sampling and analysis required to comply with the IPC authorisation, Glaxo Wellcome also undertake routine Toxicity Testing on both High and Low BOD effluent streams, utilising their own expertise and equipment. Toxicity testing is a developing technique which could be used in future as a control limit by the Agency when there is more confidence in the methodology.

Bacteriological Testing

Currently the bathing water at nearby Bardsea Beach is failing to comply with the EU Bathing Water Directive. Discharges of effluent from Glaxo Wellcome are one of a number of possible contributory causes which are being investigated by the Agency. A diversion of toilet facilities from the High BOD system has taken place and a clean up programme was carried out during the 96 shutdown period.

Physical Characteristics of The Effluent Systems

A visible plume of effluent can be observed in the estuary from the high BOD discharge. The discharge rate has been agreed following extensive research and should not be altered without prior consultation with the Agency. The potential for stratification of effluent in the High BOD tank during the filling period needs to be considered.

Safeguarding of the Site Effluent Systems During Emergencies

The site fire service is operative 24 hours per day. The full time crew are supplemented by retained fire fighters. Assistance from Cumbria County Council fire service is summoned as required according to a procedure. The 3 full time staff appeared well trained and motivated. Equipment is carried for use on spillage containment/control and is used in practice.

The Service can be summoned by a variety of methods ie telephone, alarms, bleepers etc. An incident can be attended within 3 minutes. Response plans, procedures, maps and site plans are available at the station. Staff appear well versed in the procedural aspects of the job, but did not appear fully aware of environmental implications. Obviously saving life has to be their priority.

There is a requirement for a contingency plan should a major spillage occur. There is some potential storage in both the High BOD and Low BOD tanks depending on rainfall, but additional storage would be a useful facility in emergency situations.

23.4 Conclusions

(a) The operation and monitoring of discharges to controlled waters has been assessed and appears to work satisfactorily but there are a number of recommendations for improvements which are listed below.

(b) The Company has taken a number of measures to protect bathing water quality in the area but at the time of this audit the effects of these measures are not known.

(c) Physical characteristics may influence the effects of the effluent discharges on the environment, and may require further consideration.

(d) The Site Fire Service are well trained and equipped as a first response for dealing with site emergencies.

23.5 Recommendations

Operation & Monitoring of the High BOD and Low BOD Effluent Systems

(a) A bullet point protocol for operation should be located at all operational sites for reference. All operatives should carry a laminated copy. Pictorial representations of systems requiring checking should be considered. A review of procedures in order to simplify the systems should be initiated.

(b) When logging data all spaces should be filled and date/time given as appropriate. If no action is taken it should be recorded. All log entries should be signed.

(c) Installation of TC meters, or other systems, should be considered to warn of spillages into the Low BOD system.

(d) The Company should review the location of all alarms for the effluent systems, to better utilise a 24 hour control room with personnel trained in appropriate responses.

(e) All sample bottles should be labelled prior to sampling in such a manner that it is not affected by the liquid being sampled.

Bacteriological Testing

(f) Glaxo Wellcome to undertake total and faecal coliform sampling on a weekly basis for the next 3 months. Investigate the potential for additional sources of coliforms, and consider additional cleaning or sterilisation of the High BOD effluent system, or treatment with an approved biocide, after discussions and agreement with the Environment Agency.

Physical Characteristics

(g) The Company should initiate a review of the system to improve immediate dispersion of effluent and minimise the plume. Investigate whether stratification in the High BOD tidal tank is a problem.

Emergency Systems

(h) The Fire Service's procedure for response planning includes a final step which includes "wash down with detergent". This should be removed from the procedure.

(i) Drainage routes are well known and most manholes are mapped and marked with individual numbers. Any remaining manholes require labelling and the maps updating. Equipment to safely seal drains at ground level should be obtained.

(j) The Company should investigate utilising the 'mothballed' treatment plant facility, temporary tanks, road tankers etc, as methods of temporary containment.

(k) Additional environmental awareness training for the site Fire Service staff should be provided.

Section 24 Waste Management

24.1 Introduction

Glaxo Wellcome have no specific Waste Management Licenses for the Ulverston site, but they do have a registered exemption under the Waste Management Licensing Regulations 1994 for the baling, sorting and shredding of waste cardboard and plastics. However, in dealing with waste which is removed from the site for disposal or recycling the Company must comply with a number of Waste Management Regulations:-

(i) The Duty of Care Regulations introduced in the Environmental Protection Act 1990.

(ii) The Control of Pollution (Special Waste) Regulations 1980, and The Special Waste Regulations 1996

(iii) The Registration of Carriers introduced under the Control of Pollution (Amendment) Act 1989 and the Controlled Waste (Registration of Carriers and Seizure of Vehicles) Regulations 1991

In carrying out the waste management audit, procedures were requested, reports were examined, checks were made on documentation, and areas of the site were inspected. Personnel responsible for waste management, were interviewed about their knowledge of procedures used on site. Several matters which the inspector became aware of during the familiarisation days were followed up during the main audit.

24.2 Objectives

24.2.1 To consider how the site complies with the Duty of Care Regulations 1991 and how this is translated into a site procedure.

24.2.2 To consider how the site complies with The Control of Pollution (Special Waste) Regulations 1980 and The Special Waste Regulations 1996.

24.2.3 To examine the systems used for the collection, storage, and disposal of waste and ensure they comply with any exemptions, and that waste is stored securely and can be traced its origins.

24.2.4 To further investigate a number of matters which arose during the familiarisation visits.

24.3 Discussion

Duty of Care Notes

Three types of duty of care records were examined.

(i) Duty of Care transfer notes.
(ii) Registration of carrier documents.
(iii) Audits of disposal sites.

Generally all duty of care documents were in good order. However, staff from the Company's Waste Management team, and not the waste producer were signing the declaration on the form that the waste was as described on the note.

On further questioning, it was found that there is a supplementary record called the 'purchase requisition' form. On this form, the waste generator gives a description of the waste which is then passed to a designated member of the Purchasing Group. After finding a disposal route, the form is passed to the Waste Management team to organise the disposal operation. Any subsequent loads are dealt with via a verbal request to Waste Management Section. The procedure is documented.

On the duty of care document, however, the Waste Management team member is signing to say that the waste description is correct without having inspected the load.

Registration of Carrier Documents

When a disposal route is found for a new waste stream, the carrier details are checked and a copy of the registration certificate is obtained. Subsequent checks on registration at carriers are made randomly, but not regularly. Checks are also made to ensure that the disposal site has a current waste management licence.

Disposal Sites Audited by Glaxo Wellcome

The Waste Management companies Morgan's and Caird's have been audited by Glaxo Wellcome/Furness Waste Consortium. A report has been produced for each audit which includes the company's authorisations, waste management licence and carrier registration certificates. The audits have a number of recommendations to be followed up.

Special Waste Management

The special waste consignment notes were checked and were found to be satisfactory. A member of the Waste Management Team in consultation with the Safety Health and Environment Team makes the decision on whether the waste is special. This is acceptable.

Waste Collection, Storage and Disposal

Four areas concerned with waste collection and disposal were examined. They included the Baling Exemption, collection points for general wastes, storage of scrap metal, and the storage and handling of waste drums.

(i) Baling Exemption

The area is undercover in a building and has a concrete base. The area was tidy and clear of loose litter, and complied with the conditions of the exemption and relevant objectives set out in Schedule 4, of the Waste Management Licensing Regulations 1994.

