UNITED STATES
NUCLEAR REGULATORY COMMISSION
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ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION - QUESTIONS AND ANSWERS ON THE NEW PART 20 (SP-92-141)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....XX

OTHER INFORMATION.....

Supplementary information: Enclosed for your information are three sets of questions and answers on the revision to Part 20. These documents are to be used to help clarify the meaning of the new Part 20. The first set of questions and answers were in the 1992 Part 20 training manual. Later revisions of the manual will contain all questions. This information has been made publicly available.

If you have further questions regarding this correspondence, please contact the individual named below.

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Enclosure:
As stated

FIRST SET OF QUESTIONS AND ANSWERS ON THE NEW PART 20

Following are 55 questions concerning the new 10 CFR Part 20 (10 CFR Part 20 Sections 20.1001 - 20.2401) and its implementation. These questions and answers have been compiled primarily for use in training NRC Regional inspection staff members, but they are being made publicly available for information of interested organizations and individuals and to encourage communications between the public and the NRC staff concerning this new rule. Additional questions and answers are being compiled and will be made publicly available at a later date.

The questions included here were provided by individuals and organizations outside the NRC and by individual NRC staff members. Answers to these questions have been prepared by, and reviewed by, NRC staff members in the NRC Offices of Nuclear Regulatory Research, Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, Governmental and Public Affairs (State Programs), and the five NRC Regional Offices. The questions and answers also have been reviewed by a senior attorney in the NRC Office of the General Counsel who participated in the development of the new 10 CFR Part 20.

Additional information about the questions and answers follows:

- Questions and answers are arranged in the order of appearance in Part 20 of the section of Part 20 to which the question appears to be most closely related. Questions on Part 20 itself are followed by questions concerning conforming changes to other parts of the regulations and to regulatory guides.

- The questions are not in numerical order because the number assigned to each question is merely an identifying (accession) number that is being used in an internal NRC database. This number has no relationship to the subject of the question.

- Unless otherwise indicated in an answer, a reference to a Federal Register volume and page number (e.g., 56 FR 23377) refers to a page number in the May 21, 1991 edition of the Federal Register which contained the new Part 20, and related information, on pages 23360-23474.

10 CFR 20.1002 Scope

QUESTION 5: Who is responsible for regulating radium - the State or NRC?

ANSWER: The NRC regulates radium when it is in NRC-licensed uranium or thorium ores (source material, as defined in Part 20) or in tailings or wastes from processing these ores (byproduct material, as defined in Part 20). The control of radium that may be incidental to NRC-licensed operations is evaluated by NRC as required by NEPA. Releases of radium from a site, other than from NRC-licensed material (ores or tailings), may be required to meet State release limits. Also, an NRC licensee may be required to get a State license for the radium in naturally-occurring radioactive material (NORM) if the State requires a license for the use and possession of this material. (References: 20.1001, 20.1002, 20.1003)

10 CFR 20.1003 Definitions

QUESTION 1: If a licensee decides to implement Part 20 in mid-year, how does the licensee treat the annual dose limits? Prorated? Add contributions from beginning of year before the new Part 20 was adopted?

ANSWER: The licensee must define the "year" consistent with the definition in 10 CFR 20.1003. If a licensee intends to implement the revised Part 20 at any time other than the beginning of the year, the licensee must subtract the dose received for the current year prior to the revised Part 20 dose being adopted from the revised Part 20 dose limit. The difference need not be prorated. For example, assume a licensee adopts the new Part 20 on July 1, 1992, and defines its dose year as January 1 - December 31. If the worker had received 1.5 rems between January 1 and June 30, 1992, he or she would have (5 - 1.5) = 3.5 rems available for the remainder of the year. If the worker already has more than 5 rem (e.g., two 3-rem quarters), the licensee must shift the worker to tasks in which the worker will receive no occupational radiation exposure. (Reference: 20.1003)

QUESTION 40: Assume a licensee has defined its compliance year as January 1, 1993 to December 31, 1993. What is the mechanism to change its definition of year? For example, the licensee wants to monitor from January 31, 1994 to January 30, 1995, how should it account for the lost days January 1 - 30, 1994? Is it acceptable to prorate the doses?

