

L. Y. SPEARINST 5100.18

16 OCT 1989

QUALITY ASSURANCE PROGRAM
FOR THE PACKAGING OF
RADIOACTIVE MATERIAL FOR TRANSPORT AND TRANSPORTATION
OF RADIOACTIVE MATERIAL UNDER CERTAIN CONDITIONS (10CFR71)

NAVY RADIOACTIVE MATERIALS PERMIT

No. 59-05851-A1NP FOR GAMMA RADIOGRAPHY

AND

No. 59-05851-C1NP FOR RADIAC CALIBRATION

PERMIT HOLDER:

DEPARTMENT OF THE NAVY

USS L.Y. SPEAR (AS-36)

FPO NEW YORK

09547-2600

Encl (1)

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DEFINITIONS

The following terms are defined as they are intended to be used in this instruction.

CFR - Code of Federal Regulations.

Licensee - Department of the Navy, Chief of Naval Operations.

Licensed Materials - Those materials for which the Department of the Navy holds an NRC approved license and USS L.Y. SPEAR holds an approved Permit.

NRC - U.S. Nuclear Regulatory Commission.

NDT Laboratory - Non-destructive Test Laboratory.

Package - A shipping container for licensed radioactive materials.

Permit - Navy Radioactive Materials Permit Issued by the Licensee.

Permit Holder - USS L.Y. SPEAR (AS-36)

RASO - Radiological Affairs Support Office, Yorktown

RCF - Radiac Calibration Facility.

RCO - Radiological Controls Officer.

RMPQA Officer - Quality Assurance Officer for the Quality Assurance Program for the Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions (10CFR71).

RSO - Radiation Safety Officer.

SECTION ONE

ORGANIZATION

1.1 Purpose. This section sets forth the organizational responsibilities in the Radioactive Material Packaging Quality Assurance (RMPQA) Program.

1.2 Description. The RMPQA Program is composed of four levels of responsibility:

a. Commanding Officer - By definition, the senior official of the licensed activity, who is responsible for the establishment, execution of and authorizing revisions to the RMPQA Program. The Commanding Officer assigns and certifies the qualification of the RMPQA Officer.

b. Repair Officer - In his role as Department Head which actually uses licensed materials, the Repair Officer has a vested interest in the RMPQA Program. Therefore, he is responsible for ensuring that the RMPQA Officer has sufficient organizational freedom to fulfill his function and for ensuring that corrective action(s) is/are accomplished in an effective, timely manner and is/are not being delayed by production schedules or other conflicts.

c. Radiological Controls Officer (RCO) - Responsible for the safe receipt, handling, operation and shipment of licensed materials in/by the Radiac Calibration Facility (RCF), the RCO is responsible for the following attributes of the RMPQA Program:

(1) Ensuring that shipment of licensed materials used by the RCF are conducted in accordance with references (b), (c) and (d).

(2) Ensuring that required inspection and testing incidental to shipment of licensed materials used by the RCF are properly conducted and documented.

(3) Completing records of shipments to/by the RCF prior to releasing them to the appropriate record keeping officer.

(4) Ensuring that corrective action, when required, is accomplished by the RCF in an effective, timely manner.

(5) Ensuring that personnel under his cognizance assigned to use licensed material are trained in the requirements of this instruction and references (b), (c) and (d).

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d. Radiation Safety Officer (RSO) - Either the Quality Assurance Officer or the Non-Destructive Test (NDT) Laboratory Supervisor is normally assigned as the RSO. In addition to his/her responsibilities for ensuring the safe receipt, handling, operation and shipment of licensed materials used in radiography, is responsible for:

(1) Ensuring that shipments of licensed materials used by the NDT laboratory are conducted in accordance with references (a), (c) and (d).

(2) Ensuring that required inspection and testing incidental to shipment of licensed materials used by the NDT laboratory are properly conducted and documented.

(3) Maintaining records of shipments as required in later sections of this instruction.

(4) Ensuring that corrective action, when required, is accomplished in an effective, timely manner by the NDT Laboratory.