(ii) Waste Collection Points

Areas of the site where waste is stored pending its collection were inspected. Waste cardboard and paper, waste polythene, and waste cups are segregated for recycling purposes.

Plastic Cups
Cups are recycled and sent to Savacup who make new plastic products. They supply Glaxo Wellcome with figures on number of cups recycled. At present about 50% of cups used on the site are recycled, but this could be improved with continued education of staff.

Cardboard
Cardboard is sent to the baler and then goes for off-site recycling.

Pallets
Pallets are loaded onto a flat back trailer, avoiding the need for double handling.

General Waste/Empty Containers
On the East road, there is a waste collection point for empty containers and general waste. The signs are poor and are placed on the back wall so that when full of waste the sign will be obscured from view. The general rubbish is being stored on the ground in the bay, not in the bin provided. Also 2 empty chemical containers were being stored in the general waste store. The waste is loose on the ground, and needs to be secured either by gates or placed in a skip.

(iii) Scrap Metal
The scrap metal is stored in a secure manner in a locked compound. The Waste Management Team hold the key to the compound and therefore maintain control of the system. Scrap metal can only be put in the skips if it has a de-contamination certificate.

(iv) Waste Drums
Waste drums such as solvents awaiting incineration and empty drums are stored in the drum compound next to the control office. A number of drums awaiting off-site disposal are labelled with U.N. classifications, eg.'toxic waste solid n.o.s'. The identity of these drums and their source was known only to a member of the Waste Management team. A crude tracking method is employed which consists of a plan of the compound with yellow post-it stickers attached to identify the wastes. The system copes at present, as quantities are low, but if the operation gets any bigger there is a danger of the identity of the drums being lost.

Additional Matters
During the introductory visits the inspector discovered a quantity of inert road building waste had been fly-tipped on Glaxo Wellcome land near to the effluent plant. This was checked during the main audit and the material had been levelled. Glaxo Wellcome's Environment Department has been supplied with a registration form to register the activity under Paragraph 19 of Regulation 17 of the Waste Management Licensing Regulations 1994. The situation is now satisfactory.

The inspector had also noticed that an open skip was being used to collect screened waste from the discharge from the tidal Low BOD Effluent system. Rain water will collect in this skip and lead to contamination. At the time of the main audit the inspector noted that the open skip had been replaced with a lidded skip.

The inspector was pleased to note that fluorescent light tubes are segregated, and a suitable disposal route has been found. This offers a way of recycling the glass and recovering the mercury.

Training records of waste management personnel were examined and found to require some updating.

24.4 Conclusions

Duty of Care

(a) Waste producers bear the main responsibility for the description of waste and therefore it is good practice for producers to sign the declaration on the Duty of Care transfer note.

(b) As the checks on carriers and disposal routes are random and not regular, a carrier may not re-register or a licence could be suspended or revoked, without Glaxo Wellcome's knowledge.

(c) There is good compliance with duty of care regulations in respect of checks on disposal sites, but more follow up is needed to see if audit recommendations are carried out.

Special Waste Regulations 1980 and 1996

(d) No problems were noted with the way the site meets the requirements of the Special Waste Regulations 1996.

Exemption Conditions and Storage of Waste

(e) General waste and empty containers could be stored in a more secure manner with better instructions for staff to prevent different types of waste being collected at the same point.

(f) There is good control of scrap metal recycling.

(g) The system for tracking waste drums in the drum compound could be improved to ensure the identity of the drums is not lost.

24.5 Recommendations

Duty of Care

(a) Glaxo Wellcome should introduce a system where either -

  (i) The Waste Management team inspects each load prior to signing transfer documents, or preferably

  (ii) The waste generator signs the forms.

(b) Glaxo Wellcome should make regular checks, at least annually, that waste carriers are registered and the disposal sites are licensed to take the types of wastes generated by the Company.

(c) Glaxo Wellcome should make checks at the disposal site to see if recommendations from previous audits have been carried out. If the matters of concern are serious and the recommendations have not been carried out the Company should consider whether the site is acceptable as a disposal route.

General Waste Collection and Storage

(d) Install better signs on waste collection points in more prominent positions.

(e) General waste should be deposited into skips rather than on the ground, or gates should be installed to retain the waste in the collection bay.

(f) A tracking and logging procedure should be introduced for waste drums in the drum compound. This may refer to the numbering system given on the purchase requisition but must also include the unique identification on the drums themselves. The drum compound should be segregated, and storage bays numbered for identification purposes.

Section 25 Emergency Procedures Exercise

25.1 Introduction

Glaxo Wellcome recognise that on chemical plants of this nature there is always the potential for an incident which may have consequences inside or beyond the site boundaries. This is because of the type of plant operated, and the quantities and properties of some of the materials handled. Incidents can range from minor unauthorised releases to the environment, to those which could affect the safety of those outside the site.

The Site Emergency Procedures set out the actions to be taken in all such events. These are rehearsed at frequent intervals in exercises often involving the emergency services and the District and County Emergency Planning Departments. Residents and businesses within 1Km of the site have been issued with a booklet advising actions to take in case of a major emergency.

Spillage and Release Index

It is a requirement of all IPC authorisations that the Company notifies the Environment Agency of any incident which results in the unauthorised release of any substance which causes, or has the potential to cause, harm to the environment, unless the release is so trivial that it cannot cause harm.

In order to help to define whether an incident is serious or trivial Glaxo Wellcome have developed a system known as the Spillage and Release Index which they have agreed with the Site Inspector. It is a simple method which gives weighted scores to three aspects of the incident:- the nature of the substance released, the size of release, and the fate of the release. Each of the three scores is multiplied together to give the spillage index. A copy of the Spillage Release Index is shown in Appendix 5.

A score of 300 or more must be reported to the Environment Agency without delay as required by the authorisation. For a score of less than 200 there is no need to inform the Agency. Between 200 and 300 the incident must be discussed with the Agency on the next working day.

The system offers benefits to both the Company and the Agency in that it is clear to all concerned which incidents must be reported to the Agency and which are trivial. There are no areas for misunderstanding where the Company could be held liable for failing to notify the Agency of an incident. Equally the Agency's resources are not wasted following up trivial incidents. It is a system which could well be tailored to suit many IPC authorised processes and deserves to be widely publicised.

Notified Releases

In the time that the site has been authorised under IPC there have been a few minor incidents when the site has had cause to notify the regulatory authorities of unauthorised releases to the environment.

In 1996 there was an incident involving the spillage of a significant quantity of solvent which ultimately resulted in exceeding a limit for the discharge of Low BOD effluent. The incident was jointly investigated by officers from HMIP and NRA (before the formation of the Environment Agency) and resulted in HMIP issuing an Enforcement Notice requiring seven improvements, including two concerning the management of accidental spillages.

The Company has satisfactorily completed all the required improvements in the set timescale and this has been acknowledged by The Environment Agency. This audit has provided an opportunity to verify that improvements have been made following the earlier incident and that staff are capable of responding to such incidents in order to minimise harm to the environment.

25.2 Objectives

25.2.1 To assess the ability of the site personnel in dealing with an emergency situation at night which could cause harm to the environment.

25.2.2 To determine whether there were sufficient resources including analytical facilities to assist those responsible for managing such situations.

25.3 Discussions

Glaxo Wellcome had been informed that inspectors would wish to visit the site at night during the audit, but the date and purpose of the visit had not been disclosed.

