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August 22, 1994

Office of Nuclear Regulatory Research
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Office of Administration, Distribution & Mail Services

Subject: PUBLIC COMMENTS on DRAFT REGULATORY GUIDE DG-6002

Source production and Equipment Co., Inc. is a manufacturer of industrial radiography devices, sealed sources and Type B radioactive material packages. We appreciate the opportunity to comment on the NRC draft Regulatory Guide DG-6002 titled "ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR THE MANUFACTURE AND DISTRIBUTION OF SEALED SOURCES AND DEVICES CONTAINING BYPRODUCT MATERIAL." It is a well-crafted document. It complements the QA Program requirements in 10 CFR Part 71 and it specifies comprehensive and realistic requirements for manufacturers of sealed sources and devices.

GENERAL COMMENTS:

The draft is limited to devices and sources only. It should apply to applicable associated equipment also. In the case of industrial radiography the associated equipment is critical to safety. They are subject to requirements specified in 10 CFR Part 34.20 and in the ANSI N432 and ISO 3999 Standards for radiography equipment.

The draft expands to role of the QA Program beyond typical industry practice. It imposes requirements on fabrication personnel bayond their specific QA related responsibilities in some instances. It includes requirements related to transportation of radioactive material packages that are addressed in other regulations. The draft should avoid imposing redundant regulations on licensees.

The draft VALUE/IMPACT STATEMENT states "The NRC plans to revise the references to QC standards in the regulations and include a statement that the registrants are required to implement an approved QA program." I assume that this will be required of Agreement State licensees. Manufacturers of Type B packages in Agreement States are already required to have an NRC approved QA program. Agreement State manufactures of other devices will also be required to have an Agreement State approved QA program. There should be a provision to allow either Agreement State or NRC QA Program approval, but not both.

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It is not clear what the draft requirements will be for distributors of devices that are manufactured by persons who are not NRC licensees. This is particularly evident in cases where the manufacturer is not a domestic manufacturer and does not have an NRC approved QA Program. The draft should not create an economic advantage for foreign manufacturers by allowing a reduced level of QA responsibilities to be assumed by a domestic distributor or redistributor of their products.

The draft does not specify clear and comprehensive QA requirements regarding the inspection, repair and maintenance of devices by distributors and redistributors. The distinction between repair and maintenance and the respective levels of QA control is significant to safety, particularly for radiography devices. The entire draft should be revised to address repair and maintenance requirements.

SPECIFIC COMMENTS:

B. DISCUSSION

Add definitions for:

A. Defect
B. Malfunction
C. Nonconforming material or item
D. Items critical to safety
E. Maintenance "The replacement or routine servicing of used items in accordance with manufacturers' written procedures."

Revise definitions for:

D. Service; "Any operation pertaining to the maintenance of the device, associated equipment, or part thereof as a result of a defect, malfunction or scheduled periodic safety inspection procedure."
E. Specifications; Delete "customer." The customer cannot have the authority to impose requirements on the manufacturer.

C. REGULATORY POSITION

1st Paragraph:
Delete the following statement; "This document provides guidance on preparing applications for radiation safety evaluation and registration of devices and sealed sources containing byproduct material." Regulatory Guides 10.10 and 10.11 provide that guidance. This document provides guidance in the requirements of a QA Program.

2. PERSONNEL

2.4 Revise to require that the applicant should have applicable medical records on file, not the QA department. This could conflict with federal laws regarding worker privacy.

3. EQUIPMENT

2nd Paragraph:
The draft should clarify when calibrations are required to be directly traceable versus indirectly traceable depending on the potential impact on safety.

3.1
Delete the requirement for a log of equipment used "... in the production of the device, enhances the quality of the device." This is vague, costly and unnecessary. All equipment involved with nonconformances or defects are traceable by the production records.

3.2
Delete the requirement for the calibration log to include the list of names of persons qualified to calibrate the equipment. This is a redundant requirement also specified in 2.3.

3.5
Delete the requirement for the calibration marking on the equipment to include the person or company who performed the calibration. This information is in the calibration record.

3.6
Clarify the requirement to audit calibration suppliers "like all other suppliers." Audits that pertain to suppliers of materials are able to be based on receipt inspections. The draft should clarify if it is the NRC intent that applicants perform an inspection or test to verify the accuracy of the calibration service to audit calibration suppliers.