ANSWER: No. The question refers to the definition of "year" in 10 CFR 20.1003. The licensee is not allowed to make the one-step change as postulated in the example in the question because, as indicated in the question, that change involves omitting certain days. Omitting days, even with dose proration, is not allowed. However, the license could accomplish the desired change in two steps, one step in each of two consecutive years, that would give a "year" beginning 1/31 of one calendar year and ending 1/30 of the following

year. The first step, using the example, would be a change, at the beginning of 1993, to a "year" of 1/1/93 to 1/30/94 (13 months). The second step would be a change, at the beginning of 1994, to a "year" of 1/31/94 to 1/30/95. This two-step change meets the requirement of "years" that begin in January with no day omitted or duplicated in consecutive years. (Reference: 10 CFR 20.1003)

QUESTION 4: How is the dose from radon considered? What about technologically enhanced radon at a licensed facility? [Note: Technologically enhanced natural radiation sources have been defined as "truly natural sources of radiation... which would not occur (or would be increased by) some technological activity not expressly designed to produce radiation." Reference: T.F. Gesell and H.M. Prichard, Health Physics 28, 361-366, April 1975.]

ANSWER: How the dose from radon is treated depends upon the source of the radon. If the source is NRC-licensed material (mill tailings, which are byproduct material, and ores that are source material), then the dose from radon and its particulate daughters should be included in estimates of doses to workers or to members of the general public (except for 40 CFR Part 190 evaluations which exclude radon). If the source of the radon is from radium that is not licensed or controlled by any agency, then the dose from radon and its daughters is considered background radiation and may be excluded from occupational or public dose estimates, whether there is any technological enhancement of the concentrations or not. Many states are working toward licensing certain materials containing radium and these sources will need to be known to licensees even if they are not the persons licensed by the States. (See defintions of "background radiation," "source material," and "byproduct material" in 10CFR20.1003). (References: 20.1001, 20.1002, 20.1003)

QUESTION 25: Does the definition of a "member of the public" mean "all" individuals? If so why is the exception statement added to the definition?

ANSWER: No. A particular individual can be a "member of the public" at some times and not at others. For example an individual who works at a nuclear power plant and receives an "occupational dose" is not a member of the public while at work, but is a "member of the public" during off-hours at home. (Reference: 20.1003)

QUESTION 57: The definition of a very high radiation area (10 CFR 20.1003) and the requirement for control of access to very high radiation areas specify an absorbed dose of 500 rads in an hour. Is this a deep dose, a shallow dose, or an eye dose?

ANSWER: The 500-rad dose is intended to be a deep dose, evaluated at a tissue depth of 1 cm (1000 mg/cm^2). (References: 20.1003, 20.1602)

10 CFR 20.1008 Implementation

QUESTION 30: If a license condition ties the licensee to a section in the old Part 20 and there is no corresponding section in the new Part 20, does the requirement in the old Part 20 stay in effect after implementation of the new Part 20.

ANSWER: Yes. See 10 CFR 20.1008(e). The license condition that ties the licensee to a section in the old Part 20 "remains in force until there is a technical specification change, license amendment, or a license renewal that modifies or removes this condition." (Reference: 10 CFR 20.1008(e))

QUESTION 58: Before implementing all of the provisions of the new Part 20, would a licensee be in violation of 10 CFR 20.1008(a) if the licensee voluntarily adopted the provisions of 10 CFR 20.1208 for protection of the embryo/fetus?

ANSWER: No, licensees can voluntarily provide protection for the embryo/fetus in accordance with the provisions of 10 CFR 20.1208 before implementing all of the provisions of the new Part 20. However, licensee would have to be clear that they are not "adopting Part 20" because that would require it to be adopted in full. (References: 20.1008(a), 20.1208)

10 CFR 20.1101 Radiation Protection Programs

QUESTION 7: Relative to 20.1101, radiation protection programs, what would a typical radiography licensee have to do beyond what that licensee is doing now?

ANSWER: Ensure that the program was documented and review the program's content and implementation periodically (at least annually). (See Regulatory Guide 10.6 for additional information). If the licensee does not have a radiation protection program, then such a program must be developed. (Reference: 20.1101)

QUESTION 11: Should the Radiation Protection Program be a stand-alone document or can it be the sum of many documents or manuals (e.g., a requirement for HP audits included as part of a QA audit program document)?

ANSWER: Section 20.1101 requires a documented radiation protection program. This documentation does not have to be a stand-alone document but it must be reviewed annually. (Reference: 20.1101)

QUESTION 62: With 10 CFR 20.1101(b) making ALARA a requirement (a "shall" instead of a "should"), does the NRC staff plan or anticipate any significant change in inspection program focus or in enforcement activity with respect to ALARA for occupational exposure at nuclear power plants?