A team of three inspectors arrived at the site unannounced just after 9 pm in the middle of the audit week. On arrival at the gatehouse the inspectors showed their warrants to the security staff, and requested to see the Shift Manager. When he arrived they explained that they wished to carry out an emergency response exercise as part of the audit and described their proposals for the exercise.

It was explained that the exercise would involve a simulated spillage of solvent in the Solvent Recovery Area. No materials were actually to be spilled and it was not the intention to interfere in any way with production. Outside agencies would not be contacted, but if thought appropriate the site's own fire brigade could be involved and staff could be called in if this was the normal practice. The exercise would be abandoned if there happened to be a genuine emergency anywhere on site during the exercise.

<u>The Agency Inspired Exercise Scenario</u>
On the previous day one of the inspectors, who was not to be involved on the night, had been given the task of developing a feasible scenario for the exercise whilst carrying out an audit of the area.

> "During routine operations on No1 site in Solvent Recovery Area, the Column 1 product line transferring recovered acetone to Tank 23 suffers a major leak at a joint on the pipebridge, and acetone spills to the floor. The area is drained by a floor gulley directly to the Low BOD drain and 2000 litres of neat acetone reaches the Low BOD effluent pumping station situated at the Memorial Gardens."

The Team Manager for the Solvent Recovery Area was contacted and briefed about the scenario ready for the start of the exercise. Inspectors acted as observers, making notes and recording a log of the actions taken whilst Glaxo Wellcome staff handled the incident.

One inspector added inputs to the exercise at appropriate points to maintain the momentum. At a later stage another inspector - The Water Quality Manager, took on his normal role as the Agency officer called out to respond to the incident.

A list of the main personnel involved in the exercise, together with a detailed log of the incident recorded by one of the Inspectors acting as an observer, is shown in Appendix 6. It is included in this report in order to capture the timescale, the decision processes, and actions which were taken by Glaxo Wellcome personnel in controlling and managing the incident to minimise the effects on the environment.

25.4 Conclusions

(a) The exercise provided an effective means of assessing the Company's response to an emergency situation occurring outside of normal office hours.

(b) All Glaxo Wellcome staff were fully co-operative and joined in the spirit of the exercise with enthusiasm giving an added sense of realism.

(c) The Team Manager knew where to find his copy of the Site Emergency Procedures manual, and demonstrated familiarity with its contents.

(d) Use of Glaxo Wellcome's "Spillage and Release Index" system was demonstrated.

(e) There were adequate means available for analysing effluent samples making use of facilities in the QC laboratory and the COD monitoring equipment in the Environmental Laboratory.

(f) Control of the incident was by a joint core team which evolved as the situation progressed. Although the Site Emergency Procedures specify who has the main authority, on this occasion there was no obvious leading figure. This was not a problem as the structure was clearly understood by those involved.

(g) As a result of the exercise, questions were asked for the first time about how to empty the contents of one of the Low BOD effluent tidal tanks into road tankers. Mobile pumps held by the site fire brigade were found to be capable of providing the required lift. On-site storage capacity was also examined and found to be adequate.

(h) The advice of the Environment Agency officer was acted on and given priority over other business considerations.

(i) Overall the audit inspectors felt confident that the site personnel are adequately trained, and are fully capable of dealing with an emergency situation which could arise outside of normal hours.

(j) All staff involved, including the process operating team, the site fire brigade, and senior managers, dealt with the situation in a competent, professional manner to ensure compliance with environmental requirements and minimise harm to the environment.

25.5 Recommendations

(a) There are a number of learning points resulting from this exercise which need to be communicated to others who may be involved in a similar situation.

(b) The procedures for operating the COD analytical equipment should be amended to take into consideration different dilution ratios.

(c) The "Spillage and Release Index" system for classifying incidents should be widely publicised to assist the operators of other IPC authorised processes to determine whether incidents should be notified.

Section 26 Operator and Pollution Risk Appraisal (OPRA)

26.1 Introduction

As part of the methodology used to carry out the audit, the IPC inspectors made use of the techniques outlined in a revised draft of the Operator and Pollution Risk Appraisal (OPRA) issued in June 1996. OPRA is a system which was first developed for trial purposes in 1995 by HMIP and was released as a consultation document to around 2000 groups including operating companies, trade associations, public groups, environmental specialists, and local and central government. The results of the trials and consultation has caused some revisions of the methodology which is contained in the latest draft.

The main purpose of OPRA is to provide an objective and consistent basis for work planning and allocating Agency resources to the many processes regulated under IPC. The system provides quantitative data which reflect the factors contributing to both high and low risk of pollution to the environment. OPRA is intended to provide both a recognition of the efforts expended by operators in achieving high standards, and an incentive to operators to strive to the highest standards in their sectors.

The method is in two parts, an Operator Performance Appraisal (OPA) and a Process Hazard Appraisal (PHA). Each includes an evaluation of seven main attributes which determine operator performance and pollution hazard, and a simple method for rating these to provide overall OPA and PHA scores for the process. The attributes included in the OPA part of the study are:-

Recording & Use of Information
Knowledge & Implementation of Authorisation
Plant Maintenance
Management & Training
Plant Operation
Incidents, Complaints and Non-Compliance Events
Auditable Environmental Management Systems

Each attribute is assessed and given a score from 1 to 5 where a score of 1 is a poor performance and 5 is excellent. A score of 3 represents the expected industry standard for a company fully complying with its environmental requirements. The scores themselves are a matter for discussion between the operating company and the inspector. There is no intention to publish them because, taken on their own without the justification, the scores could be misinterpreted.

In the Glaxo Wellcome audit inspectors chose only to carry out the OPA part of the method as the purpose of the audit was to determine the performance of the operator, not the inherent risk of the processes.

26.2 Results of the OPA Study

An Operator Performance Appraisal was carried out for each of the process areas reported in Sections 16 to 21 of this report. In carrying out the studies using the revised draft OPRA methodology, all seven attributes were considered and given ratings, but

inspectors found some difficulty in precisely allocating scores for some of the attributes, and noticed a number of inconsistencies in the guidance available.

Their comments have been fed back to the working party developing the OPRA method, and further revisions have now been made in a later version of the draft.

In view of the developing nature of the method, and the fact that the scores are of a subjective nature intended only for discussion between the inspectors and the company, it is not appropriate to include the results in this report. However the inspectors felt that the OPA method was a valuable inspection tool and enabled them to reach the conclusions shown below.

26.3 Conclusions

(a) For most attributes included in the OPA study all of the authorised processes operated by Glaxo Wellcome performed equal to or better than the industry standard for a plant fully complying with environmental requirements.

(b) In only one case was an attribute marked below this standard and this was in the Solvent Recovery Area. The attribute "Incidents and complaints over the previous twelve months", scored a low mark due a single incident.

(c) The overall OPA scores for the main process plants were high indicating a good environmental performance with lower risk of causing environmental problems.

(d) The two areas with the lowest total scores were both support activities - Solvent Recovery and the Boilerhouse, but their average scores were still above the industry standard.

(e) From the two paragraphs above, it could be assumed that processes which up to now have been subjected to frequent inspection and auditing by health and pharmaceutical regulators from around the world have a higher standard of environmental performance. The introduction of IPC is now raising the environmental profile and standards for ancillary support plant to that required for production plant in the pharmaceutical industry.

Appendices

Appendix 1

Glaxo Wellcome
Corporate Environmental Policy

Corporate and Environmental Policy

Glaxo Wellcome plc recognises the importance of managing health, safety and environmental matters effectively as an integral part of its business activities.

