

QUALITY ASSURANCE MANUAL

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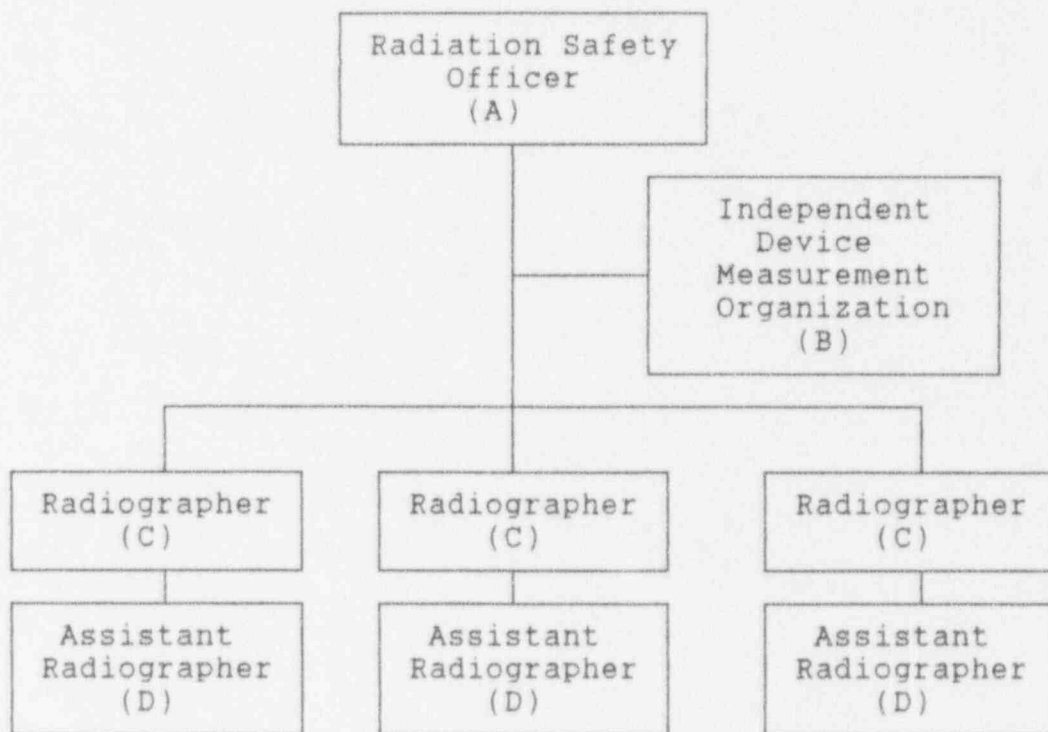
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QUALITY ASSURANCE PROGRAM
APPLICABLE TO THE PROCUREMENT, USE
MAINTENANCE, AND REPAIR OF PACKAGING USED IN TRANSPORT
OF RADIOACTIVE MATERIAL

1.1 Organization

1.1.1 Structure and Authority

In order to ensure that all the appropriate elements of Subpart H of 10 CFR Part 71 will be implemented, the following organizational structure and authority assignments have been made for W.I.X. Inspection, Inc. (herein-after called the Company):



Responsibilities and Authorities

A - Radiation Safety Officer

Responsibilities: Procurement, inspection, & package preparation for delivery of radioactive materials, loading and unloading procedures, quality assurance, quality control

Authority : Final authority and responsibility for for quality assurance. Responsible for receipt/return of nuclear sources, verification of proper insertion in cameras/packaging, transportation containers and procedures, control procedures, monitoring, corrective

action. May stop any work in progress upon determination of any unsatisfactory conditions

B - Independent Device Measurement Organization

Responsibilities: Calibration of meters (measuring devices), reporting of calibration to Radiation Safety Officer

Authority : Authority, independent of W.I.X. Inspection, Inc., to require replacement of any or all measuring devices

C - Radiographer

Responsibilities: Inspection, loading and unloading procedures, reporting of all readings, immediate notification of any malfunctions or unusual readings

Authority : May stop any work in progress upon determination of any unsatisfactory conditions

D - Assistant Radiographer

Responsibilities: Functions under the direct supervision of the Radiographer.

Authority : May stop any work in progress upon determination of any unsatisfactory conditions

Qualifications

A - Radiation Safety Director/Officer - Larry D. Wicks

ASNT/TC1A Wyoming Certified Level III Radiographer since 1987.

Quality Assurance/Control ASNT Seminars 9-8-87, 5-23-90 in Salt Lake City, Ut.

