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Secretary U.S. Nuclear Regulatory Commission Washington DC 20555

Attention: Docketing and Service Branch

Subject: Comments on NRC Proposed Rule for Licenses Radiography and Radiation Safety Requirements

Radiographic Operations

Reference: 10 CFR Parts 34 and 150, RIN 3150-AE07

The following comments are submitted for NRC review.

PART 34--LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

SUBPART A - GENERAL PROVISIONS. 34.3 Definitions.

Comment: Definitions should be added for following terms:

Modification.
This term is referenced in 34.20(b)(3). A definition is needed to clarify if interchangeability of replacement components on devices and associated equipment from the original manufacturer or other manufacturers are permitted.

Defect.
This term is referenced in 34.45(a)(9), 34.73(a). The definition should be consistent with the definition in 10 CFR Part 21. A definition is needed to distinguish a defect from a malfunction.

Malfunction.
This term is inferred in 34.101(a). A definition is needed to distinguish a malfunction from a defect. We feel that a malfunction is any condition that results in the incidents described in 34.101(a).

Associated equipment.
Add collimator and exposure head to the list of example items.

Certifying entity. Replace "Agreement State" with "State".

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# SUBPART B - SPECIFIC LICENSING PROVISIONS 34.13 Specific license for radiography.

- 34.13(e) See comments on 34.43(d) regarding field inspections.
- 34.13(g) The applicant shall designate and identify a Radiation Safety Officer responsible for implementing the licensee's radiation safety program. The Radiation Safety Officer shall meet the qualifications and duties described in 34.42.

Comment: The Radiation Safety Officer should be responsible for managing, not necessarily "implementing", the licensee's radiation safety program. The Radiation Safety Officer qualifications described in 34.42(a) should be revised to specify alternate requirements for individuals who do not meet all the radiographer experience requirements.

Subpart C - Equipment 34.20 Performance requirements for radiography equipment.

34.20(c)(2): This securing system may only be released by means of a deliberate operation on the exposure device.

This is not a new proposal, but it should be Comment: deleted nevertheless. Certain types radiographic operations prohibit or restrict the ability of the radiographer to reach the exposure device after it has been placed in final working location. In such cases, some radiographers may risk hazards by either handling the exposure device after releasing the source or by intentionally defeating automatic securing mechanism. It should be noted that one obvious means to defeat the mechanism be to intentionally refrain from retracting the source fully into the shielded position of the exposure device after the preceding exposure.

Deleting the current requirement will allow the optional use of a system which can remotely release the automatic securing mechanism on the exposure device. This option would not compromise the safety of the system.

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34.20(f) All associated equipment acquired after January 10, 1996, must be labelled to identify that the components have met the requirements of this section."

Comment: The proposed rule should be revised to address concerns regarding (1) labeling of older equipment, (2) selection of components to be labelled and (3) the cost of labeling. Each issue is discussed separately below.

- 1. Labeling of Older Equipment.

  A large amount of associated equipment that meets ANSI N432-1986 and 10 CFR Part 34.26 currently in use is not labelled Compliance can be determined only when equipment is manufactured, not after distribution to users. Therefore, existing used equipment cannot be retroactively labelled or marked to indicate compliance. We are concerned that qualified associated equipment may not be authorized for use.
- Selection of Components to be Marked. Labeling all components would be impractical. For example: labeling or marking control gears, guide tube fittings, outlet nipples, etc. may not be practical despite how critical these items are to safety. Labeling only one component of a piece of equipment may misrepresent the qualification For example, control the equipment. of specific ANSI assembly conduits must meet requirements in order to be labelled. However, conduit compliance is not the only requirement to qualify a control assembly. The issue of which components must be marked should be resolved.

This issue becomes more complicated when considering the affect of replacing a component. For example, a labelled control assembly may not meet the ANSI requirements after one component is replaced with a labelled replacement component from a different manufacturer.

3. Cost of Labeling. We cannot determine the cost to comply with this proposed requirement until this issue is clarified.