ANSWER: No. In general, the recent performance of the nuclear power reactor industry has been good with respect to efforts to achieve occupational doses

that are ALARA. Collective doses (person-rem) for both PWRs and BWRs have been declining since the early 1980s. The NRC staff is not planning any significant change in the depth or scope of inspections with respect to ALARA and, therefore, no significant change in the inspection program and procedures. NRC headquarters does plan to review all draft notices of violation of 10 CFR 20.1101(b) in order to monitor proposed enforcement actions in this area to ensure that a responsably consistent approach is established. Consistent with current and past policy, the NRC Regional Offices will continue to allocate increased inspection resources (e.g., ALARA team inspections) to inspections of poor ALARA performers. (References: 20.1101(b))

10 CFR 20.1201 Occupational Dose for Adults

QUESTION 2: What are the requirements for including dose from non-NRC-licensed sources (x-rays, accelerators, NORM) as part of occupational dose?

ANSWER: The combined total of the doses from licensed and unlicensed sources (other than background and medical radiation) must be below the Part 20 occupational dose limits. The requirement for inclusion of doses from non-licensed sources is intended to account for occupational doses received while working for activities or with materials that are licensed or controlled by organizations other than the NRC, e.g., states, DOE, etc.. Thus licensees must record and add the doses from non-licensed sources to the doses from licensed sources to obtain the total dose for comparison with the occupational limit. (References: 20.1001, 20.1002, 20.1003, 20.1201)

QUESTION 3: What do you do about hot particles?

ANSWER: Until changed by rulemaking, the dose limits in Part 20 (10 CFR 20.1201(a)(2)) apply. Special rulemaking on "hot particles" is still pending. Until rulemaking is accomplished the NRC will continue handling hot particle enforcement issues in accordance with the stated Enforcement Policy published in the Federal Register (55 FR 31113, 7/31/90) and transmitted to nuclear reactor licensees as Attachment 2 to NRC Information Notice 90-48 (8/2/90). (References: 20.1201, U.S. NRC Enforcement Policy)

QUESTION 6: What if an NRC licensee hires a DOE employee who earlier in the year received an internal exposure of less than 5 rems annual effective dose equivalent, but greater than 5 rems committed effective dose equivalent?

ANSWER: Previous occupational exposures, even those received at an unlicensed DOE facility, count against the limit. If the worker is to be monitored the worker could not be allowed further radiation exposure for the year (except a planned special exposure). (Note: There are also licensed DOE facilities.) (References: 20.1201, 20.2104)

QUESTION 33: What is the dose limit for visitors entering a restricted area (e.g., visitors to a hospital, patients' relatives, escorted tourists)?

ANSWER: Occupational dose limits apply to all individuals who enter a "restricted area." This is also the case under the old Part 20. "Visitors to a hospital, patients' relatives, escorted tourists" who do not enter a restricted area are not subject to the occupational dose limits. Therefore, there is a need to clearly designate the particular areas in a hospital that are "restricted areas." (Reference: 10 CFR 20.1201)

QUESTION 34: What are the applicable radiation limits in a controlled area if the licensee does not allow members of the public to enter the area?

ANSWER: Occupational dose limits apply to individuals who receive an "occupational dose" in a "controlled area." (See definitions of "occupational dose" and "controlled area" in 10 CFR 20.1003.) (References: 10 CFR 20.1003, 20.1301)

QUESTION 41: Licensee A questions a new employee about outside employment. The employee states that he is only working at that facility. After 3 months, the employee starts working, in the evenings, at another licensed facility (Licensee B). The employee does not tell A about B; therefore, Licensee A does not take the exposure received by the employee at facility B into account when he calculates the employees annual total effective dose equivalent (TEDE). Will Licensee A be in noncompliance for not knowing about the dose received by the employee at Licensee B? If licensee A was made aware of the exposure at Licensee B after-the-fact, must Licensee A go back and account for this exposure when calculating TEDE? If Licensee A finds out about the worker's exposure at Licensee B after the year's end, and if the sum of the exposures exceeded the annual limit, is Licensee A obligated to record and report the overexposure and deduct it from the 25 rem lifetime PSE limit?