It is the policy of the Group that each company:

* provides and maintains facilities, plant, equipment, systems and working conditions which are safe and without risk to the health of employees, visitors, contractors and the public;

* provides information, instruction, training and supervision for all staff to enable them to carry out their duties in a safe, environmentally responsible and effective manner;

* takes full account of health, safety and environmental considerations in project planning and decision making;

* assesses and seeks to minimise the impact of business activities on the environment;

* provides proactive and effective occupational health and hygiene programmes commensurate with Glaxo Wellcome's position as a leading healthcare organisation;

* develops and maintains appropriate emergency response procedures and contingency plans;

* pays special regard to environmental protection in the communities in which its operations are located;

* seeks to co-operate actively with the appropriate authorities and other relevant bodies to resolve issues and improve performance;

* seeks to achieve continuous improvement in its health, safety and environmental performance;

* treats local health, safety and environmental laws as minimum standards to be improved on whenever practicable considering technological and economic factors.

This policy statement applies to every company within the Glaxo Wellcome Group throughout the world.

Appendix 2

Implementing the Safety, Health & Environment Policy at Ulverston
Extracts from
Glaxo Wellcome Safety, Health & Environment Policy at Ulverston

Our Responsibilities

All Staff

A safety and environment conscious culture cannot prosper unless everyone working within it actively fulfils their share of this large responsibility. All members of staff must act responsibly and do everything that they can to prevent injury to themselves and their colleagues and minimise impact on their environment. It should be recognised that negligence in this respect will be treated as a serious matter. In particular they must:

* Have read and understood the Safety, Health and Environment Policy and the Site Implementation Statement.
* Observe the requirements of their area safety and health, and environment management plans.
* Use all equipment and substances in accordance with instruction and training received.
* Take care of safety equipment.
* Report immediately any defects in the workplace equipment or machinery provided.
* Report immediately any work situation which requires the implementation of an emergency procedure and follow that procedure.
* Report all accidents, incidents and near misses.
* Report medical conditions or injuries which may affect their ability to work safely.
* Share their knowledge and skills concerning safe practice and good environmental practice, with other members of staff in order to help one another get it right.

Site Management Committee (SMC)

The SMC takes overall responsibility for safety, health and environment standards within the factory. The SMC is advised by the Safety, Health and Environment Manager. The SMC:

* Provides a point of reference for managers with conflicting safety, environment and production or other business demands.
* Fixes the accountability for safety and environment management in the same manner as other management functions.
* Resources the provision of plant and equipment which is safe and environmentally acceptable.
* Resources the provision of competent employees including specialist support for management.
* Ensures the implementation, maintenance and monitoring of this policy.

Operations Managers

Operations Managers are responsible for the preparation and annual review of safety and health, and environment management plans for each area under their control, and in particular:

* The creation of a SHAPE safety management plan on an annual basis.
* The definition of annual health and safety targets relating to positive initiatives for the areas and staff under their control, and their subsequent progress review.
* The definition of IPC compliance action and improvement plans and their progress review.
* The implementation of waste minimisation plans.

Team and Support Managers

Team and Support managers are responsible for the implementation of their area's safety and health, and environment management plans, and for the application of basic safety and environment management techniques. In particular:

* Initiating hazard and risk assessment studies during the design, installation, maintenance and operation of plant and equipment.
* The provision of procedures for safe and environmentally acceptable operations.
* The provision of necessary information, instruction and training so as to ensure staff are capable in safety, health and environment terms.
* The preparation of local emergency procedures and organisation of practice drills.
* The investigation of accidents, incidents, work related ill health cases and near misses, and the implementation of necessary remedies.
* Organising inspections, surveys and safety meetings.
* The issue of safety devices such as protective equipment.
* Ensuring that any machinery, equipment, substances, means of production, abatement equipment and safety device is used in accordance with pertinent procedures, instruction and training provided. Also the observation and auditing of these activities at such a frequency that will ensure that this objective can be met.
* The arrangement of any necessary reports and maintenance on their plant and equipment.
* The maintenance of good housekeeping and occupational hygiene standards in their areas.
* Counselling and correcting immediately all examples of non compliance with safe and environmentally acceptable practice.
* Maximising staff involvement in establishing team standards and continuous improvement.

Our Approach

Our site will use a wide range of safety, health and environment management techniques:

Leadership and Discipline

The commitment of managers will be demonstrated by:

* Leading by setting an excellent example of personal behaviour.
* The recognition and positive encouragement of good behaviour.
* The correction, in a positive manner, of poor working practice.
* Special area disciplinary codes.
* Site disciplinary procedure.
* Target setting.

Communications and Consultation

Communication and consultation with staff and their safety representatives will be formally provided through collaborative involvement in:

* Area safety meetings.
* Factory Health and Safety Committee meetings.
* Monthly team briefings.
* Formal accident and incident investigations.
* Scheduled safety inspections and surveys.
* Continuous Improvement projects.

Communication with our neighbours will take place through the Environmental Liaison Committee and the provision of an environmental information newsletter.

Monitoring

A number of monitoring techniques will be operated within the factory, many with support from Safety, Health and Environment, including:

* Informal safety tours, formal safety inspections and surveys.
* Auditing of selected activities.
* Occupational Hygiene monitoring and inspections.
* Health surveillance.
* Fire prevention surveys.
* Compliance monitoring of authorised releases to air and water.
* Environmental impact assessment and monitoring.
* The Self Audit Scheme.

Sources of Information

Sources of information which are provided and regularly updated include:

* Design and Safety Guides.
* Design and Safety Site Procedures.
* Substance Information Sheets.
* Hazard Data Sheets.
* SHAPE Toolkits.
* 5 Steps Manual.
* HELPS Manual.

Techniques used for the Selection and Design of Equipment, Processes and Facilities

A number of hazards identification and risk evaluation techniques will be applied, with assistance from Safety, Health and Environment where necessary, including:

* Hazard and Operability Studies.
* Job Safety Analyses.
* Specific assessment procedures, e.g. COSHH assessments and manual handling assessments.
* Quantitative risk assessment procedures.
* Environmental Impact Assessment.

Written Safe Systems of Working

Written safe systems or working will be defined in several forms including:

* Plant Operating Instructions and Procedures.
* Safe Working Procedures.
* Plant logsheets.
* Engineering method statements or workplans.

Permits to Work and other safety certificates

Three types of permitry system are operated in the factory:

* General Permit to Work.
* Source of Ignition Certificate.
* Confined Space Entry Certificate.

They are issued by staff who have undertaken training and competence assessment for each type of permit.

Emergency Procedures

Contingency plans for predictable factory emergency scenarios are in place. Each area also maintains a suitable range of emergency procedures in which staff are trained. Emergency procedures include:

* Fire alarm procedure.
* External toxic gas release procedures.
* Factory spillage management procedures.
* Confined space rescue procedures.
* First aid emergency call out procedure.
* Local departmental gas, fume or vapour release (within a building) procedures.
* Provision of information to site neighbours.
* Site and Off site serious emergency procedures.

Accident and Incident Procedures

The following procedures are in operation:

* Notification of accident reporting procedure.
* Lost time (and other serious) accident procedure.
* HSE reportable accidents and dangerous occurrences procedure.
* Notification of spillages and other releases to the Environment Agency procedure.
* Unusual Incident Report (UIR) procedure.
* Notification of industrial disease or work related ill health procedure.
* Accident and Unusual Incident Report form analysis via area record files, and for the site as a whole via Safety, Health and Environment.