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- 34.23 Locking and relocation of radiographic exposure devices, storage containers and source changers.
- 34.23(b) Radiographic exposure devices, source changers, and storage containers, before being moved from one location to another, must have the guide tubes and control cables disconnected, safety plugs or covers applied, locked and physically secured to prevent accidental loss, tampering or removal of licensed material, and must be surveyed to assure that the sealed source is in the shielded position.

Comment: This proposed rule should be revised to exempt instances when the movement is within the restricted area.

### 34.25 Radiation survey instruments.

34.25(a) The licensee shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material is present to make the radiation surveys required by this part and by Part 20 of this chapter. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 Sievert (1 rem) per hour. Survey instruments must be checked for operability before use each day. This may be accomplished by evaluating the instrument response to the previously measured fields at the projection sheath port or the control cable sheath port on a radiographic exposure device.

Comment: The rule should require that the individual who will be using the survey instrument must be the person to perform and record the operability check.

- 34.25(b) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated —

  (1) At intervals not to exceed 6 months and after instrument servicing, except for battery changes;
  - Comment: There are few safety problems associated with survey instruments being somewhat out of calibration. However, performing a calibration often determines when an instrument is malfunctioning. The small cost savings of the proposed rule does not justify the potential safety problem of working with a malfunctioning primary safety instrument.

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34.25(c) The licensee shall maintain records of the results of the instrument calibrations in accordance with 34.65.

Comment: A record of the daily operability check should be required. There are proposed requirements to record the operability and/or daily maintenance inspections of devices and associated equipment, but not for the survey instrument which is the primary safety instrument.

## 34.27 Leak testing and replacement of sealed sources.

34.27(f) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be periodically tested for DU contamination. This test can be performed by the licensee using available test kits or method approved by the Commission or an Agreement State, or the exposure device could be returned to the manufacturer for such testing. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Commission or an Agreement State to perform analysis. This test must be undertaken at intervals not to exceed 12 months and should such testing reveal the presence of DU contamination, the exposure device must be removed from use and arrangements for repair or proper disposal in a facility licensed under 10 CFR Part61 must be made. A record of the DU leak-test must be made in accordance with 34.67.

Comment: We agree with the intent of this proposed rule. Some malfunctions have been caused by excessively worn S-Tubes (but usually caused by weak control assemblies in conjunction with a worn S-Tube). However, the requirements for daily and quarterly equipment inspections should detect any potential malfunction. If a malfunction is detected the device should be returned to an authorized licensee for repair or disposal. This would be less expensive than the proposed rule. Also, the disposal should not be limited to facilities licensed under 10 CFR Part 61.

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- 34.31 Inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers.
- 34.31(a) The licensee shall visually check for obvious defects in radiographic exposure devices, storage containers, associated equipment, and source changers before use each day the equipment is used to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made in accordance with 34.73.
  - Comment: The daily check is generally a combination of visual inspections and operability checks, not just visual inspections. Therefore, the daily checks are intended to detect equipment malfunctions also, not just defects. This should be reflected in the rule.
- 34.31(b) Each licensee shall have a program for inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment and storage containers at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. Records of these inspections and maintenance performed must be made in accordance with 34.73. If defects are found, the equipment must be removed from service until repaired, and a record must be made in accordance with 34.73.
  - Comment: The rule should be revised to reflect that quarterly inspections are intended to detect equipment defects and malfunctions, not just defects. The rule should specify that the record of repairs must be maintained even if the repairs are made by another licensee (e.g. the equipment manufacturer).
- 34.35 Labels, storage, and transportation precautions.
- 34.35(a)(2) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR Part 71, including documentation of the Quality Assurance (QA) program requirements outlined in 71.105.
  - Comment: The QA program requirements described in 71.105 should be included in 34.13 Specific License for Radiography. It is an unnecessary additional

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expense for radiography licensees to obtain separate NRC authorization as a user of radioactive material packages when the packages used are limited to radiography exposure devices and source changers.

