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10 CFR, PART 71
QUALITY ASSURANCE PROGRAM
FOR
INDUSTRIAL RADIOGRAPHY LICENSEES

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QUALITY ASSURANCE PROGRAM
REVISION SHEET

REV. NO.	REV. DATE	SECTION NO.	SECTION PAGES	DESCRIPTION OF CHANGE	REFERENCE INTEROFFICE MEMORANDUM
0	04-01-91	All	All	Initial Release	---

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REVISION SHEET

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II	0	2	0	2	0				
III	0	3	0	3	0				
		4		4	0				
				5	0				

SECTION 5.0		SECTION 6.0		SECTION 7.0	
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1	0	1	0	1	0

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REVISION SHEET

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QUALITY ASSURANCE PROGRAM

1.0 QUALITY PROGRAM

1.1 Introduction

CTI, Inc., hereinafter referred to as the Company, defines, establishes, and implements by means of this Quality Assurance (QA) Program a formal and comprehensive system to assure that the quality of the radiation safety for packaging of radioactive material for transport and transportation of radioactive material conforms to subpart H, 10 CFR, Part 71 requirements.

The 10 CFR, Part 71 Quality Assurance Program of the Company is described by the policies and objectives set forth in this manner.

A Quality Control Manual shall be developed to identify, assign, and control the activities performed in accordance with 10 CFR, Part 71. It shall include the duties, responsibilities, and organizational level of those persons charges with establishment and enforcement of the quality requirements.

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.

1.2 Issuance and Control of the Manual

1.2.1 The Radiation Safety Officer is responsible for the preparation, issuance, maintenance and control of this Quality Assurance Program Manual. He will determine those functions within the Company performing activities affecting radiation safety quality, and shall provide controlled copies of this manual to appropriate personnel.

1.2.2 All controlled copies of the manual will be individually numbered for control purposes. A controlled record (Form 102, Figure 1) of each manual holder will be kept by the Manager of QA. Should the holder's requirements for a manual cease, he shall promptly return this copy to the Manager of QA.

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1.2.3 It is the responsibility of each holder of the manual to keep his copy current and to enter all revisions. All revisions shall be distributed to all persons on the controlled distribution list. Controlled copies of the Quality Assurance Manual may not be used by others outside of the Company except with permission of the Radiation Safety Officer and with written agreement that the manual will not be reproduced, copied, or used in whole or in part except as permitted.

1.2.4 Copies for general information shall be issued as "uncontrolled" copies. The holder shall be responsible for verifying that the contents of a reference copy is current prior to use.

1.3 Program Review

1.3.1 Review of the Quality Assurance Program will be conducted on an annual basis by management, the Radiation Safety Officer, the laboratory and the project managers. They shall verify the adequacy, completeness and effectiveness of the Program.

1.4 QA Program Control and Revisions

1.4.1 Revisions to this Quality Assurance Program are authorized when recommended by the Radiation Safety Officer and approved in writing by the President. A revision is defined as a permanent change to the QA Program Manual and which is distributed to all manual holders by the Radiation Safety Officer in the form of printed replacement pages.

1.4.2 The Nuclear Regulatory Commission shall be notified of all revisions and a copy submitted to them for approval.

1.5 Approval

1.5.1 All Quality Assurance Program changes shall receive the approval of the NRC prior to their implementation.

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1.6 NRC Access

1.6.1 The NRC shall have access to Company operations and documentation as required to assure conformance to all 10 CFR, Part 71 requirements.

1.7 Quality Assurance Indoctrination and Training

1.7.1 The Radiation Safety Officer shall be responsible for developing and implementing indoctrination and training programs for employees whose function will be subject to the requirements stated in this manual.

1.8 New and Transferred Radiographers

1.8.1 The purpose of the QA indoctrination and training program is to familiarize radiographers with the Quality Assurance Program, stressing the importance and meaning of Quality Assurance as it applies to 10 CFR, Part 71.

1.8.2 The Quality Assurance indoctrination and training will be conducted by the Radiation Safety Officer or a designated representative. The indoctrination may be accomplished either as a group lecture or personnel interview. During the lecture or interview, the following items will be covered:

a) Objectives of the Quality Assurance Program.

b) Quality Assurance organization and how it affects the duties and responsibilities of radiographers.

c) Contents of the Quality Assurance Program and applicable Quality Control procedures with specific emphasis placed on those sections which most directly affect the Radiographers' safety duties.

d) Control of the characteristics of the package which are critical to safety.