ANSWER: In order to meet the requirements of 10 CFR 20.1201(f), the licensee must establish some means to have each employee inform the licensee when that employee is receiving occupational dose from sources outside the licensee's control. It is not sufficient merely to ask each employee once (as in the example), with no continuing provision for employee notification. Assuming that Licensee A made no provision for learning of the new employees subsequent concurrent employment in other jobs that resulted in occupational dose, Licensee A would be in noncompliance for not determining the dose received on the job at Licensee B. If Licensee A was made aware of the exposure at Licensee B after-the-fact, Licensee A must go back and account for this exposure when calculating TEDE. If Licensee A finds out about the worker's exposure at Licensee B after year's end, and if the sum of the exposures exceeded the annual limit, Licensee A is obligated to record and report the overexposure and to deduct it from the 25 rem lifetime PSE limit. Although the question and preceding answer are provided in terms of Licensee A's responsibilities with respect to doses received at Licensee B's facility, Licensee B has the same responsibilities with respect to doses received at Licensee A's facility. (Reference: 10 CFR 20.1201)

QUESTION 45: In determining the "eye dose equivalent," can credit be taken for shielding provided by eyeglasses/safety glasses?

ANSWER: Yes. (Reference: 20.1201(a)(i))

QUESTION 46: Will determination of the "eye dose equivalent," at a tissue depth of 300 mg/cm^2, be included in the NVLAP personnel dosimetry accreditation program?

ANSWER: Not until ANSI N13.11, which defines the testing program used in the NVLAP accreditation program, is revised to include tests for the 300 mg/cm^2 depth and this revised standard is adopted by the NVLAP program. (Note: Requirements under the old Part 20 include the determination of the dose to the eye at a tissue depth of 300 mg/cm^2. See Instructions for Preparation of NRC Form 5, Item 5. (Reference: 20.1201(a)(2)(i))

10 CFR 20.1202 Compliance with the Requirements for Summation of External and Internal Doses

QUESTION 9: A licensee monitors a worker for both external and internal exposure under §20.1502, but the internal exposure for the year is less than 10% of the dose limit. Does the licensee add it to the external exposure?

ANSWER: If both internal and external doses were required to be monitored (see 10 CFR 20.1502 for these requirements), then they must be summed. If only the internal or external dose required monitoring, then they don't have to be summed. (References: 20.1202, 20.1502)

QUESTION 38: Can the results of bioassays alone be used to determine if the licensee must sum internal and external doses under Part 20?

ANSWER: No. Summation is required if the licensee is required to monitor for both external and internal doses. The results of bioassays alone cannot be used to determine if the licensee must monitor internal exposures or sum internal and external dose under 10 CFR Part 20. Monitoring for internal is required for adults "likely to receive" in a year an intake greater than 10% of the limit. Determination of what an individual is likely to receive is a prospective assessment of intake. Bioassay is a retrospective assessment of intake. Future intakes are not necessarily the same as past intakes. However, bioassay data may be used together with other information as a basis for the prospective intake assessment. For example, if the uses of radioactive materials in a facility are not going to change significantly and bioassays of individuals employed in the facility have shown that no one has ever received an intake greater than 10%, then one might reasonably conclude that no one is "likely to receive" an intake in excess of 10% of the limit. (Reference: 10 CFR 20.1202)

10 CFR 20.1203 Determination of External Dose from Airborne Radioactive Material

QUESTION 50: Does the footnote to 10 CFR 20.1203 mean that DAC-hours, and not measurements of external dose (using personal dosimeters), should be used for determining worker exposures to noble gases?

ANSWER: No, as clarified in draft Regulatory Guide 8.N8, the preferred method of determining worker exposure to noble gases is by radiation dose measurements using personnel dosimeters. However, such dosimeters may not be capable of measuring the skin dose resulting from certain noble gas radionuclides that emit weak beta radiation (e.g., Xe-133 and Xe-133m). In such cases it is necessary to calculate the skin dose using measurements of the concentrations of these noble gases to which the workers were exposed. (Reference: 20.1203 Footnote)

10 CFR 20.1204 Determination of Internal Exposure

QUESTION 47: Will the NRC provide guidance on the preparation of applications pursuant to 10 CFR 20.1204(c)(2) for approval to adjust DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive materials (e.g., aerosol size distribution or density)?

ANSWER: The NRC staff is considering developing such guidance. Some limited guidance on "adjusting DAC's for particle size" is included in draft Regulatory Guide 8.25, Rev. 1, Section 3.7; however, the staff recognizes that more extensive guidance, including considerations of other physical and chemical characteristics of particles, may be needed. (Reference: 20.1204(c)(2))

10 CFR 20.1206 Planned Special Exposures

QUESTION 8: Under what circumstances are planned special exposures permitted?

ANSWER: The statement of considerations indicates that the intent of the planned special exposure was that it be used infrequently in circumstances where the elimination of the 5(N-18) lifetime cummulative limit might create a severe handicap to the licensee's operation. See Regulatory Guide 8.N6, for further detailed guidance. (Reference: 20.1206)

QUESTION 24: Will consultants or vendors be able to routinely come on site to do jobs under the Planned Special Exposure section of the new Part 20 if their annual exposure becomes limiting?