#### SUBPART D - RADIATION SAFETY REQUIREMENTS 34.41 Conducting radiographic operations

34.41(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 43(b). The additional qualified individual(s) shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

Comment: We strongly support this proposed rule. The probability that two qualified individuals would willfully and concurrently violate safety requirements is much less than when only one radiographer is working.

## 34.42 Radiation Safety Officer.

34.42(a) The RSO's qualifications must include:

(1) Completion of the training and testing requirements of 34.43(a); and

(2) 2000 hours of documented experience in industrial radiographic operations, with at least 40 hours of formal classroom training with respect to the establishment and maintenance of a radiation protection program.

Comment: The Radiation Safety Officer should be responsible for managing, not necessarily "implementing" the licensee's radiation safety program. The Radiation Safety Officer qualifications should be revised to allow an exemption to be requested by individuals who meet all the training requirements for radiographers in 34.43(a), but may not have 2000 hours of documented experience. The topics required in the 40 hour formal classroom training should be listed. It should consist of all applicable regulations and regulatory guides.

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- 34.42(b) The specific duties of the RSO include, but are not limited to the following:
  - (4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 20.2203; and

Comment: Add "34.101" (Notifications for malfunctions).

Comment: Add (6) Quarterly inspection and maintenance of devices, associated equipment and survey instruments. Perform safety reviews of radiographers and radiographer assistants. Perform quarterly inventory and equipment maintenance inspections.

of should be a description There qualification requirements for individuals that the are designated by the Radiation Safety Officer to perform some of the duties assigned to the Radiation Safety Officer. The proposed rules allow for delegation of some specific duties, such as the determination of an individual's radiation exposure per 34.47(d). Other duties should be allowed to be delegated by the RSO, such as equipment quarterly maintenance inspections and radiographer safety reviews. Duties should not be delegated to an individual who is not fully trained and qualified. The qualification requirements of designees should be equal to the requirements for the RSO for the specific duty that is delegated.

## 34.43 Training.

- 34.43(a)(2) Is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this part.
  - Comment: Mandatory certification will be cost effective to licensees only if the program is actively enforced. Sanctions must be imposed for willful failure to properly perform radiation surveys, and the sanctions must be recognized by all certifying entities. I approve of this proposed rule based on my understanding that the NRC will develop the means to effectively enforce the certification program if the proposed rule is approved.

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34.43(a)(5) Has demonstrated competence in the use of the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments.

Comment: Revise to include demonstrated competence in the daily inspection of devices and associated equipment (not related handling tools), and operability checks of survey instruments. This important requirement is implied in the proposed rules, but it is not specifically identified.

34.43(b)(2) Has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, and radiation survey instruments that the assistant will use.

Comment: See comment on 34.43(a)(5).

34.43(d) The licensee shall conduct an annual inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Commission's regulations, license requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic

operation at intervals not to exceed 12 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than 6 months since the last inspection, the individual's performance must be observed and recorded when the individual next participates in a radiographic operation.

Comment: The proposed reduction in the frequency of field inspections should be deleted. Field inspection is an important element of an enforcement program, it is not part of the training program. Inspections should not be reduced due to proposed increases in individual's training and qualification requirements. Annual inspections will diminish the motivation of some workers. A minimum of semi-annual inspections are required.

I question the proposed requirement to inspect individuals who have not performed radiographic operations for more than six months "the time they next participate in a radiographic operation." This reduces the element of

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surprise. Instead, radiographers should be required to redemonstrate their knowledge of the training requirements of 34.43(a)((6), and radiographer's assistants should be required to redemonstrate their knowledge of the training requirements of 34.43(b)(2) and (3). This is a more reliable means to verify the individual's knowledge and will be less expensive to the licensee when the individual is sent to a remote job site.

34.43(f)(2) Radiation detection instruments including —

(i) Use, operation, calibration, and limitations of radiation survey instruments;

Comment: Revise to include training to perform operability checks.

34.43(f)(3) Equipment to be used including --

Comment: Revise wording to "Use of equipment including --"

The 40 hour formal training is often provided by a third party and cannot be required to provide training in the specific equipment "to be used". The training is often generic in reference to the equipment.

