
Sealed Source & Device Newsletter



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Courtesy of the
Sealed Source
Safety Section

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With technology constantly changing and the need to protect public health and safety, it is imperative that communications between the U.S. Nuclear Regulatory Commission (NRC) and Agreement State programs and also between these regulatory authorities and users of radioactive sealed sources and devices be open and cooperative. The NRC Sealed Source Safety Section (SSSS) is providing this newsletter to promote such communications.

TECHNICAL ISSUES

APGEE CORPORATION 10 CFR PART 21 REPORT OF DEFECT IN SOME LB 7400 SERIES DEVICES

Apgee Corporation, Berthold Systems, Incorporated, and the manufacturer continue to investigate the defect in the shutter mechanisms of some Berthold model LB 7440 and LB 7442 devices. Berthold indicates that all licensees who received the initial bulletin have responded and that all shutter mechanisms have been tested for the potential defect. Of the 400 devices tested, 50 (12.5 percent) showed signs of the defect. Positive results of the defect were distributed over a variety of industrial applications, with rates of occurrence ranging from 9 to 25 percent and with no particular industry seeing a significantly higher frequency. Apgee expects to complete the analysis and issue a report of findings to the NRC soon.

Possessors of Berthold model LB 7400 series devices received between 1991 and 1992, who have not been contacted by Apgee/Berthold, should contact Mr. Bud Smith of Apgee/Berthold directly at (412) 378-1900.

CLARIFICATION OF THE NEW RADIOGRAPHY EQUIPMENT RULE REQUIREMENTS FOR ASSOCIATED EQUIPMENT

Recently, a radiography equipment manufacturer requested clarification on several issues concerning

the requirements for radiography associated equipment. The questions concerned generic issues that may be applicable to all manufacturers and users of radiography equipment. The NRC response was based on current requirements contained in 10 CFR Part 32 and Part 34, and those that become effective on January 10, 1996. Below is a summary of the questions asked and the answers NRC provided:

- Q: Is associated equipment, shown to meet 10 CFR 34.20 requirements with one camera model, automatically approved for use with other camera models with which it has not been tested?
- A: Associated equipment that meets 10 CFR 34.20 equipment requirements when tested with one camera is not allowed to be used with another camera unless it has either: passed all appropriate tests; been shown through engineering analysis that it would likely meet the test requirements; or been granted a license exemption. In all cases, before the equipment may be used, NRC or an Agreement State must have deemed it acceptable, for licensing purposes.
- Q: What are the requirements for approval of one manufacturer or suppliers associated equipment with an another approved camera, and who is responsible for meeting these requirements?
- A: All associated equipment must either be listed on a registration certificate as specifically approved for use with the radiography camera

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or have been granted a license exemption. For the associated equipment to be approved, a safety evaluation must be performed, and a determination made that the equipment meets the requirements in 10 CFR Part 34.

The regulations in 10 CFR Part 34 are user-based. Therefore, the licensee/user is ultimately responsible for ensuring that its radiography equipment (regardless of manufacturer or supplier) has met the appropriate requirements or has been granted a license exemption. In addition, 10 CFR 30.32, Application for specific licenses, states under paragraph (g), that the applicant (licensee) must either Identify the source or device ... as registered with the Commission ... or an Agreement State, or provide the information identified in 10 CFR 32.210(c). In most cases, for efficiency and convenience, the manufacturer submits the information and request to register the equipment.

Manufacturers or suppliers of associated equipment seeking approval of their components for use with other cameras must provide, to the appropriate licensing authority, the information necessary to perform a safety evaluation, as outlined in 10 CFR 32.210, and demonstrate that the component meets 10 CFR 34.20 requirements. If the associated equipment is deemed acceptable for licensing purposes, a registration certificate or similar document, stating that this component is approved for use with the radiography camera, will be generated. This document will be forwarded to the applicant, to the appropriate person(s) in NRC regional offices and Agreement States, and to any other concerned parties, as appropriate.

Q: What are the regulatory requirements for labeling associated equipment to indicate it meets 10 CFR Part 34.20 requirements?

A: To identify associated equipment — used with a radiography camera or changer and that has an effect on the overall safety and/or integrity of the camera, changer, or source — that has been shown to meet 10 CFR 34.20 requirements, our policy is that the equipment be labeled, and in such a manner that the labeling cannot easily be removed. The associated equipment includes guide tubes (including J or similar-type guide tubes), control tubes, control/drive cables, and collimators that could come in contact with the sealed source. By labeling the equipment, the manufacturer and/or licensee is indicating that the component is expected to meet the requirements in 10 CFR 34.20. The ability of a component to meet these requirements may be demonstrated by having either a prototype

component, built to the same specifications, subjected to, and pass the appropriate equipment tests, or by providing an engineering analysis that demonstrates the component would be expected to pass the tests.

