UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAY 14 1980

FCTC:RHO
71-0387

Massachusetts Materials
Research, Inc.
ATTN: Mr. Michael J. Stewart
241 West Boylston Street
West Boylston, MA 01583

Gentlemen:

This refers to your application dated April 23, 1980, requesting approval of your Quality Assurance (QA) program as meeting the QA program requirements of 10 CFR §71.51.

In connection with our review, we find the enclosure to your April 23, 1980 letter approximates what we require. However, the many references to other documents tend to detract from the submittal, since we are reviewing only the description of the QA program. The QA program description should contain commitments which are met by following procedures and filling out forms which are documented elsewhere, such as in MMR's Administrative Manual or Operating and Emergency Procedure Manual. Also, we require an organization chart.

An example of a commitment which we require but which is not made in the enclosure to your letter is a commitment that shipments will not be made unless all tests, certifications, acceptances, and final inspections have been completed. It may be that your procedures do, indeed, require this; but we cannot accept the description of your QA program unless such a commitment is contained in it.

To assist you in revising the description of your QA program, we have enclosed a draft QA program description which contains the commitments we require. Please prepare a QA program description which is responsive to the enclosure and resubmit it within 60 days from the date of this letter. If you have any questions, please call Jack Spraul on (301) 492-7741.

Sincerely,

Charles E. MacDonald, Chief
Transportation Certification Branch
Division of Fuel Cycle and Material
Safety, NMSS

Enclosure:
Draft QA Program
Description

Draft
March 27, 1980
(Revision 2)

10 CFR PART 71 QA PROGRAM

FOR INDUSTRIAL RADIOGRAPHY LICENSEES

1. Organization

The final responsibility for the Quality Assurance (QA) Program for Part 71 Requirements rests with (Company Name). Design and Fabrication shall not be conducted under this QA Program. The QA Program is implemented using the following organization:

Note: The Organizational Chart as used in the license application should be presented. It may be advisable to designate the Radiation Safety Officer as the responsible individual for the Part 71 QA Requirements.

The Radiation Safety Officer is responsible for overall administration of the program, training and certification, document control, and auditing.

The Radiographers are responsible for handling, storing, shipping, inspection, test and operating status and record keeping.

2. Quality Assurance Program

The management of (Company Program) establishes and implements this QA Program. Training, prior to engagement, for all QA functions is required according to written procedures. QA Program revisions will be made according to written procedures with management approval. The QA Program will ensure that all defined QC procedures, engineering procedures, and specific provisions of the package design approval are satisfied. The QA 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 QA Program approved by the Nuclear Regulatory Commission for all packages designed or fabricated after January 1, 1979. This requirement will be satisfied by receiving a certification to this effect from the manufacturer.

3. 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.

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

4. Handling, Storage, and Shipping

Written safety procedures concerning the handling, storage, and shipping of packages for certain special form radioactive material 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.

Radiography personnel shall perform the critical handling, storage, and shipping operations.

5. Inspection, Test, and Operating Status

Inspection, test, and operating status of packages for certain special form radioactive material will be indicated and controlled by written procedures. Status will be indicated by tag, label, marking, or log entry. Status of nonconforming parts or packages will be positively maintained by written procedures.

Radiography personnel shall perform the regulatory required inspections and tests in accordance with written procedures. The Radiation Safety Officer shall ensure that these functions are performed.

6. 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 identified and retrievable. A list of these records, with their storage locations, will be maintained by the Radiation Safety Officer.

7. Audits

Established schedules of audits of the QA 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.