34.43(f)(3)(iii)Maintenance of equipment.

Comment: Revise to "Inspection and maintenance of equipment".

It is rare that a radiographer will be required to perform maintenance, but he/she will be required to preform equipment inspections on a daily basis.

### 34.45 Operating and emergency procedures.

34.45(a) Operating and emergency procedures must include, as a minimum, instructions in at least the following:

(7) The inspection and maintenance of radiographic exposure devices and storage containers;

Comment: Add a requirement for inspection, maintenance and operability checks of survey instruments. This requirement may be implied in the proposed rules, but it is not specifically identified.

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(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by Part 21 of this chapter;

Comment: The rule should be revised to clarify that the procedure(s) for identifying and reporting malfunctions and defects by individuals to the licensee may be different from the licensees requirements to report defects and malfunctions in accordance with 10 CFR Part 21 and 34.101. See comments on 34.101.

(12) Source recovery procedures if licensee will perform source recovery.

Comment: We recommend that the procedures include the following topics; advance preparations, initial response, retrieval planning guidelines, retrieval operation guidelines, and post retrieval tasks.

### 34.47 Personnel monitoring.

34.47(g) Each alarm ratemeter must -(3) Be adequate to alert the individual regardless of the environmental conditions (e.g., high ambient noise levels).

Comment: This requirement will do more harm than good regardless of the cost. It attempts to elevate the perception of reliability of the alarming ratemeter beyond its capability. The continued NRC emphasis on the use of the ratemeter confuses workers regarding the relative importance of the use of the survey instrument as the primary safety device. This proposed rule should be deleted along with the entire existing rule that requires alarming ratemeters. There is mounting scientific evidence that cautions against regulations that reduce the perception of risk to workers by requiring less reliable "redundant" safety devices.

# 34.49 Radiation surveys. The licensee shall:

34.49(d) Conduct an adequate survey with a radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in 34.3) to ensure that the sealed source is in its shielded position.

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Comment:

This should be revised to specify exactly which radiation levels (if any) must be recorded. Verification of compliance with the radiation level requirements specified in 34.21 consists of 12 to 18 radiation measurements (i.e., there is a minimum of six surfaces to be measured at the surface or 50mm and one meter). This seems to be beyond the intent of this rule. We recommend that a survey be required to verify that the source is in its shielded position without the need to record the radiation measu ments at various specific locations around the exposure device. At the most, only one radiation measurement should be required at a specific location identified in the licensees operating and emergency procedures (e.g. at the middle of the right side surface). Performing a survey periodically at exactly the same location should detect unusual radiation levels which may indicate a defect. It should be noted that small differences in survey technique often results in large differences in radiation level measurements.

We agree on the proposal to delete the burdensome requirement to survey the entire circumference of the camera. Our experiments have shown that this is not necessary to verify that the source is properly secured in the device. We note that some NRC overexposure incident reports reflect the claim made by workers that the required survey was performed but failed to detect the high radiation because he/she did not survey the front of the camera. We challenge any such claim. A survey that is performed in any location close around the camera will clearly detect if a source is not properly shielded, even if the source capsule is located slightly inside the DU shield at the outlet port. In all cases, a survey performed at the outlet port of a camera is effective.

34.49(e) Conduct a survey of the storage area to ensure that radiation levels do not exceed the limits specified in 10 CFR 20.1301. These surveys must be performed initially with radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change (i.e.,

Comment: We recommend that licensees be allowed to create a "worst case" situation to establish the shielding capability of the storage area based on initial survey, placement of the radioactive material in

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the storage area, and extrapolation to a maximum allowable content. This will delete the requirement to survey when increases in radioactive material or changes in arrangement of the radioactive material occurs as long as neither change exceeds the predetermined shielding capability of the storage area. The quarterly survey should be retained.

# SUBPART E - RECORDKEEPING REQUIREMENTS 34.65 Records of radiation survey instruments.

Each licensee shall maintain records of the calibrations of its radiation survey instruments and retain each record for 3 years after it is made.