The manufacturer and/or licensee determines the label content (i.e., company logo, model number, etc.) using size, durability, uniqueness, and ease of identification as criteria. Information on labeling of components is typically found in the labeling section of the associated camera's registration certificate, and includes only those associated equipment items that have been approved for use with the camera. The location of the label shall be such that modification of the component could be easily recognized. For example; guide tubes and guide tube connectors are important for the safe operation of the system and are required to pass certain performance tests in ANSI N432-1980. One way these components have been labeled so that modifications are recognizable is that the connectors themselves have been labeled. To shorten a guide tube, the guide tube must be cut (thereby removing a connector), and another connector reattached. If the new connector is not labeled appropriately (i.e., not supplied by the manufacturer for an approved modification or labeled in accordance with the licensee's approval of the modification) or contains no labeling, this would be an indication to an inspector that the guide tube has been modified and may not be authorized for use.

This policy has been implemented for all radiography equipment manufacturers that have sealed sources and/or devices registered with NRC.

Q: What are the quality control requirements for manufacturers and suppliers of associated equipment?

A: Manufacturers and suppliers of associated equipment must have adequate quality assurance and control programs, approved in accordance with 10 CFR 32.210 requirements, to ensure the equipment meets 10 CFR 34.20 requirements, and any additional requirements listed in a certificate of registration or approval document issued by an appropriate licensing authority.

Q: How are various manufacturers source models determined to be compatible for use with a specific source changer? Who is responsible for providing the information necessary to make this determination?

A: The process to verify that one manufacturer's source model is compatible for use in another

manufacturers source changer is similar to the process used to verify that one manufacturers source is compatible for use in another manufacturers camera.

The manufacturer/distributor of the source model or source changer, or a licensee/user may request a particular combination be approved for use. The request, regardless of who makes it, must include an application for safety evaluation of the proposed combination. The safety evaluation will consist of a review and analysis of the information as required by 10 CFR 32.210 and 10 CFR 34.20 to ensure that the radiation safety properties of the source and device, when used together as intended, are adequate to protect health and minimize danger to life and property.

The basic procedure for verifying that one manufacturers source is compatible for use in another manufacturers source changer is summarized below:

1. Get drawings, including tolerances, of the changer and sealed source.
2. Compare dimensions to ensure the components are compatible when manufactured within tolerance.
3. Verify that the combination has been shown, either through prototype testing or engineering analysis, to meet the equipment requirements in 10 CFR Part 34.
4. Verify the external radiation levels are within the limits specified in 10 CFR 34.21.
5. Verify the source changer locking mechanism will work properly with the proposed sealed source. This may be demonstrated through a review of the design drawings, a visual check/demonstration of the actual products, the manufacturers statements/descriptions, and prototype testing results.

LICENSING OF THE AMERSHAM MODEL 650L RADIOGRAPHY SOURCE CHANGER

NRC plans to use licensing discretion to allow licensees, authorized for possession and use of Amersham Model 650 source changers, to possess and use Model 650L source changers without a license amendment. This action is based on the similarity of the construction and use of these devices, and is needed to enable these licensees to obtain approved source changers for use after January 10, 1996.

DOE/NRC ACCEPTANCE PROGRAM UPDATE

The following are the current actions with the U.S. Department of Energy (DOE), under this program:

- DOE is reviewing a proposed Memorandum of Understanding (MOU) intended to codify and formalize the program. The MOU was drafted as a joint venture between NRC and DOE staff and has been signed by the Director, Office of Nuclear Materials Safety and Safeguards.
- DOE is working to resolve a State of Illinois request for assistance with the retrieval of several Am/Be well logging sources.
- DOE assisted the State of Texas with the retrieval and control of a damaged Am/Be well logging source.

In addition, NRC has published the procedures NRC staff should follow when considering requesting DOE assistance under this program. The procedures are contained in Inspection Manual Chapter 1303, and Policy and Guidance Directive 9-12. Agreement State personnel may use these procedures as a guide when considering submitting a request for DOE assistance to NRC.