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SECTION TRANSMITTED (TITLE)	SECTION NO.	REV. NO.	REV. DATE	TRANSMITTED TO	DATE	ACKNOWLEDGED BY	DATE

FIGURE 1

Form 102

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QUALITY ASSURANCE PROGRAM
ORGANIZATION AND PLANNING

2.0 ORGANIZATION AND PLANNING

2.1 The Quality Organization

2.1.1 The President is the chief operating officer. Each project and the laboratory is charged by the President and Operations Manager with the responsibility for assuring that all radiation safety tests, inspections, examinations, services and operations performed will conform to 10 CFR, Part 71, requirements.

The final responsibility for the Quality Assurance (QA) Program for Part 71 requirements rests with CTI, Inc. Design and fabrication shall not be conducted under this QA Program.

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

The Radiographers are responcible for handling, storing, shipping, inspection test, and operating status and recordkeeping.

2.1.2 The Radiation Safety Officer is appointed by the President and is responsible for directing the development and implementation of the Quality Assurance Program and the surveillance and auditing of the QA Program and Quality Control procedures. He reports to the President for management and administrative guidance. He is also responsible specifically for:

a) Directing the preparation and implementation of QC procedures for the laboratory and projects.

b) Directing the preparation of Quality Control procedure for all activities.

c) Directing the preparation of test and inspection procedures.

d) Performing and directing scheduled monitoring and surveillance of the quality program at the laboratory and all projects.

e) Determining and issuing of stop-work/resume work orders.

f) Reviewing the QA Program and reporting the status to the Operations Manager and the President.

2.1.3 A Manager of Technical Services is directed by the Radiation Safety Officer for the purpose of implementing the Quality Assurance and Quality Control procedures. The Manager of Technical Services is responsible for the implementation and surveillance of the Quality Control procedures for the laboratory and projects. He reports directly to the Radiation Safety Officer on matters relating to the radiation safety program. He is also responsible specifically for:

a) Development, implementation and control of receiving, packaging and inspection procedures.

b) Directing and monitoring of personnel qualifications and certifications.

c) Directing and monitoring of personnel training.

d) Providing assistance to the Radiation Safety Officer in the auditing and inspection of the laboratory and projects.

e) Functional relationship between the Radiation Safety Officer and radiography personnel.

2.1.4 The President has established the quality program so its functions are not influenced by operations or production, and that the management and direction of the Radiation Safety Officer is his responsibility. The Radiation Safety Officer shall report directly to the President and interface with laboratory and project managers and other management and supervisory personnel. Figure 2 is a chart of the quality organization.

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ORGANIZATION AND PLANNING

2.2 Quality Control Manual

The purpose of the Quality Control Manual is to outline the methods to be used in administering those elements of the Quality Assurance Program applicable to 10 CFR, Part 71 projects and to the laboratory. For projects, the Quality Control Manual shall contain all of the specific procedures applicable to any field project. For laboratories, the Quality Control Manual shall describe the operat[illegible] and specific safety quality requirements for the labor[illegible]; it shall also include how these elements are imp[illegible]d by detailed procedures. The Radiation Safety [illegible] is responsible for directing the development of [illegible]lity Control Manual.

2.2.1 The laboratory and project manager is res[illegible]ible to the Technical Services manager for the planning, administration and performance of rec[illegible]ving, packaging and inspection of radioactive mat[illegible]s.

2.2.1.1 Procedures for the required radiation transport operations are found in the Quality Control Manual for laboratories and for projects. The Manual will includ[illegible] directions, work instructions, drawings, forms and controls to assure that activities and operations performed conform to the required quality level.

2.2.1.2 The receiving, pack[illegible]ving, shipping and inspection proc[illegible]es include:

a) Type of operations to be performed.

b) Equipment to be used.

c) Procedures for directing and controlling operations.

d) Work instructions.

e) Identification of items on which the operation is to be performed.

f) Results.

g) Documentation of work performed.

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ORGANIZATION AND PLANNING

2.2.2 The Quality Control Manual will consist of four sections and include the subjects listed below:

a) Section 1.0 Organization - this section will contain an organization chart for the facility, the functions and responsibilities of the key positions, and the management control system.

b) Section 2.0 Administration - This section will contain or reference the correspondence and filing system, document control system, procurement system, and any other administrative functions affecting radiation safety materials.

c) Section 3.0 Operations Quality Control Procedures - This section will contain or reference procedures for:

1) operations
2) material receiving
3) handling and storage
4) identification and control of processed materials and items
5) nonconformance and corrective action
6) calibration of measuring and test equipment
7) quality control inspections and records
8) other quality related items as may be necessary

d) Sections 5.0 Audits - This section shall contain the procedure to be used. This procedure will identify audit frequency, items to be audited, and include the audit form to be used.