(5) Ensuring that personnel under his cognizance, who are assigned to process licensed materials are trained in the requirements of this instruction and references (a), (c) and (d).

e. RMPQA Officer. The RMPQA Officer shall be certified as to his qualification and appointed by the Commanding Officer. His/Her primary function in the RMPQA Program is the verification of the credibility of the program. In this regard he/she is responsible for:

(1) Development of an audit schedule for approval by the Commanding Officer.

(2) Conducting or directly supervising the conduct of all audits of the RMPQA Program.

(3) Conducting or directly supervising the conduct of unannounced spot checks of the RMPQA Program.

(4) Reporting his findings directly to the Commanding Officer with copies to the Repair Officer, Radiological Controls Officer and Radiation Safety Officer.

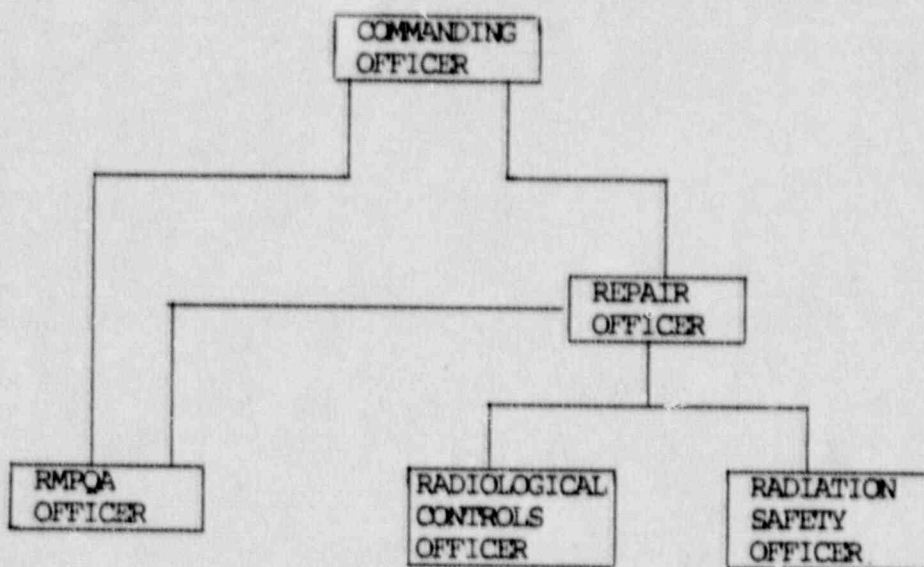
(5) Conducting follow-up audits to ensure corrective action is accomplished.

f. Appendices. Appendices (A) and (B) to this section contain an organizational chart and matrix which graphically displays the division of responsibility of the above functions into five levels of responsibility.

SECTION ONE

APPENDIX "A"

ORGANIZATIONAL CHART



SECTION ONE

APPENDIX "B"

RESPONSIBILITY MATRIX

<u>FUNCTION</u>	<u>COMMANDING OFFICER</u>	<u>REPAIR OFFICER</u>	<u>RADIOLOGICAL CONTROLS OFFICER</u>	<u>RADIATION SAFETY OFFICER</u>	<u>RMPQA OFFICER</u>
PROGRAM	A	E	E	E	E
TRAINING	A	C	D,E	D,E	
CERTIFICATION		B	E	E	
TESTING		B	E	E	
DOCUMENT CHANGES	A	C	D	D	
SHIPPING	A	C	E	E	
AUDITS	B				E
AUDIT SCHEDULE	A	C			D

LEGEND

A - Approve
B - Accept
C - Concur
D - Initiate
E - Perform

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SECTION TWO

QUALITY ASSURANCE PROGRAM

2.1 Purpose. This section specifies the necessary action which must be undertaken to successfully establish and execute a viable quality assurance program for packaging licensed materials.

2.2 Discussion. USS L.Y. SPFAR holds a permit to use certain radioactive materials as specified in reference (a) and (b). As an end user, USS L.Y. SPEAR receives these materials from NRC licensed suppliers in NRC approved containers. Therefore, the thrust of the QA Program aboard USS L.Y. SPEAR shall be directed toward establishing proof of and maintaining the quality of provided containers. Manufacture or repair of shipping containers for licensed materials shall not be conducted aboard USS L.Y. SPEAR without prior approval by the NRC.