MECHANICAL FORENSICS

The following is an overview of salient points taken from an article in the October 1995, edition of *Equipment Today*. The article is entitled *Mechanical Forensics: Dead Machines Tell No Lies*. The author notes that Mechanical Forensics is the proper term for the process of failure analysis and is quick to note that Murphys law usually dictates when a failure occurs. Several points in the article may interest readers and are presented below:

Failures occur for many reasons, including normal wear and tear, abuse, manufacturing and/or material defects, insufficient design, and improper or insufficient maintenance. Every failure has a cause, and every cause has a reason...it is these reasons that mechanical forensicologists seek. The tricky part is that equipment is made of a system of interacting components, and problems have a way of chainreacting through the system, obscuring the cause and results.

Determining the cause of a failure has benefits: you can change the factors responsible and avoid future failures. To do this, an investigation should, at a minimum, encompass the following steps:

1. Clearly state the exact problem/failure.
2. Organize your fact gathering. 3. Carefully observe and precisely record the facts.
4. Incorporate all facts in a logical manner.
5. Identify the root cause. 6. Communicate with the party responsible for the failure (i.e. manufacturer, servicing agent, user).
7. Make recommended repairs.
8. Take steps to avoid similar problems in the future.

Start the investigation by a visual inspection of the failed equipment. This usually requires some basic tools to separate machine parts; a magnet to determine ferrous and non-ferrous metals, a magnifying glass, and a good flashlight. A camera is also useful to record the findings.

When investigating the cause(s) of a fractured metal part, it is important to keep in mind that parts typically break at their weakest point, and with metals, higher temperatures mean a decrease in strength. In addition, the type of fracture is an important consideration and may provide clues to the cause of the failure. The three types of metal fractures follow:

1. Brittle fractures are linked more to results than root causes, happen quickly, produce fragments, and the parts are not usually bent or deformed.
2. Ductile fractures are also related more to results than root causes, typically occur quickly (although not as fast as brittle fractures), and some twisting and stretching of the part is typically evident.
3. Fatigue fractures result from a combination of cyclical loads and physical irregularities (known as stress raisers) in the part. The fracture surface is typically flat, smooth, and light in color, and is characterized by semicircular benchmarks radiating from the fracture origin.

Metal part fractures are caused by an applied load to the part, sufficient to exceed the parts limit of strength. Loads may be applied suddenly or cyclically over time. Typical load types include:

- Impact loads: a sudden external load caused by improper equipment operation, or the failure of another component. This type of

load can cause both brittle and ductile fractures if in excess of the metals yield strength.

- Overloads: a sudden internal load, often related to the same causes and exhibiting the same effects as impact loads.
- Cyclic loads: Repetitive loads, typically less than the yield strength of the metal, created by the normal operation of the machine. This type of load may lead to fatigue fractures.

THE SSSS CONDUCTS A SEALED SOURCE AND DEVICE (SS&D) WORKSHOP

During the week of September 12-15, 1995, the SSSS conducted a SS&D workshop intended to provide training and background information on performing SS&D safety evaluations. Participants included representatives from each Agreement State, several non-Agreement States who have applied for Agreement State status, and the NRC Office of State Programs. Feedback from participants has been mostly positive and supportive. A number of participants indicated that they felt the workshop was helpful and worthwhile, and several suggestions for improvements were provided for future workshops.

ONGOING PROJECTS

SS&D TESTING CONTRACT

As reported in the last issue of the newsletter, Southwest Research Institute was issued Task Order One for the testing of industrial radiographic equipment. However, because of SwRI's estimate of substantial additional costs and delays for completion of the Task, and the lack of deliverables received from SwRI, it was decided to stop work on this Task. In accordance with the contract, SwRI will deliver all test data and equipment to NRC.

SwRI has been working to complete four final reports for publication. The report on the Troxer source cap investigation was submitted in final form by SwRI and published as NUREG/CR-6074, 04-4448-010, Vol. 5. In addition, reports on the failed brachytherapy source wire investigation, the brachytherapy needle applicator investigation, and the General Radioisotope Products sealed source investigation have also been submitted in final form by SwRI for publication by NRC. These reports will be published as NUREG/CR-6074, Vols. 2, 3, and 4, respectively. Published reports are available from the NRC Public Document Room or the

Government Printing Office. The SSSS will also have a limited number of extra copies that may be requested. Questions concerning this contract should be directed to Doug Broaddus, the contract technical monitor, at (301) 415-5847. In addition, if you believe that a particular device or sealed source may be a candidate for testing under this contract (e.g., product design is questionable for its intended or actual conditions of use, or the product has potential inherent problems), please inform the SSSS so that the product may be considered for future testing.