Nine years experience in radiography. Five years experience in radiographic management, quality control and quality assurance.

B - Independent Device Measurement Organization

Currently (3/1/92) MetChem Testing Laboratories, 369 W. Gregson, Salt Lake City, Ut., 84115. Certified with the Nuclear Regulatory Commission for calibrating survey meters and measuring devices for radioactive substances.

C - Radiographer

Any radiographer employed by the Company does and will possess a current ASNT/TC1A Wyoming Level II Radiographer Certification; pre-employment and post-employment testing for knowledge of proper control and usage of radioactive materials is performed on all Radiographers as specified in the Company Operating and Safety Procedures Manual accepted by the Nuclear Regulatory Commission August 1991. 1991

1.1.2 Endorsement

It is the hereby expressed personal commitment and Company policy of Larry D. Wicks, Corporate President of W.I.X. Inspection, Inc. that a dedication to the performance of all work in such a manner as to maintain safety for all its employees and all non-employees be a foremost endeavor in the procurement, inspection, usage, control, documentation and transportation of radioactive materials controlled by this Company.

1.2 Quality Assurance Program

1.2.1 Scope of Quality Assurance Program

- a. Items designated for control under this program are:
 - i. Radiographic Exposure Devices (cameras)
 - ii. Radioactive Material (Source) Changers
 - iii. Over-packs for containment and shipping of radioactive material

All items designated for control under this program will meet the minimum requirements of Class "B" packaging and be manufactured under a quality assurance program as defined by the Nuclear Regulatory Commission in US NRC 10 71.107 and so signified by a Certificate of Compliance from the manufacturer. Special attention will be paid to the adequacy of all packages ordered, received, and handled by personnel within the Company to this requirement. This shall be the responsibility of the Radiation Safety Officer.

- 1.2.2 All items designated for control under this program will be subject to the same quality control measures to determine compliance with quality standards regardless of usage or shelf life.

- 1.2.3 Subsequent to employment but prior to any transport or usage of any radioactive materials controlled by the Company, each employee having responsibilities as listed in section 1.1 of this manual will be given training involving packaging and transport of all radioactive materials used by the Company.

Scope - each phase of transport procedures and documentation commensurate with his activities with the material and those activities and responsibilities of the Company
Objective - understanding of commitment toward safety of all Company and non-company personnel and the procedure for the accomplishment of that safety

Method - safety demonstrations based on ASNT, ASME, or ANSI guidelines involving the equipment which each employee will be using. Tests covering the safety procedures and documentation will be given to assess the understanding level of each employee.

All training and tests will be given by the Radiation Safety Officer, and all duty assignments will be given by that Officer upon the completion of a satisfactory understanding level of each employee.

In addition, ASNT, ASME, or ANSI Certification for non-destructive testing will be kept on each employee noting which guideline has been used, the date of the Certification, the period of Certification, & conditions under which recertification would be required if necessary.

1.2.4 Implementation of activities important to safety are contained in the Company's Operating and Emergency Procedures Manual (accepted by the Nuclear Regulatory Commission August 1990¹⁹⁹¹ and placed in each portable darkroom facility as well as the main Company facility), and QA/QC procedures for purchasing, storage, and transportation are herein delineated. A copy of this manual (along with the Company's Operating and Emergency Procedures manual will be placed within access of each employee during any phase of his job functions relevant to the items designated for control in this program. This manual will identify each procedure by number and title, provide a brief description of the content, and provide cross-references applicable under the program. (See Table of Contents)

1.3 Document Control

The Radiation Safety Officer will review all documents and changes thereto prior to their issuance. The Radiation Safety Officer will also ensure that current issues of all applicable documents are available at the location where the activity is being performed to preclude use of obsolete or superseded documents. All control items affected by design or manufacturing changes will be checked to verify that they are in accordance with the appropriate revision.

Documents under the control of this QA program include:

- a. QA and QC manuals
- b. Operating Procedures and Emergency Procedures
- c. Maintenance Procedures
- d. Inspection and Test Procedures
- e. Loading and Unloading Procedures
- f. Packaging for Transport Procedures
- g. Repair Procedures

1.4 Procurement Document Control

1.4.1 Packaging Procurement

Procurement of control items will be from a company whose packaging design was accomplished under control of an NRC-approved QA program.

All items designated for control under this program will be ordered, received, and handled with specific attention paid to the supply of adequate certification signifying the compliance of the shipper with quality assurance standards for transportation according to the applicable regulations of the Department of Transportation. Any purchase orders used for procurement will specify these required elements in writing.

