HITTMAN MATERIALS & MEDICAL COMPONENTS, INC.

OPERATING PROCEDURE

OP-168

DATE: February 5, 1980

TITLE: 10 CFR 71 Quality Assurance Program for the Use of DOT 6M Drums In Shipping Special Form Pu-238

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1. This program is established for the use of DOT 6M shipping drums only (49CFR 178.104). These drums shall be used only for packaging and shipment of medical grade plutonium-238 encapsulated for use as heat sources in radioisotopic thermoelectric generators. These heat sources must qualify as "special form" radioactive material for shipment under this Q.A. program. (10 CFR 71.4 (O))

2. ORGANIZATION

The full responsibility for this Q.A. program, established to meet the requirements of 10 CFR 71.12, is with Hittman Materials & Medical Components, Inc. (HMMC). The Radiation Safety Officer (RSO) is responsible for overall administration of the program, training and certification, document control and auditing. The Health Physics Department is responsible for handling, storing, shipping, inspection, test and operating status and record keeping.

(Note: The RSO is a member of the Health Physics Department.)

3. QUALITY ASSURANCE PROGRAM

The management of H.M.M.C. establishes and implements this Q.A. Program. Training, prior to engagement, for all Q.A. functions is required according to written procedures. Q.A. Program revisions will be made according to written procedures with management approval. The Q.A. Program will ensure that all defined Q.C. procedures, engineering procedures, and specific provisions of the package design approval are satisfied. The Q.A. Program will emphasize control of the characteristics of the package which are critical to safety.

The Radiation Safety Officer shall assure that all radioactive material shipping packages are designed and manufactured under a Q.A. Program approved by Nuclear Regulatory Commission for all packages designed or fabricated after the effective date of the Q.A. Program. This requirement can be satisfied by receiving a certification to this effect from the manufacturer.

4. DOCUMENT CONTROL

All documents related to a specific shipping package will be controlled through the use of written procedures. All document changes will be performed according to written procedures approved by management.

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The Radiation Safety Officer shall insure that all Q.A. functions are conducted in accordance with the latest applicable changes to these documents.

5. HANDLING STORAGE AND SHIPPING

Written safety procedures concerning the handling, storage and shipping of special form Pu-238 in DOT 6M drums will be followed. Shipments will not be made unless all tests, certifications, acceptances, and final inspections have been completed. Work instructions will be provided for handling, storage, and shipping operations.

The Health Physics Department personnel shall perform the critical handling, storage and shipping operations.

6. INSPECTION, TEST AND OPERATING STATUS

Inspection, test and operating status of DOT 6M drums for shipment of special form Pu-238 will be indicated by tag, label, marking or log entry. Status of nonconforming parts or packages will be positively maintained by written procedures.

The Health Physics Department personnel shall perform the regulatory required inspections and tests in accordance with written procedures. The RSO shall ensure that these functions are performed.

7. QUALITY ASSURANCE RECORDS

Records of package approvals (including references and drawings), procurement, inspections, tests, operating logs, audit results, personnel training and qualifications and records of shipments will be maintained. Descriptions of equipment and written procedures will also be maintained.

These records will be maintained in accordance with written procedures. The records will be identifiable and retrievable. A list of these records, with their storage locations, will be maintained by the RSO.

8. AUDITS

Established schedules of audits of the Q.A. Program will be performed, using written check lists. Results of audits will be maintained and reported to management. Audit reports will be evaluated and deficient areas corrected. The audits will be dependent on the safety significance of the activity being audited, but each activity will be audited at least once per year. Audit reports will be maintained as part of the quality assurance records. Members of the audit team shall have no responsibility in the activity being audited.

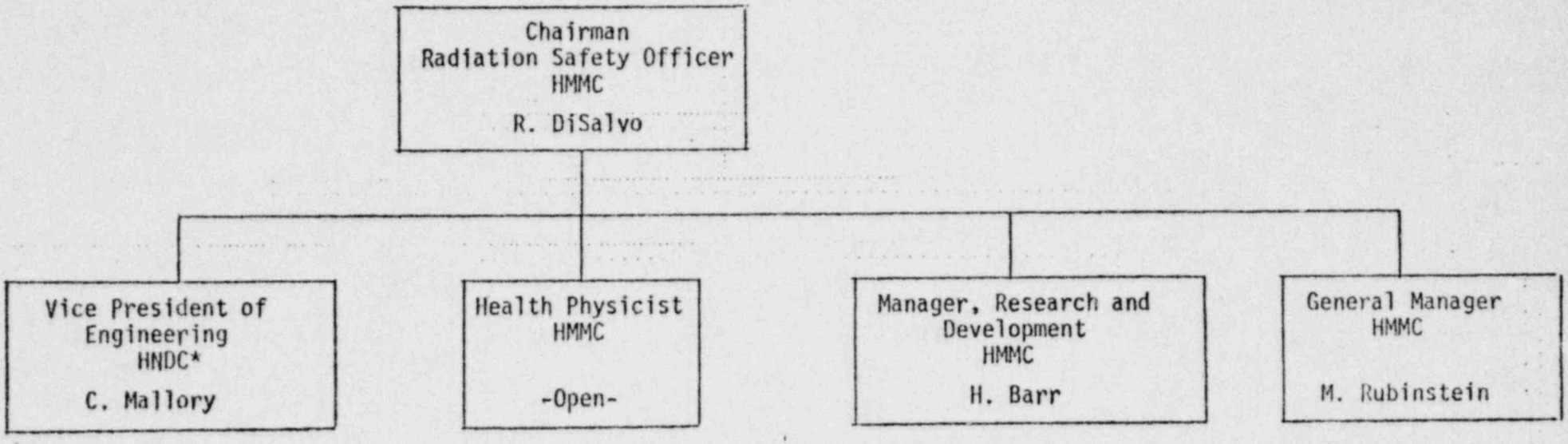
Rick DiSalvo

Approved: RADSAFE Committee Date: 2/26/80

HITTMAN MATERIALS & MEDICAL COMPONENTS, INC.

RADSAFE COMMITTEE

ORGANIZATION CHART



*HNDC is Hittman Nuclear and Development Corp.

Date 2/26/80

OP-169

2/19/80