AN INTEGRATED APPROACH TO PLANT SAFETY

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Abstract
An innovative safety approach to the design of plant used in the manufacture of a wide range of radioactive products for healthcare, life science research and industrial applications at Amersham International is described.

The paper also describes how the techniques for reviewing the design of new plant have been adapted to the review of operational facilities and the decontamination and decommissioning of facilities at the end of their production life.

Introduction
Over the last five years safety review arrangements have been developed consistent with those applied in the nuclear industry but adapted in an innovative way to reflect the requirements of a commercial manufacturing environment. These arrangements have been applied to the design of new facilities; reviews of operating facilities; and the decontamination and decommissioning of redundant plant.

Classification and Project Phases
A multistage procedure for safety approval is applied to all new facility projects. At the start, the project is classified by a senior health physicist into one of four categories, depending on its safety significance. Higher significance construction projects are split into 4 stages - Concept, Final Design, Pre-Operational Commissioning and Operational Commissioning.

Hazard Identification/Hazard and Operability Study
A Hazard Identification review is carried out at the Concept stage by a small team using a check list. This early review ensures that the designer is aware of the main safety issues and can take account of them in the facility design.

The developed plant design and process are subjected to a Hazard and Operability Study (HAZOP) to identify all possible deviations from the way the design is expected to work and all the issues associated with these deviations. The group performing the study are selected from the Safety, Manufacturing and Engineering functions. The Manufacturing representative is a supervisor or operator with experience of the type of plant and process being designed.

The technique uses a structured approach for the identification of hazards by the generation of deviations from design intentions using guide words. Many of Amersham's operations are 'hands on' and the guide words may be applied to operator actions as well as plant components.

The HAZOP sessions have become an integral part of the design process and, although when initially introduced were viewed with some suspicion, they are now welcomed as a thorough vetting of the design before potential errors and omissions prove more costly. Having carried out the HAZOP it is possible to quantify the risk of the plant/process to operating staff or the general public by using techniques such as Fault Tree Analysis. The HAZOP is as much a review of quality as it is of safety issues and the technique has been successfully applied to manufacturing operations where the quality of the product is the principal objective.

Peer Review
The HAZOP provides an excellent basis for writing the 'Final Design' Safety Clearance document. This is then subjected to a review by a Peer Group which brings together the design team and an independent group of experienced staff selected from Site and Corporate Safety, Engineering and Manufacturing. The proposals are presented by the design team and subjected to challenge by the Peer Group. All points of view can be balanced at this session and it has proved to be much more effective than using individuals to review a document in isolation. Following this review the 'Final

Design' Safety Clearance is formally approved by the relevant Manufacturing Manager, the Site Engineering Manager and the Site Radiological Safety Officer. Peer Reviews may be held at other stages of the project if deemed necessary by the Peer Review Group Chairman.

The Arrangements in Practice

Amersham is currently investing in new pharmaceutical manufacturing facilities. Two semi-automated production suites situated in a clean-room complex carry out the final stages of radiopharmaceutical manufacturing. They will handle stock dilution, vial filling, sealing and labelling operations and waste management. Nine radionuclides, including Sr-89, Ga-67 and In-111, will pass through the plant which has been constructed and is currently undergoing pre-operational commissioning tests. This was a particularly challenging project to marry the stringent requirements of pharmaceutical regulators where Good Manufacturing Practice guidelines must be observed and radiological protection requirements for protection of operators from radiation exposure. The principal pharmaceutical and radiological design issues and identified solutions are shown in the Table below:

Pharmaceutical design requirement	Radiological design requirement	Solution
Operate pharmaceutical clean rooms at slight overpressure to protect product from particulate	Handle radioactive products in rooms at slight underpressure to prevent escape of product following a spill	Clean room surrounding radioactive handling area at positive pressure. Radioactive material handling room/ enclosures at negative pressure
Deliver air to product to pharmaceutical standards and ensure flow is away from product	Direct air away from operators and towards interior of enclosures containing the radioactive product	Pharmaceutical requirements at point of vial filling and stock bottle emptying. Enclosures at negative pressure to protect operator
Provide minimum disturbance to laminar air flow close to vial filling	Surround the vials with lead shielding as they are filled	Provide some shielding local to the vials but supplement with full shielding on face of enclosure
Label vials after dispensing with product to prevent errors	Label vials before dispensing to reduce operator dose	Label vials after dispensing but automate and provide shielding local to vial location
Provide easy accessibility to dispensing line for full line clearance at end of product run	Provide shielding and remote operation to control operator dose	Bulk stock separated from dispensing line and heavily shielded. Filled vials lightly shielded and shielding designed for easy removal at end of run
Remove radioactive waste after each product run	Store radioactive waste in facility until decayed	Highest activity liquid waste stored. Bulky solid waste removed by remote transfer

Periodic Reviews of Safety

Formal major reviews of safety are carried out for all facilities on a 5 year rolling programme. The plant, process and safety management arrangements are considered in each review which covers normal operating conditions and also reasonably foreseeable fault conditions arising from plant failures, operating failures and external hazards. The HAZOP technique is used as a tool for fault identification.

A report with recommendations for improvements is submitted to a Peer Review in the same way as a new plant safety clearance. The Manager is then required to prepare an Action Plan for improvements which is monitored through to completion.

Examples of areas where improvements have been required are: radiation shielding; fire detection; fire compartmentation; transfers of radioactive material; containment; extract filtration/traps; safety management; barrier monitoring arrangements; activity in air alarm monitoring.

Decontamination and Decommissioning Projects

The main distinction between new plant projects and decontamination and decommissioning projects is the amount of 'on the ground' operational safety issues to be resolved. A round-the-table HAZOP is first carried out on the proposed approach, in order to identify the main protective features required to control contamination and radiation dose and to test the operability of the method. The HAZOP may also identify the need for a 'mock up' and trial operation to be carried out prior to the actual job to confirm its practicability and this enables operating times to be measured where dose control is critical. Detailed Method Statements are produced by the staff who are going to undertake the work. These Method Statements are subjected to a HAZOP approach in the workplace in order to identify potential safety problems before the task is undertaken. A system for ensuring that the significance of deviations from Method Statements are assessed has been developed. The whole process is overseen by the operational Health Physicist.

Conclusion

The integrated approach to plant safety responds effectively to rapidly changing manufacturing requirements and has resulted in real improvements to 'on the ground' operational safety without imposing unacceptable bureaucratic restrictions.