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Bulletin 95-01: Quality Assurance Program For Transportation of Radioactive Material

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

OMNB No.: 3150-0011
NRCB: 95-01

January 13, 1995

NRC BULLETIN 95-01: QUALITY ASSURANCE PROGRAM FOR TRANSPORTATION OF RADIOACTIVE MATERIAL

Addressees

For Action - All radiography licensees

For Information - None

Purpose

The U.S. Nuclear Regulatory Commission is issuing this bulletin to (1) notify action addressees about the failure of some licensees to have NRC-approved quality assurance (QA) Programs for transportation of radioactive material, (2) request that all action addressees implement the actions described herein, and (3) require that all action addressees answer the questions in Attachment 1 and return the completed form to NRC.

Description of Circumstances

Most radiographers perform activities that require NRC-approved QA Programs. These activities involve transport, or delivery to a carrier for transport, of licensed material in Type B packaging. Examples include transport of radiography devices to and from work sites, and shipment of radiography sources to source suppliers. However, NRC has noted that not all radiographers have NRC-approved QA Programs. Furthermore, a review of NRC materials license records shows that there are radiographers who may be transporting, or delivering to carriers for transport, licensed material in Type B packagings without having NRC-approved transportation QA Programs.

NRC has also conducted inspections of radiographers with NRC-approved QA Programs applicable to procurement, use, maintenance, and repair of Type B packaging used in transport of radioactive material. These radiographers transport special form radioactive material in packagings for which certificates of compliance (COCs) have been issued by NRC. The inspections were conducted to determine compliance with the transportation QA requirements of 10 CFR 71.12.

The results of the inspections showed that four out of the five radiographers inspected had serious shortcomings in the implementation of their transportation QA programs. In most instances, procedures used to implement their transportation QA programs were incomplete, were not available, or were not followed. QA records, which document the results of required QA activities, were found to be incomplete, inaccurate, or missing.

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Discussion

The provisions of 10 CFR 71.12 provide for the issuance of a general license to radiographers to transport, or deliver to a carrier for transport, licensed material in a packaging for which a COC has been issued by NRC. To comply with the general license provisions of 10 CFR 71.12, the actions requested to be taken by radiographers before transportation activities are performed include the following:

1. Obtain NRC approval of transportation QA Programs.
2. Implement transportation QA Programs using written procedures.
3. Review records on activities affecting quality.
4. Register with NRC as users of Type B packagings utilized in transportation activities.

Requested Actions

Radiographers are requested to fill out the enclosed form, return the completed form to NRC, and take the following actions relating to compliance with regulatory requirements:

1. QA Program - Review your operating activities. If you perform transportation activities, as described in 10 CFR 71.12(a), and you do not currently have an NRC-approved transportation QA Program, prepare and submit to NRC, within 60 days of the date of this bulletin, a transportation QA Program that satisfies the requirements of Subpart H of 10 CFR Part 71. A \$370.00 application fee, as required by 10 CFR 170.31(10)(B), must also be submitted with the application. Please note that Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," may be helpful to you in developing your transportation QA Program.
2. Implementing Procedures - Review your operating procedures. If you are required to have a transportation QA Program, as required by 10 CFR 71.12(b), and do not have written procedures that implement each element of your transportation QA program in accordance with the requirements of 10 CFR 71.111, develop these procedures and implement them within 60 days of the date of this bulletin. Please note that methods for complying with each of the criteria of Subpart H of 10 CFR Part 71, applicable to your transportation activities, and all other activities important to safety, must be prescribed and accomplished in accordance with documented procedures, instructions, and drawings. The procedures should not be submitted to NRC at this time. However, these procedures must be implemented and kept on file at your location for future

inspections. .

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3. QA Records - Review your operating records. If you do not maintain records describing activities affecting quality, maintain records of each shipment of licensed material, and maintain records furnishing evidence of the quality of Type B packaging in accordance with the requirements of 10 CFR 71.135, 71.91(a), and 71.91(c), respectively, you should:
 - a. Identify all of the records that are required by your transportation QA Program and the records that are incomplete or missing.
 - b. Document, in a status report, all the instances where you find that your QA records are incomplete or missing, and keep this status report on file.

Caution: Do not attempt to falsify any QA records. If QA records are incomplete or missing, state so in your status report. The status report should not be submitted to NRC at this time. However, this information must be documented and kept on file at your location for future inspections. Full compliance must be achieved within 60 days from the date of this bulletin.

- c. Take the necessary corrective steps to assure that you document, in the future, the results of all QA activities that are described in your transportation QA Program.
4. Packaging Registration - Review your transportation packaging registrations. If you are not registered as a user of all the models of Type B transportation packagings you are utilizing, submit to NRC within 60 days of the date of this bulletin a written request to be registered in accordance with 10 CFR 71.12(c)(3). You are also required to submit to NRC, before the first use of new Type B packaging models, a written request to be registered as a user of the Type B packaging. The requests should include the radiographer's name, NRC license number, transportation QA Program approval number, Type B packaging identification numbers, and corresponding COC numbers.

Transportation QA Programs, application fees, and requests to be registered as users of packagings should be sent to Mr. Robert L. Baer, Chief, Source Containment and Devices Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Please note that it will be considered a willful violation of NRC regulatory requirements, therefore subject to civil penalties and criminal penalties under 10 CFR 71.100, if, subsequent to the issuance of this bulletin, you perform transportation activities requiring an NRC-approved QA Program and do not: have, or take steps in accordance with this bulletin to put into effect, an NRC-approved QA Program for transportation; implement your QA program through detailed procedures; maintain QA records; or register as a user of the Type B transportation packagings you are utilizing. All such transportation activities must be stopped until you have a transportation QA Program approved by NRC, have procedures in place that implement your transportation QA Program, and are registered as a user of the Type B transportation packagings.