Procedure:

The receipt of any radioactive materials and/or control items will be accompanied by documentation (including the model and serial number) from the company of purchase as to the compliance of all packaging with US NRC 10 CFR 7-1.107.

Also included will be any documentation noting inspections and tests required during use and maintenance of the item.

Such documentation shall also include a "Competent Authority Certification for a Type B (U) Radioactive Materials Package Design Certificate", a "Radioactive Material Shipping Report", as-built drawings, use and maintenance manuals, and all other documents referred to in the Certificate of Compliance.

All certification/documentation will be placed in a folder labeled so as to reflect the identity of the radioactive material (hereinafter called "source"), its current packaging, and any control item to which the source is transferred. A copy of the Shipping Report will remain with the camera at any time of transport and shall contain the following information:

- a. Name of the company who shipped the source
- b. Proper shipping name radioactive materials special form N.O.S.
- c. Class or Division of radioactive material
- d. U.N. or I.D. number
- e. Current number of curies
- f. Name of the company receiving the source
- g. Category of labels
- h. I.D. number of D.O.T. Package
- i. Additional handling for air transport if Air Cargo
- j. Name and title of Radiation Safety Officer
- k. Emergency telephone number
- l. Signature of shipper

Radiation surveys will be taken and a Transport Container Form will be filled out by the Radiation Safety Officer

for each source and control item received identifying the following information:

- a. Manufacturer/supplier
- b. camera # received (or to which source was transferred)
- c. type of radioactive material
- d. identification # of source
- e. # of active curies upon receipt
- f. date received
- g. survey meter readings at 6", Transport Surface, & 39"
 - i. front
 - ii. back
 - iii. left
 - iv. right
- h. survey meter type, serial #, reading date
- i. signature of Radiation Safety Officer performing the survey

A Transport Container Log will be kept by the Radiation Safety Officer identifying the following information for all sources and control items received and/or transferred to others:

- a. type of radioactive material
- b. camera # received (or to which source was transferred)
- c. identification # of source
- d. date received
- e. freight company/carrier of receipt
- f. # curies upon receipt
- g. date removed and transferred to others
- h. freight company/carrier of return
- i. any comments concerning transfer of source

1.4.2 Replacement Parts Procurement

Replacement parts for any control items shall be ordered by the Radiation Safety Officer with attention paid to the order that suppliers of those parts meet the NRC and DOT qualifications of the original manufacturer of the control item and that all technical and documentation requirements are specified and met for delivery.

1.5 Loading and Unloading of Radioactive Material

Loading and/or unloading of radioactive material will be performed within the confines of the shop portion of the Company facility utilizing approved control items at such a time of day as is consistent with the least amount of personnel or public traffic in close proximity. NO non-employee of the Company will be in the shop premises at the time of any loading or unloading. A survey of the area immediately preceding loading or unloading will be done to verify this condition.

Procedure:

The personnel performing the loading/unloading of radioactive materials will:

- a. Radioactivity surveys of the containers to or from which radioactive materials are to be exchanged will be taken and results will be recorded on a Utilization & Dosimeter Log form assuring that radioactive readings are within NRC requirements.
- b. Connect the short source guide tube (supplied with the source changer) to the "Old Source" side of the changer and to your camera.
- c. Connect the drive cable to the source in the camera.
- d. Unlock the exchanger and the camera and crank the source that is in the camera into the "Old Source" side of the exchanger and relock the exchanger.
- e. Make a radioactivity survey of the changer and source guide tube to ensure radiation levels are within limits.
- f. Disconnect the source guide tube from the changer and disconnect the drive cable from the from the old source 'pigtail'.
- g. Turn changer around and connect drive cable to "New Source" pigtail.
- h. Reconnect source guide tube to changer and unlock "new Source" side of changer.
- i. Retract (crank in) the drive cable which will pull the new source into the camera.
- j. Make a radioactive survey of the camera, changer, and source guide tube and lock the camera when it is certain that the new source has been appropriately installed in the camera.
- k. Disconnect drive cable from new source pigtail and replace dust cover.
- l. Disconnect source guide tube from both devices.
- m. Remove old source identification plate from camera and place it on changer on the "Old Source" side. Affix the supplied identification for the "New Source" to the camera.

1.6 Handling, Storage, and Shipping
1.6.1 Storage and Handling

Procedure:

All Radiation Exposure Devices will be stored and transported in approved/certified Over-packs with attention paid to appropriate closure/safety devices and any malfunctions being immediately reported to the Radiation Safety Officer. Adequate handling and care of all control items will be performed so as to ensure the integrity of the items.