2.3 Procedure

a. The promulgation and enforcement of this instruction by the appropriate level of the chain of command establishes and implements the RMPQA Program.

b. Training and experience for all RMPQA Program functions shall be in accordance with established procedures.

(1) The Commanding Officer, Repair Officer and Radiological Controls Officer are specifically assigned by the Bureau of Naval Personnel in accordance with established directives.

(2) The Radiation Safety Officer shall be assigned and certified by the Commanding Officer in accordance with reference (a).

(3) The RMPQA Officer shall be assigned and certified by the Commanding Officer following completion of Appendix "A" to this section.

(4) Radiographers shall be qualified in accordance with reference (a).

(5) RCF Technicians shall be qualified in accordance with reference (b).

c. Revisions to the QA program may be made only by a formal change to this instruction signed by the Commanding Officer. Revisions which would significantly alter the program must be approved by the RASO. Each revision shall be entered in the manner directed by the revision and documented on the Record of Revisions page.

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d. Prior to use, all defined quality control procedures, engineering procedures and specific provisions of the package design approval shall be satisfied for any shipping package used in conjunction with licensed materials.

(1) Documentation of this shall be maintained on board USS L.Y. SPEAR for any contractor supplied shipping containers for use with licensed materials.

(2) Specific approval by the RASO shall be obtained, documenting the above attributes prior to locally fabricating, repairing or altering a shipping container for use with licensed materials.

e. While in the custody of USS L.Y. SPEAR, shipping containers for use with licensed materials shall be controlled in such a manner that those characteristics of the package which are critical to safety are maintained.

(1) Damage to shipping containers shall be reported immediately to competent authority.

(2) Shipping containers for use with licensed radiographic sources shall be maintained and used in accordance with reference (a). They shall be stored in the Radiation Vault when not in use.

(3) Shipping containers for licensed radiac calibration sources shall be maintained and used in accordance with reference (b). They shall be stored in the locked section of the RCF when not in use.

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SECTION TWO

APPENDIX "A"

From: _____
(RMPQA Officer Designate)

To: Commanding Officer, USS L.Y. SPEAR (AS-36)

Subj: Training and Experience as RMPQA Officer

1. I have reviewed and am familiar with the most recent revisions to the following instructions and regulations:

Title 10, Code of Federal Regulations, Part 71.

USS L.Y. SPEARINST 5100.18, RMPQA Program.

USS L.Y. SPEAR RMPQA Records and Audits.

USS L.Y. SPEAR Navy Radioactive Materials Permit No. 59-05851-ALNP for Gamma Radiography.

USS L.Y. SPEAR Navy Radioactive Materials Permit No. 59-05851-CLNP for Radiac Calibration.

2. I am prepared to assume the responsibilities of the USS L.Y. SPEAR RMPQA Officer.

Signature

Approved:

Commanding Officer / Date

SECTION THREE
HANDLING, STORAGE AND SHIPPING

3.1 Purpose. This section describes those aspects of handling, storage and shipping of packages which are important to safety and includes assignments of responsibilities for the critical aspects of handling, storage and shipping.

3.2 Discussion

a. Established safety restrictions concerning the handling, storage and shipping of packages for 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 have been provided for handling, storage and shipping operations for those shipping containers in use. Work instruction will be provided for handling, storage and shipping operations for those shipping containers contemplated for future use.

b. The responsibilities of certain personnel involved in the RMPQA Program are described in section one. This section provides amplification of those responsibilities by specifying requirements for the aspects of handling, storage and shipment of packages which are considered critical.

3.3 Procedure

a. The Radiological Controls Officer is responsible for the critical handling, storage and shipping operations for each shipment of licensed materials by the RCF. He/She shall ensure, for each shipping container, that:

(1) Established safety restrictions concerning the handling, storage and shipping of packages for certain special form radioactive material are being followed.

(2) Shipments are not made unless all test, certification, acceptances and final inspections have been completed.

(3) Work instructions have been provided for handling, storage and shipping operations.

b. The Radiation Safety Officer is responsible for the critical handling, storage and shipping operations for each shipment of licensed material by the NDT Laboratory. He/She shall ensure, for each shipping container, that:

(1) Established safety restrictions concerning the handling, storage and shipping of packages for certain special form radioactive material are being followed.