ANSWER: No. Planned Special Exposures are not to be used "routinely." See definition of Planned Special Exposure in 10 CFR 20.1003 and requirements for Planned Special Exposures in 10 CFR 20.1206. (References: 20.1003, 20.1206)

10 CFR 20.1208 Dose to an Embryo/Fetus

QUESTION 59: How does the U.S. Supreme Court decision in the case of United Auto Workers (UAW) vs Johnson Controls affect the NRC requirement in 10 CFR 20.1208, "Dose to an embryo/fetus," and the guidance in Regulatory Guide 8.13, "Instruction Concerning Prenatal Exposure?"

ANSWER: That decision has no effect on either the requirement or the guide, which are consistent with that decision. (Reference: Letter from Bill M. Morris, NRC/RES, to William E. Morgan, the Boeing Company, August 2, 1991).

For the information of those not familiar with this decision, the Supreme Court in this case overturned a U.S. Court of Appeals decision. In its decision, the Supreme Court responded in the negative to the question, "May an employer exclude a fertile female employee from certain jobs because of its concern for the health of the fetus a woman might conceive?" The court held that Title VII of the Civil Rights Act of 1964, as amended, forbids sex-specific fetal-protection policies. The majority of the court concluded with a very strong statement: "It is no more appropriate for the courts than it is for individual employers to decide whether a woman's reproductive role is more important to herself and her family than her economic role. Congress has left this choice to the woman as hers to make." (References: 20.1208, Regulatory Guide 8.13)

10 CFR 20.1301 Dose Limits for Individual Members of the Public

QUESTION 42: A nuclear medicine technologist becomes contaminated with I-131 as a result of her job in nuclear medicine which results in an internal uptake of iodine. She continues to breast-feed her baby. Is the licensee responsible for controlling the dose to the baby as a member of the public in an unrestricted area? If so, what are the dose limits?

ANSWER:
The licensee is responsible for the licensed material that has internally contaminated the technologist. The limit for a member of the public applies to the baby. (References: 10 CFR 20.1201 and 20.1301)

The licensee is responsible for performing a "survey" to assess the magnitude of the dose to the baby [10 CFR 20.1501(a)].

With respect to the continued breast-feeding of the baby, in the situation described, there are important legal, moral, and ethical considerations (including the rights of the technologist) that are outside the limited scope of 10 CFR Part 20. Both NRC and the licensee would have to address these considerations if such a situation were actually to arise.
(References: 10 CFR 20.1201 and 20.1301)

QUESTION 48: In 10 CFR 20.1301(a)(2), does "...0.002 rem (0.02 mSv) in any one hour" apply to the dose in any single hour or can it apply to the average over a discrete period of time.

ANSWER: The phrase "0.002 rem in any one hour" means a cumulative dose of 0.002 rem in any period of 60 consecutive minutes regardless of the dose rates within that 60-min. period. It does not mean a dose rate, in units of rems per hour, obtained by averaging over a time period greater than, or less than, one hour. (Reference: 20.1301(a)(2))

10 CFR 20.1302 Compliance with Dose Limits for Individual Members of the Public

QUESTION 28: How are annual average concentrations (AAC) to be calculated, and is it acceptable for nuclear power plants to use this AAC in lieu of instantaneous limits (as currently required by the operating license) which are derived from NUREG-0133?

ANSWER: AACs are calculated by multiplying the annual effluent release of individual radionuclides by the annual average atmospheric dispersion factor for the most prevalent downwind sector at the controlled/unrestricted area boundary. The instantaneous limits, on the other hand, are based on a whole body dose limit of 500 mrem/y and a thyroid dose limit of 1500 mrem/y for gaseous releases and Appendix B concentration values for liquid releases. In both cases, the dose rate or concentration values are applied on an instantaneous maximum basis at the boundary of the unrestricted area. Annual average dispersion estimates are used to relate the concentration or dose rate to a release rate, and, ultimately, to an effluent monitor alarm set point. For purposes of maintaining effluent releases ALARA pursuant to 10CFR50, Appendix I, power reactor licensees are restricted by Technical Specifications to the instantaneous limits. To permit effluent releases at levels corresponding to the AAC described above would not enable a licensee to meet the Appendix I design objectives. (Reference: 20.1302(b)(2))

QUESTION 29: If a licensee controls exposure to members of the public using the new Part 20.1302(b)(2) at the boundary of the unrestricted area, how does a licensee insure that members of the public inside the controlled area do not exceed this limit?

