

Quality Assurance Program

1. Organization: Responsibility for the Quality Assurance (QA) Program rests with Simon Lake. The QA Program is implemented using the following organization:

COMMANDING OFFICER

REPAIR OFFICER

QUALITY ASSURANCE OFFICER

RADIATION SAFETY OFFICER (RSO)

RADIOLOGICAL CONTROLS OFFICER

(SHIPPING)

ASSISTANT RADIATION SAFETY OFFICER (ARSO)

SENIOR RADIOGRAPHER

RADIOGRAPHERS

The QA Officer is responsible for scheduling of audits by personnel not having direct responsibilities in the areas being audited (Audit Branch Personnel) and training of NDT personnel.

The RSO is responsible for overall administration of the program, certification, and document control.

The Radiological Controls Officer is responsible for Shipping.

2. Program: SIMON LAKE QA Program will be guided by written instruction contained herein. This instruction will be the basis of Quality Assurance and the guidance provided will be used throughout the period during which packaging is used. The components to be covered by this Quality Assurance Program include:

- (1) Model 660 Gamma Ray Exposure Device
- (2) Model 650 IR 192 Source Changer

The Quality Assurance Program requirements are based upon:

- (1) The impact of malfunction or failure of the component upon safety.
- (2) The need for special controls and surveillance over processes and equipment.
- (3) The requirements for indoctrination and training of personnel.

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Enclosure (2)

3. Procurement Documents.

Quality must be insured in documents for procurement of material, equipment and services. Procurement of IR 192 aboard Simon Lake will be guided by current directives outlined in SPCC instruction 4235.108 series, and safety precautions in accordance with 10 CFR Part 20. Documents for procurement will be controlled through use of written procedures of:

- a. NAVSUPINST 4000.34 SERIES
- b. SPCCINST 4235.108 SERIES

4. Control and Identification:

(a) Assurance must be maintained that material, equipment and services conform to specifications of the procurement. Examination of the products must be made upon delivery and will be controlled and documented in accordance with enclosure (a) of SIMONLAKESINST 9900.2 Series (NRMP No. 04697-A1NP).

(b) Identification and control measures will prevent use of incorrect or defective materials, parts, and components. Model numbers will be checked upon receipt and will be verified to be authorized by Navy Radiolactive Materials Permit. Device revival numbers will be logged in SIMON LAKE's NDT Lab "Receipt and Transfer Log" for accountability.

5. Non-conforming Materials, Parts, Components:

Written procedure established for control of materials, parts, and components which do not conform to permit provisions are in accordance with SIMON LAKE Navy Radioactive Materials Permit.

6. Handling, Shortage, and Shipping Control:

Written procedure established for handling, storage and shipping are in accordance with SIMON LAKE Navy Radioactive Materials Permit.

7. Corrective Actions: All personnel involved in the program are responsible for prompt reporting of conditions adverse to quality. Once identified, corrective action must be pursued as appropriate. Reporting will be in accordance with 10 CFR Part 21; maintenance of records will be in accordance with 10 CFR 21.51.

8. Records: Records will be maintained to furnish evidence of Quality. Records must be identifiable and retrievable. The Record Retention Program, will clearly identify the name of the record, responsibility, location and duration required to be maintained as shown in Enclosure (3).

9. Internal Inspections/Audits: Planned Audits will be conducted Semi-Annually to verify compliance with all aspects of the Quality Assurance Program. The audits will be conducted by trained personnel not having direct responsibility in the area being audited. Audit personnel will be assigned by the Quality Assurance Officer. Audit checklists and access to records/personnel will be provided by the RSO/ARSO. Written report of discrepancies noted will be forwarded to the Commanding Officer via the RSO, QA Officer and Repair Officer. Completed audits with annotated corrective action taken will be kept as record by the QA Officer (NDT LAB) and copies maintained by RSO.

Packaging 'QA' Record Retention Program

<u>Name</u>	<u>Responsible</u>	<u>Location</u>	<u>Duration</u>
Radiographer Training	R-8 Division Officer	NDT Office File	
Audit Schedule and Results	QA Office	R-8 Office	Indefinite
Shipping Container Certification	RSO/ARSO	NDT Office File	Indefinite
Exposure Device Certification	RSO/ARSO	NDT Office File	Indefinite
Copy of License of Material Receivers	RSO/ARSO	NDT Office File	Indefinite
Reports of Defects compliance	RSO/ARSO	NDT Office File	Retain Non-until after delivery of components
Leak Check Records	RSO/ARSO/R-5	NDT Office File	3 years
Package Survey (Radiation)	RSO/ARSO	NDT Office File	3 years
Package Survey (Contamination)	RADCON Officer	NDT Office File	3 years
Source Accountability and Inventory Records	RADCON Officer	NDT Office File/ R-5 Files	3 years
Quarterly Source Inventory	RSO/ARSO	NDT Office File	3 years
Receipt & Transfer Log	RSO/ARSO	NDT Office File	5 years after transfer
Written Procedures for Shipping	RADCON Officer	R-5 Files/ NDT Office Files	indefinite

SIMONLAKEINST 9893.1B

<u>Name</u>	<u>Responsible</u>	<u>Location</u>	<u>Duration</u>
RADCON Shipping Personnel Training	RADCON Officer	R-5 Files	3 years
Shipping Document Files	RADCON Officer	R-5 Files NDT Office Files	3 years

'QA' Program Audit Checklist

Pre-Req Auditor Review SIMONLAKEINST 9893.1.
 Pre-Req Auditor Review 10 CFR Part 71 Subpart H.
 Pre-Req Auditor Review SIMONLAKEINST 9900.2.

Item	Attribute	Sat	Unsat	Remarks
1.	QA Audit performed by person not having direct responsibility in area being audited.			
2.	Current QA Program approval by NRC. (NRC Form 311) Ref: 10 CFR 71.101 (C).			
3.	Current NRC approval (cert of compliance) for packages available for all components used. (NRC Form 618) Ref: 10 CFR 71.21 (A) & (B).			
4.	NRC materials license available for package receivers. (NRC Form 374) Ref: 10CFR 71.12 (A) & (B).			
5.	SIMON LAKE Navy Radioactive Materials Permit current. (NRC Form 374) Ref: 10CFR 30.3			
6.	Procurement documents available and of good quality. Ref: 10CFR 71.109/21.31.			
7.	Control and identification of packages IAW encl (8) of NRMP. Ref: 10 CFR 71.115 and 117.			
8.	Review of procedures for handling, storage, shipping control.			
9.	Non conformance of materials parts, components identified? Corrective action and reporting adequate? Records? Ref: 10CFR 71.131/21.21/21.51.			
10.	Record Retention Program in affect? Record identifiable and retrievable? Responsibility, location and duration established? Ref: 10 CFR 71.135.			

SIMONLAKEINST 9893.1B

Item	Attribute	Sat	Unsat	Remarks
11.	Audits made as per schedule promulgated by QA Officer? Previous results available? Ref: 10CFR 71.121 &.137.			

Note: Provide written report of above audit items to CO via RSO, QA Officer and RO.

DOCKET NO. 71-0261
CONTROL NO. 26094
DATE OF DOC. November 16, 1989
DATE RCVD. November 20, 1989
FCUF _____ PDR
FCAF _____ LPDR _____
I & E REF.
SAFEGUARDS _____
FCTC OTHER _____
DATE 11/20/89 INITIAL JAC