3.7
Add an additional option for the special procedures to be included in written procedures and personnel training.

4. DESIGN AND DOCUMENT CONTROL

4.2
Revise to "After a document has been revised,..." A document may be in the process of being revised for minor reasons. Until the revisions are completed and approved the existing document should be able to be used.

4.5
1st sentence: Replace "proficiency" with "authority." Proficiency is a subjective term. There are no specific requirements to measure workers' proficiency.

4.6
Add a requirement to include the review and approval records pertaining to document changes.

4.7
The draft should clarify the procedures and checklist requirements pertaining to reviews of changes to documents. This appears to be costly and unnecessary.

4.8 & 4.9
See "General Comments"
It is very unlikely that these requirements effectively impose responsibility on a distributor or redistributor to assume QA requirements that are intended to be imposed on a manufacturer. Additional discussion is needed to consider these provisions. It is not clear how the NRC intends for this to work.

5. MATERIAL AND SERVICE PROCUREMENT

5.2
Include a requirement for 100% inspection of items that are critical to safety.

5.3
Include a provision for the QA Manager to authorize procurement from suppliers that are not on the qualified supplier list for individual procurement orders.

5.4
Last sentence: Delete the requirement for an applicant to ensure that the supplier is using current documents. The applicant can only ensure that the current documents have been sent to the supplier.

5.5
Some distributors and redistributors are not licensed to use the radiography devices and are unable to perform an operational check. See paragraph 8.0 also.

7. PRODUCTION PROCEDURES AND PROCESSES

7.5
If the applicant is a distributor or redistributor that performs repairs, rework or maintenance the NRC should require that the

applicant have an approved QA program. It is contrary to safety to allow a distributor to have a lower level of QA responsibility than is imposed on a domestic manufacturer pertaining to repair and maintenance. See paragraph 9.5 also.

8. INSPECTION AND TESTING

1st paragraph.
Delete the requirement for transportation inspections. This is outside the scope for a manufacturer's QA Program. Transportation inspections are required by other regulations.

8.4
Clarify the requirement pertaining to a test for removable contamination. This is likely to be a redundant requirement that is addressed by other regulations.

10. PACKAGING AND TRANSPORTATION

Delete the requirement for transportation procedures. This is outside the scope for a manufacturer's QA Program. Transportation inspections and shipping reports are required by other regulations.

10.1
Delete the requirement for packaging procedures to include information on transportation and labeling requirements. These are required by other regulations.

10.3
If the device is shipped from a foreign manufacturer's facility on behalf of a domestic distributor or redistributor the applicant cannot comply with any QA Program requirement.

11. DEVIATIONS AND CUSTOMER COMPLAINTS

This is a difficult area that requires more discussion. It is fairly common for customers to submit a complaint by phone but then refrain from sending the device to the manufacturer for evaluation. Perhaps the customer later determines that there was no product defect or malfunction involved. Understandably, the customer is reluctant to rescind the complaint particularly when the actual problem was caused by user error. The customer is unlikely to forward the device for evaluation. The manufacturer will be subject to an unfair disadvantage in a product liability suit if the applicant is required to keep records of unsubstantiated complaints. Plaintiffs require all records related to a product. It is contrary to the right to protect

contrary to the right to protect against self incrimination to be required to keep damaging circumstantial evidence.

It is impossible to audit this requirement. The auditor has no means for knowledge of customer complaints, legitimate or otherwise, to check against to verify compliance. If the requirement cannot be audited it cannot be enforced. This, along with the liability risks, provides great incentive for a manufacturer to refrain from maintaining complaint records.

This is a further reason for the NRC to enforce the requirement for licensees to report equipment defects per 10 CFR Part 21.21 and radiography licensees to report equipment malfunctions per 10 CFR Part 34.30. Reports should be forwarded to the applicant by the NRC. The applicant should be required to respond to these complaints in accordance with QA requirements and to maintain complaint records that can be audited.

The proposed draft represents a risk to manufacturers that fully comply. It should be revised.

D. IMPLEMENTATION

The regulatory guide should be used in the evaluation of QA Programs for the design, fabrication, inspection, testing, maintenance, repair, modification, distribution and redistribution. It should not be only for manufacture, distribution or redistribution.

Thank you for the opportunity to comment on the draft. Please call me at 504/464-9471 or E-Mail via Internet at NSVN23A@Prodigy.com if you have any questions.

Sincerely,

R.D. (Donny) Dicharry
President

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