ANSWER: Principally by the control of access and, thereby, exposure time, since the licensee can require members of the public to exit the controlled area at any time. (10 CFR 20.1301(b) provides that if a licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals). (Reference: 20.1302)

20.1502 Conditions Requiring Individual Monitoring of Internal and External Occupational Dose

QUESTION 43: The licensee initially was required to monitor internal dose. The results indicate that monitoring is not required, i.e., levels are positive but less than 10% of the allowable limits. Can the measured internal dose values be ignored? If yes, will the licensee be in noncompliance if it sums internal and external doses?

ANSWER: The licensee was required to monitor internal dose [because the licensee had made a prospective determination that the individual(s) was (were) "likely to receive" an intake in excess of 10% of the limits]. The internal dose values cannot be ignored regardless of the fact that they are less than 10% of the limits.

If the licensee was not required to monitor internal dose (because the licensee had made a prospective determination that the doses likely would be less than 10% of the limits), but elected to monitor internal dose anyway, the licensee could choose to "ignore" the measured values that are less than 10% or to add those values to the external doses to obtain the sum of the internal and external doses.

Nothing in Part 20 prohibits the licensee from monitoring or summing internal doses at less than 10% of the limits; therefore, a licensee can never be in noncompliance for summing the internal and external doses. (Reference: 10 CFR 20.1502)

QUESTION 44: During 1993, the licensee performed a prospective dose evaluation, and decided not to measure internal dose. In 1994, the licensee again evaluates the internal dose and finds that the threshold for monitoring is exceeded and begins monitoring. Nothing in the facility (engineering controls or productivity levels) has changed. The licensee accounts for the internal dose contribution when calculating TEDE for 1994. Must the licensee go back and adjust TEDE for 1993?

ANSWER: Yes, the licensee must go back and adjust the TEDE for 1993, based on the best available data. The information included in the question indicates that the 1993 prospective evaluation was in error and that internal dose should have been measured; therefore, this error needs to be corrected. (Reference: 10 CFR 20.1502)

QUESTION 54: Must bioassay be performed for a worker who, without respiratory protection, is likely to receive an intake in excess of the applicable ALI(s) but who is not likely to receive such an intake with respiratory protection.

ANSWER: Yes, as indicated in a Note in the statement of considerations (56 FR 23377), the concentrations to be used (prospectively) for evaluating monitoring thresholds are those of the ambient atmosphere before credit is taken for respiratory protection factors. Routine periodic bioassays for respirator users are required to demonstrate the effectiveness of the licensee's respiratory protection program. (References: 56 FR 23377, 20.1502(b), 20.1703(a)(3)(ii))

10 CFR 20.1602 Control of Access to Very High Radiation Areas

QUESTION 49: For control of access to very high radiation areas, will physical barriers be needed to preclude unauthorized access?

ANSWER: Yes. See draft Regulatory Guide 8.N10. (Reference: 20.1602)

10 CFR 20.1703 Use of Individual Respiratory Protection Equipment

QUESTION 60: In a respiratory protection program what records are needed of evaluations that demonstrate compliance with the requirement for maintaining the total effective dose equivalent ALARA? For example, must such an evaluation be made each time an individual is to don a respirator?

ANSWER: Such records need not be made each time someone is to don a respirator. A licensee who performs and records such evaluations in accordance with the following guidance will be considered to be in compliance with the requirements for such evaluations: (References: 20.1101(b), 20.1703)

1. (a) If the licensee establishes a reasonable threshold value for prospective deep dose equivalent (rem) for an individual from a task/job below which a record of such an evaluation is not needed, and

   (b) the licensee establishes a threshold value for prospective collective deep dose equivalent (person-rem) from a task/job below which the record of such an evaluation is not needed,

   (c) in situations in which the licensee plans to use respiratory protection equipment, the licensee does not need to record such ALARA evaluations for situations in which the projected external dose to any individual is below the thresholds established under 1(a) and 1(b) above for both the projected individual external dose [1(a)] and projected collective external dose [1(b)].

2. If the licensee establishes a threshold value for prospective intake of radioactive material (as a fraction of the ALI or as DAC-hours) for an individual from a task/job below which a record of such an evaluation is not needed, in situations in which respiratory protection equipment is not planned to be used, the licensee does not need to record such ALARA evaluations when the prospective intake is below the threshold.