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you are utilizing. Your QA program, implementation procedures, QA records, and Type B packagings registration will be subject to future inspections.

Required Responses

Within 30 days of the date of this bulletin, each action addressee is required to complete and submit the form provided in Attachment 1. Address the completed form to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, under oath or affirmation, under the provisions of Section 182a, Atomic Energy Act of 1954, as amended.

In preparing your response, if you discover incomplete or missing records, you should so indicate in a status report and keep this report on file. Creation of false records may be subject to civil and criminal sanctions.

Paperwork Reduction Act Statement

The information collections contained in this request are covered by the Office of Management and Budget clearance number 3150-0011, which expires July 31, 1997. The public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011), Office of Management and Budget, Washington, D.C. 20503.

If you have any questions about this matter, please contact one of the technical contacts listed below.

/S/'D BY CJPAPERIELLO

Carl J. Paperiello, Director
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Thomas Matula, NMSS
(301) 415-7873

John Jankovich, NMSS
(301) 415-7274

Attachments:

1. Quality Assurance Program for
Transportation of Radioactive Material.
Instructions for Completing and Returning the Form

You are required to complete the questions on the following pages and complete and sign the statement following the questions.

Please remove the pages from this bulletin by tearing along the perforated line.

Fold the pages in half and staple them closed.

Apply correct postage on the back page and complete the return address

section.

Mail your response to NRC within 30 days of the date of this bulletin..ENCLOSURE TO : QUALITY ASSURANCE PROGRAM FOR TRANSPORTATION OF RADIOACTIVE MATERIAL

Radiographers are required to answer the following questions. Attach additional pages if more space is needed to provide complete answers.

Mail this completed form, with any attachments, within 30 days of the date of this bulletin to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001.

Licensee identification information:

Licensee Name: _____
Address: _____
Phone No.: _____

1. Do you have a Quality Assurance (QA) Program approved by NRC in accordance with the requirements of 10 CFR 71.12(b)?

Yes_____ No_____

a. If the answer to Question Number 1 is "Yes," enter your transportation QA Program Approval Number in the space below and skip Question Numbers 2 and 3. Answer Question Number 4.

Transportation QA Program Approval Number _____.

b. If the answer to Question Number 1 is "No," answer Question Numbers 2 and 3.

2. Do you procure, use, maintain, or repair Type B packaging for which a Certificate of Compliance (COC) has been issued by NRC? Please note that radiography devices are usually Type B packagings.

Yes_____ No_____

3. Do you transport, or deliver to a carrier for transport, licensed material in Type B packaging for which a COC has been issued by NRC? Please note that this activity includes transport of radiography devices to and from work sites and shipment of radiography sources to source suppliers.

Yes_____ No_____

a. If the answer t to have a transportation QA Program approved by NRC in accordance with 10 CFR 71.12(b). If you have not already done so, prepare and submit your transportation QA Program to NRC following the directions presented

in

"Requested Actions" (Page 2, Item 1) in the body of this bulletin.
Answer Question Number 4.

b. skip

If the answers to Question Numbers 1, 2, and 3 are "No," you may
Question Numbers 4 through 8. Complete and sign the statement
following the questions, and return this form to NRC by following

the

mailing directions at the top of this form.

4. Do you have written procedures that implement each element of your
transportation QA program in accordance with the requirements of 10 CFR
71.111?

Yes_____ No_____

a. 5,

If the answer to Question Number 4 is "Yes," answer Question Numbers
6, and 7.

b. you

If the answer to Question Number 4 is "No," and you determined that
are required to have a transportation QA program, develop these
procedures and implement them within 60 days of the date of this
bulletin as described in "Requested Actions" (Page 2, Item 2) in the
body of this bulletin. The procedures should not be submitted to

NRC

at this time. However, these procedures must be implemented and

kept

on file at your location for future inspections. Answer Question
Numbers 5, 6, and 7.

5. Do you maintain records describing activities affecting quality, your
transportation QA program, and your implementation procedures in
accordance
with the requirements of 10 CFR 71.135?

Yes_____ No_____

6. Do you maintain records of each shipment of licensed material in
accordance
with the requirements of 10 CFR 71.91(a)?

Yes_____ No_____

.7. Do you maintain records furnishing evidence of the quality of Type B
packaging for activities such as inspections, tests, and audits, and
procurement, maintenance, repair, and replacement of packagings in
accordance with the requirements of 10 CFR 71.91(c)?

Yes_____ No_____

a. If the answer to Question Numbers 5, 6, and 7 are "Yes," answer
Question Number 8.

b. program,

If the answer to Question Numbers 5, 6, or 7 is "No," and you
determined that you are required to have a transportation QA
document in a status report all the instances where you find that

your

QA records are incomplete or missing, and keep this status report on file as described in "Requested Actions" (Page 3, Item 3) in the

body

of this bulletin.

Answer Question Number 8.

8. Are you registered as a user of all models of Type B packagings that you are utilizing for which COCs have been issued by NRC in accordance with the requirements of 10 CFR 71.12(c)(3)?

Yes _____ No _____

If the answer to Question Number 8 is "No," and you determined that you are required to have a transportation QA program, prepare and submit your request to be registered as a user of packagings following the directions presented in "Requested Actions" (Page 3, Item 4) in the body of this bulletin.

Complete and sign the following statement, and return this form to NRC by following the mailing directions at the top of this form.

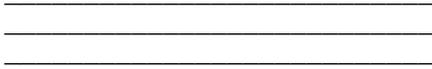
I hereby certify under penalty of perjury and under the laws of the United States of America that the foregoing is true and correct.

Name: _____

Title: _____

Signature: _____ Date: _____.

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