Information, Instruction and Training

All staff receive basic safety and environment induction training when they commence employment. Following induction, their individual information, instruction and training needs will be assessed locally, and provided according to the demands of their work. All relevant training will be recorded.

Planning, Target Setting and Performance Appraisal

Each area will devise action plans for addressing safety, health and environment improvement. Plans will specify safety, health and environment targets for all managers which are linked to the performance appraisal system. Targets for individuals will be couched in terms of positive initiatives to be implemented rather than the achievement of negative indices such as 'personally reducing accident frequencies'. Targets will address key result areas and include the use of the continuous improvement process.

Audits of Area Safety, Health and Environment Management Performance

Area safety, health, and environment management will be audited by Operations Managers on a routine basis by the systematic and critical examination of the various sources of information available to them:

* Accident, UIR and ill health report files.
* Results of emergency procedure drills.
* COSHH and manual handling assessments and implementation of actions.
* Minutes of safety meetings and staff feedback.
* Occupational hygiene monitoring results.
* IPC compliance monitoring results.
* Results of health surveillance.
* Corrective counselling and disciplinary records relating to safety, health and environment practices.
* Safety inspection and survey report files and records of actions taken.
* Staff appraised records, in respect of performance of targets from the area safety and health, and environment management plans.
* Self Audit Scheme results.
* Results from the application of SHAPE toolkits e.g. legislative compliance toolkits.
* Reports submitted by external auditors.
* The Monthly Safety Report.

Appendix 3

Text from Pocket IPC Cards Used in Solvent Recovery, Incinerator, and Effluent Areas

The authorisation granted to Glaxo Wellcome under integrated Pollution Control regulations set limits for emissions from the Incinerator and the Cephalosporins process, including Solvent Recovery and effluent discharges.

A number of EMISSION POINTS for liquid and vapour streams have been identified in SRWM Department. For releases to atmosphere these are scrubbed gases from the incinerator stack and solvent losses from storage tanks. Emission points for releases to water (effluent system) are from Site 2, Site 3 and Site 4 Solvent Recovery and the Incinerator Effluent pits and the direct discharge from Column 44. The final site discharges of High and Low BOD effluent are also identified as emission points. The emission points fro SRWM Department are listed below:

Process	Releases to	Key emissions
<u>Incinerator</u> 40m Stack Effluent pits	 Air Water	 SO_2/HCl/CO/NO_x/dioxins Volume/pH/dioxins
<u>Solvent Recovery</u> Storage tanks Site 2, 3 and 4 Effluent pits Column 44 discharge	 Air Water Water	 Solvents (VOC) pH pH
<u>Final effluent discharges</u> Low BOD tidal tanks High BOD tidal tank	 Water Water	 Volume/pH/COD/solids/metals/DCM Volume/pH/COD/solids/metals

Emission points can be fitted with some form of ABATEMENT EQUIPMENT to control emissions, including: scrubbers, condensers, filters etc. The authorised emission limits assume the processes and abatement equipment are operated correctly as described in the Solvent Recovery Guide/Plant Operating Instructions. The efficiency of abatement equipment can be reduced by failures of associated systems e.g. failure of cooling water supply to condensers, loss of scrubber liquor recirculation.

If abatement equipment or associated systems are found not to be working correctly this must be reported immediately to your Team Manager.

<u>Reporting Line</u>

Operator

Team Manager/Team Support Manager

Senior Shift Manager/SHE Department

It is a requirement for the company to inform the Environment Agency of unauthorised emissions within 24 hours.

CRITICAL PARAMETERS TO MEET AUTHORISED LIMITS

Table shows parameters that Operators must be aware of to ensure that authorised limits for processes are met. See IPC authorisation for full list of release limits.

Process	Parameter	Specification
Incinerator	General	Must burn aqueous waste or process water when burning waste solvent
	Scrubber ΔP	Not less that 1,950 mmwg when burning waste solvent
	Waste solvent blended feedstock	Not greater than 2% v/v HMDSO Not greater than 8% v/v N containing organics Not greater than 33% w/w chlorine (equivalent to 40% v/v DCM)
	Effluent pits	pH 5-9 volume 340m^3/day
Solvent Recovery	Site 2, 3 and Site 4 effluent pits	pH 5-9
	Column 44 discharge	pH 5-9
High BOD effluent	Final discharge	Time of discharge 1 hr after Barrow high tide time (GMT) Duration of discharge - 45 minutes pre-discharge pH 5-9 at mimic tank pre-discharge TC concentration < 6,200mg/l at mimic tank Volume not greater that 2,700m^3/tide
Low BOD effluent	Final discharge	Time of discharge 1 hr after Barrow high tide time (GMT) Duration of discharge - 45 minutes pre-discharge pH 5-9 at mimic tank Volume not greater than 7,200m^3/tide
General	Spillages	Low BOD effluent has authorised limit for DCM of 100 mg/l

Appendix 4

Text from Pocket IPC Cards Usedin the Site Boilerhouse

The authorisation granted to Glaxo Wellcome Operations under integrated Pollution Control regulations set limits for emissions from the Boilerhouse.

A number of EMISSION POINTS for liquid and gas releases have been identified in Utilities department. For releases to atmosphere these are the combustion gases from the boilers via the brick chimney and stell chimney. Emissions point for releases to water is from the Boilerhouse effluent pit. The emissions points for the Boilerhouse are listed below:

Utilities-Boilerhouse		
Release point	Releases to	Key emissions
Effluent pit	Water	pH
Brick chimney	Air	SO_2/NO_x/Dark smoke
Steel chimney	Air	SO_2/NO_x/Dark smoke

The control of emissions from emission points in the boilerhouse assume the processes are operated as described in the Plant Operating Instructions.

ABATEMENT EQUIPMENT is not fitted to either the brick or steel chimneys. Release from the authorised process are controlled and minimised by control over operating parameters that ensure either optimum combustion conditions, such as fuel/air ratio and excess oxygen in flue gas, or limit emissions of dark smoke. Emissions can also be affected by the type of fuel burned and in the case of HFO the sulphur content. There are no specific concentration limits for releases of SO_2 and NO_x from the Boilerhouse chimneys, although the total amount released per annum is limited to 800 tonnes for SO_2 and 200 tonnes for NO_x.

For releases to water, the Boilerhouse effluent treatment pit has been specified as abatement equipment.

If process control or abatement equipment or associated systems are found not to be working correctly this must be reported immediately to your Team Manager.

Reporting Line

Operator

Team Manager/Team Support Manager

Senior Shift Manager/SHE Department

It is a requirement for the company to inform Environment Agency of unauthorised emissions within 24 hours.

CRITICAL PARAMETERS TO MEET AUTHORISED LIMITS

Table shows parameters that Operators must be aware of to ensure that authorised limits for process are met. See IPC authorisation for full list of release limits and other operating conditions.

Release point	Parameter	Specification
Boiler stacks	Dark smoke	Not greater than Ringelman Shade 1, except for soot blowing. Fuel gun cleaning and for 15 minutes following start-up from cold or fuel changeover.
Effluent pit	pH	pH 5-9
Oil/water separator	Oil	Low BOD effluent has authorised limit for no visible oil or grease.
General	Spillages of HFO	Low BOD effluent has authorised limit for no visible oil or grease.