3. Irrespective of the statements in #1 and #2 above, the licensee does need to perform and record such evaluations for situations to which the ALARA provisions of 10 CFR 20.1703 (b)(1) apply, that is to situations in which it is anticipated that protection factor for the respiratory protection equipment to be provided is less than the multiple by which the peak concentrations of airborne radioactive materials in the working area are expected to exceed the concentrations specified in Appendix B Table 1, Col. 3.

4. Regardless of the magnitude of the projected external dose, the licensee does not need to perform or record such evaluations before requiring the use of respiratory protection equipment as a precautionary measure in situations in which there is a large uncertainty in the magnitude of the projected concentrations of airborne radioactive material to which the workers will be exposed (e.g., a new job with no history of previous similar jobs).

10 CFR 20.1903 Exceptions to Posting Requirements

QUESTION 35: Do posting requirements apply to the hospital room of a hospitalized nuclear medicine patient if the patient received less than 30 mCi and the dose rate at 1 meter is greater than 5 mrem/hr?

ANSWER: No, the hospital room is not required to be posted provided that the provision of §20.1903(b)(2) is also met. (Note that only one of the three conditions in §20.1903(b)(1) needs to be met and that one has been met). (Reference: 10 CFR 20.1903 (b)(1))

10 CFR 20.1906 Procedures for Receiving and Opening Packages

QUESTION 36: Part 20 requires that "labelled packages" be monitored. Is it correct to assume that only packages with White I, Yellow II, or Yellow III labels must be monitored, and that marked packages (LSA or radioactive markings) are not required to be monitored?

ANSWER: Yes. Based on the statement of considerations, it is correct to assume that only packages with DOT White I, Yellow II or Yellow III labels need to be monitored. (Reference: 10 CFR 20.1906(b)(1))

10 CFR 20.2003 Disposal by Release into Sanitary Sewerage

QUESTION 39: Can biological material be defined better in 20.2003? For example, is all organic material biological material? Can animal fats be released to the sewer?

ANSWER: Biological material, in its ordinary meaning, is material pertaining to living organisms (plants or animals). The statement of considerations indicates that ground-up animal carcasses are examples of such material. Animal fats are biological material and, if "dispersible," can be released to the sewer. (Reference: 10 CFR 20.2003(a)(1))

10 CFR 20.2104 Determination of Prior Occupational Dose

QUESTION 10: Why does the revised Part 20 still require Form 4?

ANSWER: Form 4 is used as a cumulative record of exposures at each licensee facility and serves as a mechanism for transmitting data from one licensee to another. Licensees must attempt to obtain the information on lifetime cummulative occupational radiation dose on Form 4, or equivalent, for all

workers requiring monitoring. Licensees must obtain that information for occupational radiation doses received during the current year and prior to permitting a Planned Special Exposure. (See 10 CFR 20.2104.) Form 4 is not transmitted to the NRC. Form 5 is a summary of annual exposure and may have more frequent entries. The data on several previous Form 5's might be used to prepare a summary Form 4. The Form 5 will be provided to the NRC annually for workers in 7 classes of licensed facilities under the new Part 20. (References: 20.2104, 20.2206)

QUESTION 51: Do 10 CFR 20.2104(a), 20.2104(d) and Footnote 4 to 20.2104(d) mean that a licensee must "backfit" effective dose equivalents (EDE) for individuals who were occupationally exposed before implementation of the new Part 20?

ANSWER: No. Such backfitting is not required. However, licensees may, if they so desire, make estimates of the EDE and committed EDE based on the occupational dose records available for this period. (References: 20.2104(a), 20.2104(d), Footnote 4 to 20.2104(d))

QUESTION 55: 10 CFR 20.2104(e)(1) prorates the 5-rem annual limit on the total effective dose equivalent at a rate of 1.25 rems per quarter for each quarter for which records were unavailable but includes no similar provisions for the other annual limits (individual organs, eye, skin, extremities). Is similar proration required for doses covered by the other limits?

ANSWER: Yes. As indicated in the statement of considerations (56 FR 23383, first column), the values for the other limits should be reduced by one quarter for each unreported quarter. (References: 20.1201(f), 20.2104(e)(1))

10 CFR 20.2202 Notification of Incidents

QUESTION 56: Would areas periodically patrolled, but not constantly manned, be considered to fall within the exception in 10 CFR 20.2202(a)(2) and 20.2202(b)(2) for "locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures?" For example, would these exceptions apply "if a hallway or cubicle in the reactor auxiliary becomes an airborne radioactivity area and auxiliary equipment operators make their rounds periodically during their shift?"