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(2) Shipments are not made unless all tests, certifications, acceptances and final inspections have been completed.

(3) Work instructions have been provided for handling, storage and shipping operations.

SECTION FOUR
INSPECTION, TEST AND OPERATION STATUS

4.1 Purpose. This section describes those aspects of inspection, test and operation status of packages which are important to safety and includes assignment of responsibilities for the critical aspects of inspection, test and operating activities.

4.2 Discussion

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

b. The responsibilities of certain personnel involved in the RMPQA Program are described in section one. This section provides amplification of those responsibilities by specifying requirements for the aspects of inspection, test and operating status which are considered critical.

4.3 Procedure

a. The Radiological Controls Officer is responsible for the critical inspection, test and operating activities associated with each shipping container which may be used for shipment of licensed materials by the RCF. He/She shall ensure, for each shipping container, that:

(1) Inspection, test and operating status of packages for certain special form radioactive material is indicated and controlled by established procedure.

(2) Status is indicated by tag, label, marking or log entry.

(3) Status of nonconforming parts or packages are positively maintained by established procedures.

b. The Radiation Safety Officer is responsible for the critical inspection, test and operating activities associated with each shipping container which may be used for shipment of licensed materials by the NDT laboratory. He/She shall ensure, for each shipping container, that:

(1) Inspection, test and operating status of packages for certain special form radioactive material is indicated and controlled by established procedures.

(2) Status is indicated by tag, label, marking or log entry.

(3) Status of nonconforming parts or packages are positively maintained by established procedures.

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SECTION FIVE
QUALITY ASSURANCE RECORDS

5.1 Purpose. This section provides the necessary requirements and guidance for satisfactorily documenting the operation of the RMPQA Program aboard USS L.Y. SPEAR.

5.2 Discussion. Adequate documentation will be maintained to demonstrate to interested parties that USS L.Y. SPEAR possesses an effective functional RMPQA Program. To this end the following actions shall be taken:

a. Records will be maintained and include operating logs, inspection, tests and audit results.

b. Other records to be maintained will include qualification of personnel and descriptions of procedures and equipment.

c. Records will be maintained according to established procedures.

d. Records will be identifiable and retrievable.

e. A list of the required records and their storage location will be maintained.

5.3 Procedure:

a. The RMPQA Officer shall maintain the original audit reports for all audits and shall maintain a master listing (index) of all required records which shows their location.

b. The Radiation Safety Officer shall maintain all other records. He/She shall maintain them in an auditable fashion, i.e., they shall be identifiable and retrievable. These shall include, but not limited to:

- (1) Operating logs, inspections and tests.
- (2) Qualification of personnel.
- (3) Descriptions of procedures and equipment.
- (4) Records of shipments.

SECTION SIX
AUDITS

6.1 Purpose. This section specifies the requirements which must be met to establish an effective audit program.

6.2 Discussion

a. Appendix (A) to this section contains the audit plan for use in audits of the RMPQA Program. This format specifies the minimum requirements of each audit. The auditor should audit to the intent rather than the letter of the audit plan. That is to say each area described in the audit plan should reveal several questions which must be answered to satisfactorily complete the audit.

b. Established schedules of audits of the RMPQA Program will be performed. Results of all audits will be reported to the Commanding Officer, with copies to the Repair Officer, Radiological Controls Officer and Radiation Safety Officer. Audit reports will be evaluated and deficient areas corrected. The audits being performed will be dependent of the safety significance of the activity being audited. Audit reports will be maintained as part of the quality control records.

6.3 Procedure

a. Audits shall be conducted by or under the direct supervision of the RMPQA Officer.

b. An audit of each receipt or shipment shall be conducted within two weeks following that receipt or shipment.

c. Semi-annually, a complete audit of the RMPQA Program will be conducted. The specific dates shall be approved by the Commanding Officer.

d. The signed audit report shall be forwarded to the Commanding Officer on the completion of each audit. Copies will be provided to the Repair Officer, Radiological Controls Officer and Radiation Safety Officer.

e. The Repair Officer will review proposed corrective actions and assign completion dates.

f. The original audit reports and original records of corrective action shall be maintained in an auditable fashion by the RMPQA Officer.