Appendix 5

Spillage and Release Index Reporting to the Environment Agency

Spillage and Release Index

Reporting to The Environment Agency

A tool for assessing the relative severity of spillages and release to air.

Index = F (Nature) x F (Size) x F (Fate) ie. $F_N \times F_S \times F_F$

Nature of Substance	**Weighting F_N**
Toxic substances (ammonia, hydrogen bromide)	15
Solvents	10
Oils	10
Corrosive Liquid	5
Others	1

Size of Release	**Weighting F_S**
Less than 10 L	0.5
10 to 100 L	1
100 to 300 L	3
300 to 1000 L	5
1000 to 10000 L	10
Over 10,000 L	25

Fate of Spillage	**Weighting F_F**
Contained in Bund	1
Contained Elsewhere (eg. effluent pit)	2
Into ground on site	5
Low BOD Tidal Tanks	5
Off site	10

Examples:

A release of 100L (as liquid) of acetone to air via a bursting disc would carry an index of 10 x 1 x 10 = 100.

A spillage of 800L of DCM onto chippings would have an index of 10 s 5 x 5 = 250.

Severity and Reporting to the Environment Agency

Release to Air/Water

300 and above	-	Reportable to Environment Agency - (Formal Notification) without delay
200 - 300	-	Discuss with the Environment Agency - next working day
< 200	-	Not Notifiable

Appendix 6

Emergency Procedures Exercise

Incident Log

Emergency Procedures Exercise

Incident Log

Main Personnel Involved:

Shift Manager (SM)
Solvent Recovery, Team Manager (TM)
Solvent Recovery, Team Support Manager (TSM)
Class 1 Operator
Site Fire Brigade Officer
Shift Engineering Manager
Senior Environmental Adviser (SEA)
Solvent Recovery Operations Manager (SRM)
Environment Agency Inspector (EA)

Exercise Log - Recorded by Environment Agency Inspectors acting as observers

TIME	ACTIONS RECORDED
21.35	Operator discovered leak, identified source, proceeded to control room.
21.37	Operator shut off appropriate solvent recovery column at control panel and manually closed valves just outside the control room.
21.38	Operator telephoned Team Manager and asked him to call Fire Brigade. (Had this not been an exercise, the operator would have activated the fire alarm to summon immediate assistance.)
21.41	Operator placed drain seal in position but decided this was a waste of time as drain was a long slit running the length of the affected area.
21.43	Marker tape placed around spillage area.
21.44	Tundish, hose, and waste drum obtained to try to contain spilling solvent.
21.46	Fire hose connected and water available for washing down drains.
21.47	Team Manager arrived at scene of incident and contacted Senior Shift Manager.
21.48	Tundish in place under leak.
21.49	Officer from the Site Fire Brigade arrived having been contacted by phone.
21.50	Shift engineer contacted, requested to fix leak
21.53	Incident control team set up in Solvent Recovery Control Room. Member of Environment Department (Senior Environmental Adviser) called out.
21.53	SM and TM consult drainage plans and decide to isolate the pumping station at the Memorial Gardens.

21.55	TSM left to isolate the Memorial Gardens effluent pumps.
21.56	Fire Brigade tannoy announcement calling fire team members.
21.56	Shift fitter arrived
21.59	Shift Engineering Manager arrived to offer assistance. Fire hose local to incident turned off.
22.01	TSM and Shift Engineering Managers left to obtain sample from Memorial Gardens.
22.03	Repair of leaking gasket complete. Plant put back on to check integrity of repair. Tundish washed down into waste drum - liquors for incineration. Senior Environmental Adviser (SEA) arrived and was briefed of incident and actions taken.
22.04	SEA calculated spillage index and decided notification to Environment Agency was required.
22.06	Fire Brigade report they are washing down drains - using hoses only so as not to flood Memorial Gardens sump.
22.07	Team Manager indicated that sample should not be taken from Effluent System Mimic tank for about 2 hours, to allow time to drain through the system (no rainfall). Shift and Team Managers discuss options - depends on result of Memorial Gardens sample but could pump to tanker or flush to tidal tanks.
22.10	Operations Manager for Solvent Recovery Area arrived.
22.12	Team Manager instructed SRWM incinerator operator not to discharge the contents of the tidal effluent tank at the discharge time (4am) but to switch over to the other tank thus isolating the spillage.
22.17	Group decided that, if decision taken to flush to tidal tank, need to sample mimic tank inlet for acetone at intervals, so they know when all spillage has reached the tidal tank.
22.19	Fermentation requested to shut down West tank.
22.24	Initial sample result shows high level of acetone in Memorial Gardens sump. Fire Brigade asked to stop flushing drains.
22.27	Incident Team relocated to Team Managers Office to review position: (1) Lost max 2000l acetone to LBOD/Memorial Gardens effluent - need to sample mimic tank at 23.30 to confirm if any acetone has gone past Memorial Gardens. (2) Tidal discharge due at 04.44. East low BOD tank currently 9-10% full. (3) Drains flushed through and tested OK with explosimeter by Fire Brigade.

22.33	GC result phoned through: .001% acetone in effluent. (ie no significant acetone in the effluent at the Memorial Gardens.)
22.34	Environment Agency inspector arrived and is briefed by Shift Manager.
22.37	EA concerned about salmon running in estuary at this time of year - asked for sample to be taken from low BOD effluent tank.
22.41	Effluent operator arrives - asked to take 2 samples (1 for glc, 1 for COD) from each of Low BOD tank and mimic tank.
22.43	Effluent operator and EA inspector set off to take samples.
22.44	TSM leaves to ask Fire Brigade to check Memorial Gardens for explosive vapours - if OK to announce all clear.
22.44	Solvent Recovery operator rang to say he would fill in Unusual Incident Report form (UIR) before end of shift.
22.46	Team checking acetone substance info. sheet for toxicity data. LC50 (trout) 5540 mg/l.
22.48	SRM asked Shift Engineering Manager to check availability of a mobile pump capable of pumping out the tidal tank (362 m3, 6m head). Other options considered; (i) Dilute and discharge, or (ii) Blow air through (discounted). Calculated COD about 5000mg/l (ie above authorised limit) - based on 2m3 acetone in 362m3 effluent.
22.56	Actions identified: Shift Engineer to contact fire station and external pump suppliers. Group decide about 20 road tankers needed.
22.57	Low BOD tank samples arrived - operator taking glc samples to QA lab.
22.57	TM noted that volume of low BOD tank would be increasing - could be at 2 x 362m3 by 4am.
23.03	Low BOD tank vol checked, now 11.2% full. COD concentration recalculated as 12000mg/l.
23.05	Team decide they need a sample of inlet to mimic tank to confirm all acetone has now passed into tidal tank, before switching tanks. (Not progressed by agreement with audit inspector.)
23.05	TSM returns - there is no explosive atmosphere in the drains.