Storage:

Upon removal or return of any control item to storage, radiation survey meter readings will be taken to ascertain the compliance with applicable radiation safety limits, and a physical inspection of the item will be made for any deficiency or malfunction of the item. Any deviation from acceptable standards will be reported to the Radiation Safety Officer immediately.

A Radioactive Utilization Log will be maintained by the Radiographer at the site of the Company storage vault identifying the following information:

- a. Removal date and time of the radioactive material
- b. identification #'s of the source, container, survey meter used for readings
- c. destination information
- d. return date and time
- e. any comments
- f. initials of radiographer responsible for removal of unit

Transportation (Handling):

Radiation surveys will be made and a Utilization Inspection & Dosimeter Log will be maintained by the Radiographer each time any source is removed from the storage vault identifying the following information:

- a. location of survey (vault/portable darkroom)
- b. package make, model, serial #
- c. source type, serial #
- d. date of inspection
- e. location
- f. transport index (mr at 1 meter)
- g. mr at 6"
- h. survey meter make, serial #, calibration date
- i. current # curies
- j. names of radiographer(s) and assistant(s) to be using the unit
- k. dosimeter readings in, out, and total

1. inspection of exposure device
 - i. surface radiation, locks, fittings, labels, safety plugs & threads
 - ii. crank assemble hardware & freedom of movement
 - iii. source tubes threads, openings, fittings
 - iv. drive cable & connections fit, wear
- m. survey meter readings of physical area
- n. hazardous material transportation documentation showing chain of location of material away from Company storage facility
- o. radioactive materials special form n.o.s. un2974 radioactive yellow ii/iii 192 transport index (mr at 1 meter) certification
- p. excessive exposure explanation

Other:

In addition to the above survey documentation, radiation surveys will be made and a Quarterly Inventory Inspection & Maintenance Log will be maintained by the Radiation Safety Officer noting the following information:

- a. package (camera) make & serial #
- b. source type, serial #, current # curies
- c. condition (satisfactory/unsatisfactory) of the following:
 - i. dust cover plug (top & bottom)
 - ii. lock mechanism
 - iii. pigtail connection
 - iv. labels
 - v. handle
 - vi. source tube & connection
 - vii. drive cable connection
 - viii. crank out (entire mechanism)
 - ix. abnormal radiation levels
 - x. location
 - xi. signature of inspector
 - xii. date of inspection

1.6.2 Preparation for Shipping

Procedure:

A. Once source exchange is complete (see loading/unloading 1.5), material to be shipped is secured into an approved type "B" package (with decay chart for that specific serial number source), lidded, bolted and security sealed.

B. The proper transport index (determined by calibrated survey meter readings at the surface and 3 meters) labeling is attached to the packaging.

C. Shipping certification is then filled out listing the following:

- i. Shipper's name, address, phone number

- ii. Recipient's name, address, phone number
- iii. Dangerous goods identification:
 - Special Form material name
 - class
 - UN or ID #
 - quantity
 - type of packing
 - number of current curies
 - packing list
 - Special Form handling information/label-see chart below
 - air cargo instructions
 - date
 - emergency telephone number

<u>LABLE</u>	<u>DISTANCE</u>	<u>MR/HR READING</u>
White I	Surface 36"	0 - .5 0
Yellow II	Surface 36"	over .5 - 50 over .1 - 1
Yellow III	Surface 36"	over 50 - 200 over 1 - 10

- iv. An approved carrier (Federal Express) is called to pick up package.
- v. A copy of the shipping certification is retained indefinitely in a folder for that particular source serial number (folder then marked "DEAD FILE")
- vi. The Transport Master Log is completed reflecting date "old" source shipped to approved receiptent (in our case, the original supplier), # curies, carrier.

1.7 Inspection, Testing, and Operating Status

1.7.1 Inspection, test, and operating status reports

All report results of measurement testing in the aforementioned procedures will remain with the control items until those items are returned to storage. At that time, they will be reviewed by the Radiation Safety Officer and filed so as to be immediately available upon necessity or request.

1.7.2 Measuring Devices

All activities important to safety as hereinafter specified in this manual will be performed with currently calibrated equipment and under environmental conditions suitable to the procedure being performed. Each piece of measuring equipment shall be tagged/labeled with the Company name, the make, model, and serial number, the date of last calibration, and the next due date of calibration.