USS L.Y. SPEAR SEMIANNUAL AUDIT CHECKLIST FOR
THE QUALITY ASSURANCE PROGRAM FOR THE PACKAGING OF RADIOACTIVE MATERIALS

	Y	N	N/O	N/A
A. RMPQA RECORDS				
1. Has the current RMPQA Officer completed Enclosure (1), Section two, Appendix A, of L.Y. INST 5100.18 (series) and has been approved by the Commanding Officer? Ref: <u>USS L.Y. SPEARINST 5100.18</u>				
2. Have all RMPQA revisions been approved by the Commanding officer and each revision entered in the record of revisions page? Ref: <u>USS L.Y. SPEARINST 5100.18</u>				
3. Are there records of completed audits for the Receipt and transfer of each source? Ref: <u>USS L.Y. SPEARINST 5100.18</u>				
4. Are there records of completed Semiannual audits? Ref: <u>USS L.Y. SPEARINST 5100.18</u>				
5. Are there records on file of the manufacturers NRC approval for each Package? Ref: <u>USS L.Y. SPEARINST 5100.18</u>				
6. Are there records on file of semiannual inventory of sources? Ref: <u>USS L.Y. SPEARINST 5100.2</u>				
7. Are there records of radiac instrument calibration for each instrument? Ref: <u>USS L.Y. SPEARINST 5100.2</u>				

	Y	N	N/O	N/A
8.				
<u>Ref:</u>				
9.				
<u>Ref:</u>				
10.				
<u>Ref:</u>				
B. SOURCE RECORDS				
<p>1. Do completed records for each radiographic source contain as a minimum the following:</p> <ul style="list-style-type: none"> Source receipt form. Source leak test form. Custody accountability form from supplier. Decay chart from manufacturer. Supplier shipping invoice. Utilization logs. Transport requests. Daily prior to use inspections. Field surveys. Source transfer form. Shipping document 1149. Acknowledgement of receipt of shipped sources by supplier. <p><u>Ref: USS L.Y. SPEARINST 5100.2</u></p>				
<p>2. Do completed records for each calibration source contain as a minimum the following:</p> <ul style="list-style-type: none"> Source receipt form. Source leak test form. Decay chart from manufacturer. Supplier shipping invoice. Utilization logs. Radiation survey records. <p><u>Ref: USS L.Y. SPEARINST 5100.2</u></p>				

	Y	N	N/O	N/A
3.				
<u>Ref:</u>				
C. QUALIFICATION RECORDS				
1. Have all radiographers completed qualification by: Completing course A-701-0033. Medically qualified radiation worker. Completed on board qual check sheet. Assigned in writing by RSO. <u>Ref: USS L.Y. SPEARINST 5100.2</u>				
2. Have all RCF personnel completed qualification by: Completing course A-670-0020 Radiac instrument maintenance. Medically qualified radiation worker. Completed on board qualification. Assigned in writing by RCO. <u>Ref: USS L.Y. SPEARINST 5100.1</u>				
3. Has the Radiation Safety Officer completed course S-4J-0016 and S-4J-0020 and been appointed in writing by the Commanding Officer. <u>Ref: USS L.Y. SPEARINST 5100.2</u>				
4. Has the Senior Radiographer completed course S-4J-0016 and S-4J-0020 and been appointed in writing by the Commanding Officer. <u>Ref: L.Y. SPEARINST 5100.2</u>				
5.				
<u>Ref:</u>				
6.				
<u>Ref:</u>				

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	Y	N	N/O	N/A
D. TRAINING RECORDS				
1. Are there records for training on the following topics: L.Y. SPEARINST 5100.18 QA Program. L.Y. SPEARINST 5100.2 GAMMA RADIOGRAPHY L.Y. SPEARINST 5100.16 CALIBRATION Title 10, CFR, Part 19 Title 10, CFR, Part 20 Title 10, CFR, Part 21 Title 10, CFR, Part 30 Title 10, CFR, Part 34 Title 10, CFR, Part 71 Title 49, CFR <u>Ref: USS L.Y. SPEARINST 5100.18</u>				
2. <u>Ref:</u>				
3. <u>Ref:</u>				
4. <u>Ref:</u>				
5. <u>Ref:</u>				