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QUALITY ASSURANCE ORGANIZATIONAL CHART

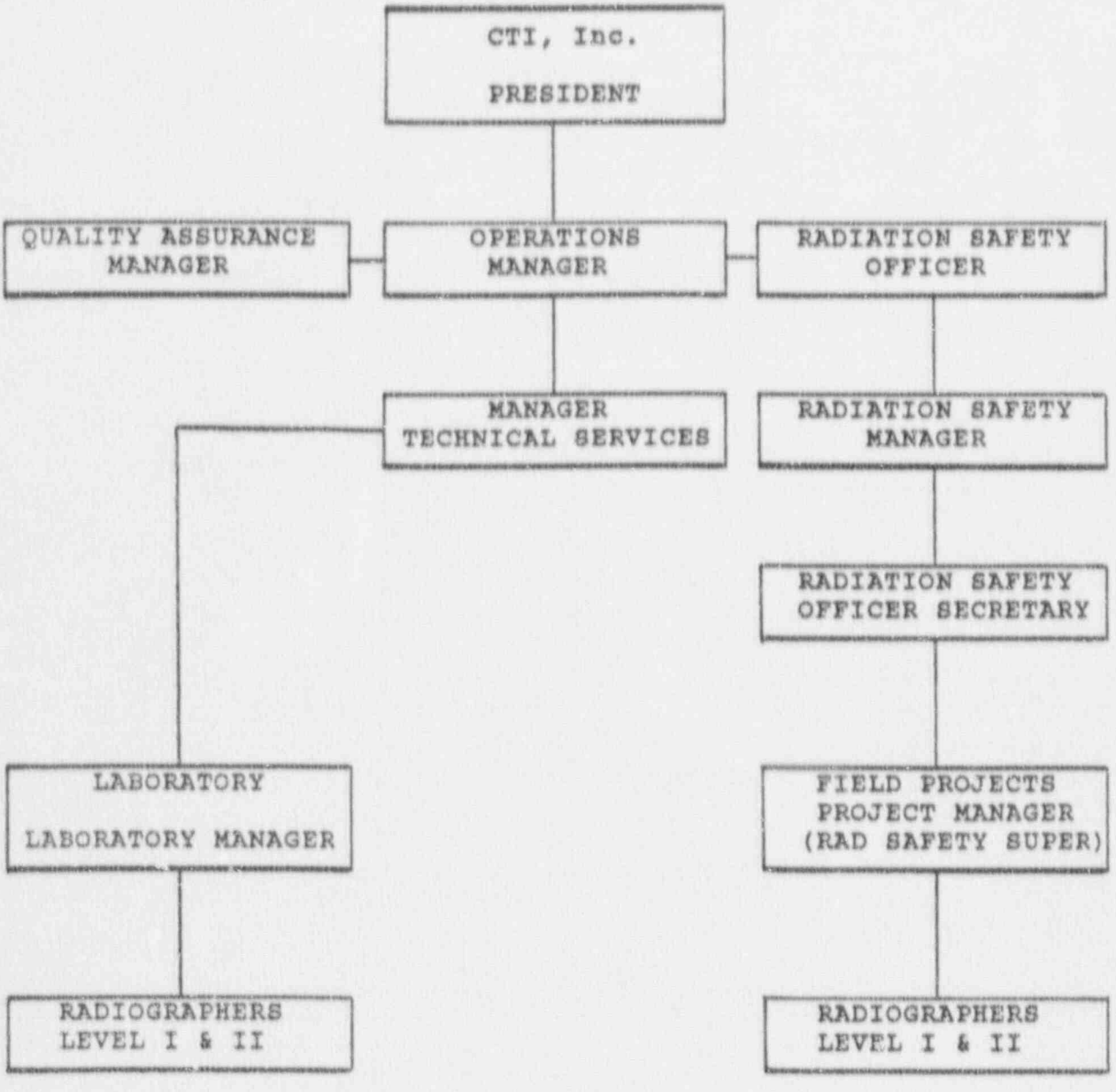

FIGURE 2

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DOCUMENT CONTROL

3.0 DOCUMENT CONTROL

3.1 All laboratory and project 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.

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HANDLING, STORAGE AND SHIPPING

4.0 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.

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INSPECTION, TEST & OPERATING STATUS

5.0 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.

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RECORDS

6.0 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.

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AUDITS

7.0 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.