THE SS&D BULLETIN BOARD SYSTEM

A new Bulletin Board System has been created on FedWorld entitled, The Sealed Sources and Devices Bulletin Board System (SS&D BBS). The SS&D BBS was created by the SSSS and may be accessed, free of charge, on the FedWorld Information Service Network. The SS&D BBS provides users access to electronic copies of materials and information dealing with the registration of sealed sources and devices and other information commonly requested from the SSSS. Much of the information contained on the BBS may be viewed on screen and/or downloaded to your computer. Examples of materials and information contained on the SS&D BBS include downloadable copies of the RADXREF and SS&D REGISTRY programs in compressed format, past issues of the SS&D Newsletter, and copies of applicable regulatory guides.

The SS&D BBS has been set up to facilitate easy access to these materials, and each screen provides either on-screen directions or an "About..." file to give you further information on how to use the features of the SS&D BBS. For best results, users should carefully read all on-screen directions and "About ..." sections. Please be aware that as changes to the system occur, these sections may also change. In addition, it is recommended that users view the "SSD Late Breaking News and Information" section each time they log onto the system. This section serves as a means to alert users to new options, changes, and updates on the SS&D BBS, and to highlight other important

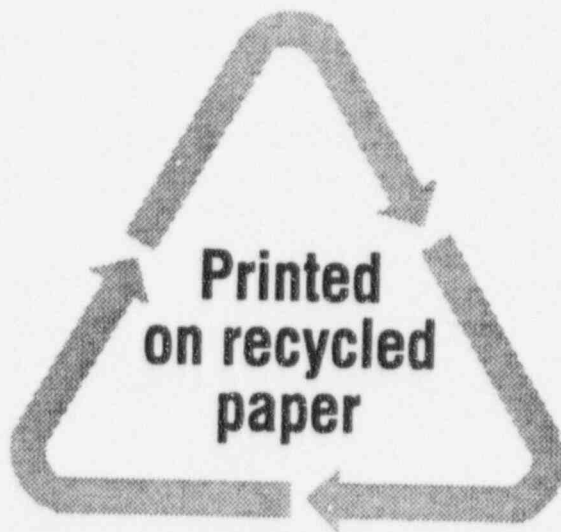
information dealing with SS&Ds. For information on connecting to and using FedWorld, please contact the FedWorld help desk at (703) 487-4608. For questions regarding the SSD BBS, please contact Michele Burgess at (301) 415-5868 or Steve Baggett at (301) 415-7273.

RADIOGRAPHY CROSS-REFERENCE PROGRAM (RADXREF)

Copies of the latest version of the RADXREF database program, Version 2.0a, dated October 1995, have been mailed to all registered users. This program is intended as a licensing guide for compatible models in industrial radiography, as indicated by current registration certificates or appropriate letters from the licensing authority. The program provides an efficient means for cross-referencing the compatibility of industrial radiography sources, changers, and cameras. Every effort has been made to ensure the accuracy of the information contained in the database. However, the program should not be viewed as the ultimate authority for determining compatibility of equipment, but, rather, applicable registration certificates should be reviewed for additional details or restrictions and for information about models that may not be listed in the program. In addition, please be aware that the database may not reflect information contained in certificates issued or amended after October 1995.

Updates to the RADXREF database and program will be made periodically, as necessary, and will be made available on the SSD BBS via FedWorld. In addition, updates may also be disseminated either via distribution of replacement data/programs on floppy diskettes or by the issuance of addendum hardcopy lists containing the changes made in the data. If you have problems downloading the RADXREF program from the SSD BBS, need a copy mailed to you, do not have access to FedWorld and wish to remain on the mailing list for future updates, or have any questions about the program, please call either Michele Burgess at (301) 415-5868, or Thomas Rich at (301) 415-7893, or write to them at the US Nuclear Regulatory Commission, Washington, D.C. 20555, Mail Stop T-8F5.

If readers of this newsletter need answers to specific questions, or have information that they believe will be valuable to other users and regulators of sealed sources and devices, we encourage them to provide this information to the SSSS. We will review the submitted information; if we find it to be within the scope of this newsletter, the information will be covered in a future issue. Send all questions, comments, requests for back issues, or articles to Kim Randall or Doug Broaddus of the SSSS at: SS&D Newsletter, US Nuclear Regulatory Commission, Mail Stop T-8 F5, Washington, DC 20555, or FAX (301) 415-5369.



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