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Environmental Compatibility of Certain Dayton Lab Operations

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Purpose: On January 28th a visit was made to the Dayton Laboratory to ascertain the environmental compatibility of certain operations, particularly the NCI contract carried out at the Dayton Laboratory.

Recommendation: It is recommended that the Medical Department in St. Louis be advised of each new custom synthesis or product made at the Dayton Lab.

Summary: During this visit interviews were carried out with Dr. Edgar Hardy, Director of the Laboratory; Dr. J. M. Butler, Manager of Polymers & Organics; and Dr. James A. Ellard, group leader for the NCI contract. These people impressed me as being very capable and aware of the hazards of the materials they are using.

Under this particular contract chemotherapy agents are produced at the request of NCI. Under another contract radioactive tagged compounds are supplied to the government for metabolic studies. The Dayton Laboratory is in the business of manufacturing small quantities of difficult to find chemicals for specific customers. A large percentage of their orders are single order contracts. On many occasions time is of the essence in obtaining orders. I believe these people are capable of operating in a safe manner when dealing with materials under a tight time schedule.

Discussion: The materials that have been supplied to NCI under this contract are listed in Table 1 of this report. Please note that these materials have been supplied for the last eight years. The chemistry for the production of methotrexate is supplied in Figure 1 of the attached. The pencilled notes are mine, arising from my interview with Dr. Ellard. This material is used as a chemotherapy agent. The waste materials from this process are diluted and sent to sewer. The mother liquor has been analyzed and no malonitrile has been detected. If it were, it could be detoxified by treatment with formaldehyde at pH 8.

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The reaction product is not considered hazardous and has been used as fertilizer. The Step 2 and Step 3 reactions are carried out sequentially in the same reactor. Other comment from telephone conversations with J. A. Ellard are to be found on the attached memorandum sent to Dr. G. Roush.

Dr. Ellard has told me that in the past he has performed his own skin irritation tests. Documents of this can be found in the two attached letters, one to Dr. Ellard from Dr. Wood, and the other from Dr. Ellard to Dr. Wood.

The shipping of material to NCI is cleared through Frank Kuziak or Orville Muth of the Central Distribution Department.

There are several legal considerations of this contract. The major advantage is that all raw materials are purchased with reference to the government contract number, and are considered the government's property by NCI. All materials at all times after purchase are the property of NCI. The Dayton Laboratory is forbidden by the contract from supplying these materials to anyone including other governmental agencies except NCI or its designated recipient. The extent of NCI's legal involvement is uncertain. They have told the Dayton Lab that they have carte blanche to any patent in the United States Patent Office and to use it freely for the synthesis of these materials with no fear of charges of patent infringement. This has been discussed with George H. Griffin.

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attachments

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