23.06	Team Support Manager leaves to carry out COD tests on Low BOD tank samples. 1. "LBOD Mimic for COD" 50 mls made up to 100 mls (as for Low BOD) 2 mls to tube, tube labelled 'M' Vol flask washed out. 2 "LBOD for COD" on paper label 50 mls made up to 100 mls fresh pipette 2 mls to tube, Tube labelled 'T'
23.25	Tubes placed in the block and left heating. Note: Tube range 150 - 1000mg/l (Amend procedure to do 1:2 & 1:20 dilution)
23.10	EA inspector advises that pump out of the tidal tank and disposal is preferred option. Shift Engineer despatched to talk to Fire Brigade about pumping capabilities. TM requests operator to isolate East LBOD tank. Effluent will then collect in West tank and this will be discharged at 0400.
23.13	SRM requested info from EA - approved list of tanker operators on 24-hour call to assist in pumping out. SRM suggested suspending further action until first light, for safety considerations. EA agreed, provided that steps taken to organise pumps and tankers. There are 7 tankers on site - enough capacity to empty into bulk tank for recovery.
23.16	Acetone in mimic tank and bulk tank < .003% (glc results)
23.18	Action plan: 1. Obtain pumps and hoses 2. Obtain 4 tankers and drivers 3. Look at rigging up solvent recovery column (col 51/63 - 10000 l/h) 4. Consider process effects 5. Arrange labour 6. Maintain routine effluent management
23.20	Shift Engineer returns from Fire Brigade - they have suitable pumps, 8m suction head, 2 x 2500 l/min, 1 x 5000 l/min.
23.32	Further agreed items for Action Plan: 7. Communication of follow-up action 8. Investigation
23.40	Exercise concluded except for COD results. Discussion of incident and feedback from Agency audit team.

00.15	COD results obtained: 226 mg/l in tidal tank, 520 in mimic tank.
00.20	**Exercise completed.**

END OF EXERCISE

Appendix 7

Full List Of Recommendations

6.4 Corporate and Site Environmental Policy

The only recommendation is that these policies are maintained, reviewed, and updated as appropriate.

7.4 Waste Minimisation Policy

The waste minimisation culture introduced at the site is to be welcomed. The Waste Minimisation Project for process activities offers substantial environmental benefits and is preferred to end of pipe solutions whenever possible. There may however be situations where end of pipe treatment is the only solution in a reasonable timescale. The Environment Agency recommends that the Company should continue to support the waste minimisation activities.

8.4 Site Energy Policy

(a) The site should re-evaluate the current and future needs for steam and power and examine how these are to be provided in the future, taking economic and global environmental aspects into account.

(b) The management should do more to encourage and emphasise energy saving measures, possibly by the re-introduction of specific targets for reducing energy consumption on the site.

9.4 Site Operating Procedures and Instructions

Some attention should be given to ensuring that all working copies of procedures are the official copies signed by the appropriate level of management, and that reviews are carried out at the frequency specified in the site instructions.

10.4 Shift Handover Arrangements

Glaxo Wellcome Operations should ensure that legible copies of plant status sheets are retained on plant for the reference of the next shift.

11.4 Internal Safety and Environmental Audits

(a) The Company should be encouraged to continue with the inter-site audits, and the Self Auditing Systems introduced at Ulverston.

(b) The use of the UIR system by other operators of processes regulated by the Environment Agency, should be encouraged.

(c) The Company should consider the re-introduction of a keyword database for assessing trends in the Unusual Incident Report (UIR) data.

12.4 Training

(a) The Company should ensure that all appropriate members of staff have attended a formal environmental awareness training session.

(b) A further level of environmental training is now needed to provide personnel with a more specific understanding of the potential environmental effects of the materials they are handling.

(c) The IPC pocket card system developed on site should be publicised for other companies to follow.

13.4 Plant Maintenance

(a) Glaxo Wellcome should Audit the transfer of maintenance/condition monitoring regimes from the manual to the computerised system, to ensure that maintenance/condition monitoring of all relevant plant items continues at the specified frequency.

(b) The requirements for maintaining and calibrating instrumentation on some abatement equipment for releases to air need to be reviewed.

(c) All maintenance and follow up work on the effluent tanks needs to be recorded formally. The maintenance requirements for the discharge valves should be included in the EPMS system.

14.4 Compliance Monitoring

(a) The formal routine schedule for monitoring releases to air should be extended to include a greater number of release points.

(b) The site should consider whether there would be any advantages gained by extending the cover provided by the Environment Unit from 5 days a week to 7 days a week, daily working.

15.4 External Relations

The Company should continue to make every effort to maintain the goodwill it has built up over the years.

16.5 Cephalosporin Plant

(a) Some of the vessels in Fermentation with release points to air are no longer used, and a minor variation is required to update the authorisation to reflect current situation.

(b) Some of the release points to air have incorrect or misleading identification labels. These need clarifying, and a site-wide system introduced to avoid confusion between release points on different authorisations.

(c) The Finishing Stages of the process which were not included in this audit should be subjected to an early routine inspection by the site inspector.

17.5 Solvent Recovery Plant

(a) Document control for some procedures needs to be improved. In the short term, redundant procedures should be removed, and any which need reviewing should be identified and modified as a matter of priority.

(b) During Shift handover the notes should be completed fully with a "None" entered rather than blanks left. Use of a whiteboard to draw attention to important matters is good, but there should always be a written record as well.

(c) Better controls and alarms are needed to prevent overfilling of some local effluent pits.

18.5 Griseofulvin Plant

(a) Glaxo Wellcome should consider the provision of additional simple alarms on a number of plant items indicated in this report, which would give early indication of faults and prevent releases to the environment.

(b) Measures should be considered to reduce releases to air from the petrol and methanol stills, and from the drying of the intermediate Griseofulvin product.

(c) Early inspection should be carried out of apparent cracks in the concrete bunds around the recovered solvent storage tanks.

19.5 Development Plant

(a) The process of fitting low flow alarms to the process scrubbers should be continued and should include those in the pilot plant.

(b) Ensure that pre-calibration tolerance errors for pH meters are recorded and reported for corrective action.

20.5 Waste Solvent Incinerator

(a) Glaxo Wellcome should establish a procedure and document control system for the Solvent Recovery and Waste Management Area, and set appropriate priorities for creating and updating procedures.

(b) In the drum off-loading area, a procedure should be established for recording all observations made on samples taken from the effluent pit prior to discharging to the site effluent system.

(c) Improved control is required for the receipt of drums and other containers of waste solvents.

(d) The use of sealed or low leak rate pumps for the transfer of waste solvents to the incinerator should be investigated as part of the site waste minimisation programme, to reduce or eliminate fugitive emissions.

(e) Improvements to labelling are needed in certain areas as indicated in this report.

(f) The emergency quench tank system should be re-examined to ensure that it can never be isolated when the incinerator is in use.

(g) Drip trays should be provided under the drain valves on the lines associated with the solvent and aqueous waste flow controllers.

(h) Consideration should be given to modifying the computer control system for the effluent pit to give early warning of pH problems and prevent overfilling.

21.5 Boilerhouse - Large Combustion Plant

In order to reduce emissions of NOx, the site should continue with the burner tip trial on Boiler No4, and consider fitting Low NOx burners on the remaining boilers, or other means, to meet tighter environmental standards.

22.5 Radioactive Substances

Glaxo Wellcome should:

(a) Include a copy of the QA department local rules in the site procedure covering the use of radioactive materials on the Ulverston site, and should amend the document to reflect the reporting requirements to the Environment Agency, the latest management structure and to correct the specified certificate reference number.

(b) Amend the QA department source records to reflect the actual source activities.

(c) Bring the source container labelling requirements for the level gauges up to the standard required by the certificate of registration.

(d) Make regular checks on the integrity of source container labelling and report any defects for corrective action and consider including these requirements in the appropriate local rules.

The Environment Agency should:

(e) Issue a cancellation notice including a notice to keep records in respect of the certificate of registration covering the keeping and use of unsealed radioactive materials.