Comment: The licensee should be required to maintain records of the daily operability checks. Inspection records are required for devices, associated equipment and area alarms. It should also be required for the check of the primary safety device. The daily operability check should be performed and recorded by each individual using the survey instrument that day.

# 34.69 Records of quarterly inventory.

34.69(b) The record must include the quantities and kinds of byproduct material (including the model number, the serial number and manufacturer), location of sealed sources, the name of the individual conducting the inventory, and the date of the inventory.

Comment: The inventory record should include all licensed devices, not just those that contain a sealed source at the time of the inventory.

### 34.71 Utilization logs.

34.71(a) Each licensee shall maintain current utilization logs at the address specified in the license, showing for each sealed source the following information:

Comment: The utilization log should include all licensed devices removed from storage, not just those that contain a sealed source at the time.

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- 34.73 Records of inspection and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers.
- 34.73(a) Each licensee shall maintain records of defects found in daily checks and quarterly inspections and maintenance of radiographic exposure devices, storage containers, associated equipment, and source changers, and retain each record for 3 years after it is made.

Comment: The record should include malfunctions also, not just defects. It should also include the inspection records of survey instruments because that is the primary safety device.

- 34.73(b) The record must include the date of check, name of inspector, equipment involved, any defects found, and repairs made.
  - Comment: The rule should require records of maintenance performed, not just repairs. The rule should specify if the licensee is required to maintain records of maintenance and repairs performed by other licensed individuals or only maintenance and repair performed by the licensee. We recommend that the notification requirements in 34.101 and 10 CFR Part 21 be considered in reviewing this requirement.

# 34.83 Records of personnel monitoring.

Comment: Records of daily operability checks of the alarm system at permanent facilities are included in the proposed rule. Records of daily operability checks and quarterly inspections of survey instruments should also be included. Records of operability checks of survey instruments are extremely important to verify compliance of the requirement to perform daily checks. Recordkeeping by the individuals using the survey instrument is also needed to emphasize the importance of the use of the survey instrument as the primary safety device.

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### 34.85 Records of radiation surveys.

Each licensee shall maintain a record of each exposure device survey conducted before placing the device in storage in accordance with 34.49(e) for 3 years after the record is made, if that survey is the last one performed in the work day.

Comment: See comments on 34.49(d).

#### SUBPART F - NOTIFICATIONS 34.101 Notifications.

34.101(a) In addition to the reporting requirements specified in 30.50 and under other sections of this chapter, each licensee shall provide a written report to the U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, DC 20555, with a copy to the Director. Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, 20555, within 30 days of the DC Washington, the following incidents of any of occurrence involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the

control cable:

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position; or

Failure of any component (critical to safe operation of the (3) device) to properly perform its intended function;

The rule should specify the difference between a malfunction that must be reported per 34.101 and a defect that must be reported per 10 CFR Part 21. In most cases it is difficult for a radiography licensee to make a reliable distinction. We feel that radiography licensees should report all of the incidents listed in 34.101(a) as malfunctions. The manufacturers should be required to report defects per 10 CFR Part 21. See comments on 34.45(a)(9).

### APPENDIX A to Part 34 Radiographer Certification

We agree with the comments developed by the G-34 Comment: committee of the Conference of Radiation Control Program Directors (CRCPD). Additional work is needed to address details of the certification requirements. We feel that the most important

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detail is to identify the means for effective enforcement and reciprocal recognition of sanctions (or other means to provide nation wide control). This is one of the main points raised by industry at the NRC workshop held May 27-28, 1992, in Mobile, Alabama.

Overall we are very pleased with the proposed rules. It is obvious that a great deal of work went into the development and preparation of the document.

For future proposed rulemaking, I urge the NRC to publish any applicable draft regulatory guides that may assist in a review of the proposed rule. This is essential during the public comment period if the guidance document explains or effectively establishes regulatory requirements that are not described in the proposed rule.

I hope our comments are useful. Please do not hesitate to contact me for any clarifications or additional information.

R.D. "Donny" Dichary President

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