Survey Meter Calibration:

Survey meters will be calibrated each 90 days (or more often if conditions suggest) by an independent company certified for such service

A file folder will be kept in the Company files for all survey meters identifying the following information:

- a. make, serial # of each survey meter
- b. certification by an independent company of all calibration records for each meter

1.7.3 All radiation exposure devices shall be tagged/labeled with the name of the manufacturer, the serial number, make, and model of the item, the type of radioactive material contained, date of insertion of radioactive material, signs noting the fact that radioactive materials are contained therein and Caution notations.

1.7.4 All Over-packs shall be tagged/labeled with the name manufacturer, the serial number, make, and model of the item, date manufactured, class/type of item, signs noting the fact that radioactive materials are contained therein and Caution notations.

1.7.5 Leak Tests

Factory leak test certifications are kept on file with each camera file.

While in possession of the Company, leak tests will be performed on each exposure device at 6 month intervals using NDS Products LTK-TEST-2 Leak Test Kits.

Tests will be performed according to instructions included in the kit, and samples will be sent to Radiation

Safety, Inc. for processing. Reports from processing will be maintained in each exposure device file for the duration of the ownership of the exposure device. Any unacceptable levels of radiation noted at any time during the test will be reported to the R.S.O. and the "source" will be removed to approved packaging and the exposure device returned to the manufacturer for repair.

1.8 Repair, Rework, and Maintenance

All control items will be monitored on a daily basis and results reported via the Utilization & Dosimeter Log. Only the following noted repairs will be done by the Company.

1.8.1 Overpacks

Specifications for the overpacks will be determined according to the Manufacturer's Certificate of Compliance on file in the Company's office. If defects are found to be in the lid, ring, or bolt on the overpack, the R.S.O. will repair/replace the defective part to bring the overpack back into compliance with the specifications listed on the Certificate of Compliance of the manufacturer. Damage to the lid or canister container on the overpack which results in a lack of integrity to the overpack will not be handled by the Company.

1.8.2 Exposure Devices

The source guide tube connector on the front may be replaced if worn or defective. Locking mechanism assemblies (not the lock-box itself) which may become worn or defective (such as a key broken off in the lock) may be replaced with approved locks by the R.S.O.

Control items on which any other defect is noted will be returned to the manufacturer for repair/replacement.

All control items will be handled in such a manner as to maintain the integrity of the item.

1.9 Non-compliance/Correction:

Safe radiation limits have been specified in the Shipping, Loading/Unloading, Storage, Transportation, and Handling procedures. Any non-compliance of these limits will be handled in the following manner:

Procedure:

1. ANY non-compliance will be immediately reported to the R.S.O. NO PACKAGE NOT IN COMPLIANCE WILL BE USED IN ANY RADIOGRAPHIC OPERATION.
2. The R.S.O. will confirm that a non-compliance does or does not exist.
3. If radiation limits for the control item are in non-compliance, the radiation source will immediately be removed to an approved package, and the item which is not in compliance will be returned to the manufacturer for repair or replacement.
4. If any control item is found to be in non-compliance at the time of receipt from shipping, at the termination of transport, or during radiographic operation (due to damage such as dropping, etc.), such damage/non-compliance shall be documented, and the N.R.C. and all persons under possible exposure (such as the shipping carrier) shall be notified.

All disputes involving quality which arise from a difference of opinion between any employees of the Company will be resolved by the Radiation Safety Officer.

1.10

1.10.1 Internal Audits

Because the small size of the Company precludes having an independent audit department, the following checklist of activities and frequencies of each activity are given:

a. Receipt/shipping of control items

*

b. Personnel training/certification

*

c. Operating/Maintenance Procedures

Each radiographer and assistant radiographer will be monitored by the Radiation Safety Officer in the form of unscheduled field inspections for procedure compliance no less than once each 90 days.

d. Inspection and Test Procedures

same as "c." above.

e. Handling and Storage

same as "c.": above.

* As this is a responsibility of the Radiation Safety Officer, all records and procedures will be audited by the NRC once yearly.

1.10.2 External Audits

The Nuclear Regulatory Commission shall have final authority in all external auditing of the Quality Assurance/Quality Control procedures of this Company. This shall be done at least once a year.

1.11 Quality Assurance Records

Records to be maintained (and the length of their retention) are:

- A. Procurement documentation
indefinitely
- B. Inspection, testing, audit
5 years
- C. Nonconformance and corrective reports
indefinitely
- D. Personnel training, dosage, and certification records
indefinitely
- E. Evidence of operational capability
indefinitely
- F. Verification of repair, replacement, and mainenance
5 years

Note: At any time cameras or other control items are determined obsolete by the Nuclear Regulatory Commission, such items shall be replaced and all accompanying documentation for the obsolete items shall follow such retention and/or disposal procedures as are at that time required.