(f) Re-issue the certificate of registration covering the keeping and use of closed radioactive sources to reflect the recent change of user name.

23.5 Aqueous Effluent Systems

Operation & Monitoring of the High BOD and Low BOD Effluent Systems

(a) A bullet point protocol for operation should be located at all operational sites for reference. All operatives should carry a laminated copy. Pictorial representations of systems requiring checking should be considered. A review of procedures in order to simplify the systems should be initiated.

(b) When logging data all spaces should be filled and date/time given as appropriate. If no action is taken it should be recorded. All log entries should be signed.

(c) Installation of TC meters, or other systems, should be considered to warn of spillages into the Low BOD system.

(d) The Company should review the location of all alarms for the effluent systems, to better utilise a 24 hour control room with personnel trained in appropriate responses.

(e) All sample bottles should be labelled prior to sampling in such a manner that it is not affected by the liquid being sampled.

Bacteriological Testing

(f) Glaxo Wellcome to undertake total and faecal coliform sampling on a weekly basis for the next 3 months. Investigation of potential additional sources of coliforms to be initiated. Investigation into additional cleaning/sterilisation of the high BOD effluent system, or treatment with an approved biocide after discussions and agreement with the Environment Agency.

Physical Characteristics

(g) The Company should initiate a review of the system to improve immediate dispersion of effluent and minimise the plume. Investigate whether stratification in the High BOD tidal tank is a problem.

Emergency Systems

(h) The Fire Service's procedure for response planning includes a final step which includes "wash down with detergent". This should be removed from the procedure.

(i) Drainage routes are well known and most manholes are mapped and marked with individual numbers. Any remaining manholes require labelling and the maps updating. Equipment to safely seal drains at ground level should be obtained.

(j) The Company should investigate utilising the 'mothballed' treatment plant facility, temporary tanks, road tankers etc, as methods of temporary containment.

(k) Additional environmental awareness training for the site Fire Service staff should be provided.

24.5 Waste Management

Duty of Care

(a) Glaxo Wellcome should introduce a system where either -

(i) The Waste Management team inspects each load prior to signing transfer documents, or preferably

(ii) The waste generator signs the forms.

(b) Glaxo Wellcome should make regular checks, at least annually, that waste carriers are registered and the disposal sites are licensed to take the types of wastes generated by the Company.

(c) Glaxo Wellcome should make checks at the disposal site to see if recommendations from previous audits have been carried out. If the matters of concern are serious and the recommendations have not been carried out the Company should consider whether the site is acceptable as a disposal route.

General Waste Collection and Storage

(d) Install better signs on waste collection points in more prominent positions.

(e) General waste should be deposited into skips rather than on the ground, or gates should be installed to retain the waste in the collection bay.

(f) A tracking and logging procedure should be introduced for waste drums in the drum compound. This may refer to the numbering system given on the purchase requisition but must also include the unique identification on the drums themselves. The drum compound should be segregated, and storage bays numbered for identification purposes.

25.5 Emergency Procedures Exercise

(a) There are a number of learning points resulting from this exercise which need to be communicated to others who may be involved in a similar situation.

(b) The procedures for operating the COD analytical equipment should be amended to take into consideration different dilution ratios.

(c) The "Spillage and Release Index" system for classifying incidents should be widely publicised to assist the operators of other IPC authorised processes to determine whether incidents should be notified.

Appendix 8

Responses to the Audit from Glaxo Wellcome

Responses to the Audit from Glaxo Wellcome

Introduction

On the last afternoon of the audit the inspectors discussed their initial findings with the Company's Site Services Manager and Environmental Managers. At the end of the meeting the audit team leader invited feedback on the Company's impressions of the audit. In a prepared response, the Company stated that they had found both positive and negative aspects of the Agency's audit.

Positive Aspects

* The two preparatory days had provided a useful introduction to the site and the processes carried out.

* A comprehensive audit had been carried out in the timescale available.

* It was useful to have the experience of an outside group in identifying and suggesting improvements.

* The audit had been an open, honest and fair process for both the Environment Agency and for Glaxo Wellcome.

* The solvent spillage exercise was a realistic scenario which had allowed Glaxo Wellcome to demonstrate their emergency response.

* The audit teams had met a wide range of staff at all levels who are directly involved with process operations. This works both ways and allows these staff to meet the Environment Agency, and at the same time raises the profile of complying with environmental requirements.

* It was useful to the operating teams to have immediate feedback from the inspectors at the end of each session.

Negative Aspects

* Large staff resources were tied up, not only during the audit week but also in preparing the familiarisation visits, and preparing the site for the audit.

* Changes to the programme caused organisational difficulties (for staff whose primary objective is to keep the plant running).

* It would have been useful if all members of the audit team had been present for both familiarisation days, as time was taken up during the audit repeating items already explained.

ACRONYMS and ABBREVIATIONS

BATNEEC	Best Available Techniques Not Entailing Excessive Costs
BOD	Biochemical Oxygen Demand
CCTV	Closed Circuit Television
COD	Chemical Oxygen Demand
ELDs	Engineering line diagrams
EPMS	Engineering Planning and Maintenance System
GC	Gas Chromatography (Analysing technique)
GLC	Gas Liquid Chromatography
GMP	Good Manufacturing Practice (Pharmaceuticals)
HBr	Hydrogen Bromide
HCl	Hydrogen chloride or Hydrochloric acid
HFO	Heavy Fuel Oil
High BOD Effluent	High strength process effluent
HMIP	Her Majesty's Inspectorate of Pollution (Now part of the Environment Agency)
HSE	Health and Safety Executive
IPC	Integrated Pollution Control
IPE	Isopropyl Ether
IRRs	Ionising Radiation Regulations 1985
Low BOD Effluent	Low strength surface water drainage, domestic, and some process effluent
MAFF	Ministry of Agriculture Fisheries and Foods
MBq	Mega Becquerels (measurement of activity of radioactive materials)
MW (Th)	Mega Watts (Thermal)

NOx	Nitrogen Oxides (air pollutants from combustion processes)
NRA	National Rivers Authority (Now part of the Environment Agency)
NWW	North West Water
OPA	Operator Performance Appraisal
OPRA	Operator and Pollution Risk Appraisal
pH	Indication of the acidity or alkalinity of a liquid
PHA	Process Hazard Appraisal
PMA	Plant Modification Authorisation
POI	Plant Operating Instructions
POP	Plant Operating Procedures
PSE	Plant Safety and Environment
QC	Quality Control
QA	Quality Assurance
RAS or RSA	Radioactive Substances (Act)
SHAPE	Safety & Health Action Planning and Evaluation
SHE	Safety Health and Environment
SMC	Site Management Committee (Glaxo Wellcome)
SRWM	Solvent Recovery & Waste Management
SSSI	Site of Special Scientific Interest
TC	Total Carbon (Effluent analyser)
TM	Team Manager (Shifts)
TSM	Team Support Manager (Shifts)
UIR	Unusual Incident Report
WRA	Waste Regulation Authority
VOC	Volatile Organic Compound

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For general enquiries please call your local Environment Agency office. If you are unsure who to contact, or which is your local office, please call our general enquiry line.

ENVIRONMENT AGENCY
GENERAL ENQUIRY LINE
0645 333 111

The 24-hour emergency hotline number for reporting all environmental incidents relating to air, land and water.

ENVIRONMENT AGENCY
EMERGENCY HOTLINE
0800 80 70 60

ENVIRONMENT AGENCY