ANSWER: No, the exception would not apply to these areas that are "periodically patrolled" or otherwise normally accessible to personnel. However, for nuclear power plants at power, primary containments are examples of "locations where personnel are not normally stationed." (References: 20.2202(a)(2), 20.2202(b)(2))

10 CFR 20 Appendix B ALIs and Concentrations

QUESTION 13: Why was a 2-hour half-life chosen as a time of reference for noble gases or short-lived radionuclides, as used in 10 CFR Part 20, Appendix B and its footnotes?

ANSWER: As indicated in Footnote 2 to Appendix B, the radionuclides that have half-lives of less than 2 hours "might include a significant contribution from external exposure." "Significant contribution from external exposure" in this footnote means that the contribution to the dose equivalent from external irradiation exceeds that from inhalation. Two hours is the half-life value below which the contribution to the dose equivalent from external exposure exceeds that from inhalation for virtually all radionuclides.

A more detailed explanation is provided below. For a given radionuclide, the ratio of the dose from external irradiation to that from internal irradiation (from inhalation) depends on the half-life of the radionuclide, the characteristics of the radiations emitted in the decay of the radionuclide, the physical and chemical properties of the radioactive material containing the radionuclides, and the physiological response of the body to intakes of this material. However, considering the effect of half-life alone, and in general, the value of this ratio increases as the half-life decreases. The Statement from the 1983 Meeting of the ICRP includes the following paragraph:

> In ICRP Publication 30 the values of DAC for occupational exposure to short-lived nuclides (other than isotopes of noble gases) are based on the dose equivalent to organs and tissues as the result of inhalation. The Commission wishes to draw attention to the fact that there is an additional contribution to these dose equivalents from external irradiation. In situations where short-lived materials are widely distributed in the workplace, this additional contribution may be greater than that due to inhalation by a factor that increases from about 1 to 100 as the half-life of the radionuclide decreases from 1 day to 10 min. Such contributions should be assessed as part of the external irradiation.

Actually, for radionuclides with half-lives of roughly 2 hours, the values of this factor fall within the range of about 1 to 10. Thus, for virtually all radionuclides with half-lives less than 2 hours, the value of this factor is greater than one. Values of this factor greater than one were selected as values indicating "a significant contribution from external exposure." (References: Part 20 Appendix B Footnote 2)

QUESTION 23: Will all of the libraries of reference data and the procedures for gamma-ray spectrometry software or appendices that contain 10 CFR Part 20 MPCs have to be changed?

ANSWER: Yes. (Reference: Part 20 Appendix B)

Conforming Changes: 10 CFR Part 19

QUESTION 37: Is it necessary to document that employees have been advised of their annual doses? Is it sufficient to let employees see the results of the monitoring? Does posting doses on a bulletin board in a common area, each month, fulfill this requirement?

ANSWER: See 10 CFR 19.13(a), which has not been revised. The licensee must provide a written report to each worker. The licensee may keep a copy of the report, or other appropriate record, on file to document compliance. (Reference: 10 CFR 19.13)

Conforming Changes: 10 CFR Part 50

QUESTION 14: Are Design Basis Accident criteria (doses) changed by the new Part 20?

ANSWER: No, only those conforming changes included in the Federal Register notice will be effective when the new Part 20 is implemented. Old dose criteria used for Design Basis Accident will retain their original definitions unless they are specifically changed in a licensing action. (References: 10 CFR 50 Appendix A, 10 CFR Part 100)

QUESTION 15: Will the reporting criteria of 10 CFR 50.72 and 50.73 have to be changed?

ANSWER: The necessary changes have been already been made. See "Conforming Amendments," in the May 21, 1991 Federal Register notice on 10 CFR Part 20 et al. (56 FR 23473). Licensee's procedures may have to be changed accordingly. (References: 50.72, 50.73)

QUESTION 16: Will the Emergency Action Levels (EAL) as part of the Emergency Plans have to be changed if based on the old Part 20 methodology?

ANSWER: The EALs are not related to Part 20. Appendix 1 of NUREG-0654 contains the descriptions for the four emergency classifications; unusual event, alert, site area emergency, and general emergency. Example initiating conditions are also found in this appendix. No reference is made to the use or applicability of Part 20 in either the regulations pertinent to emergency classifications nor in the guidance. In the class descriptions, reference is made to EPA protective action guide (PAG) exposure levels.

EPA has revised its PAG manual. EPA recommends the use of committed effective dose equivalent to replace the whole body dose for the plume PAG. The numerical values for the plume PAG remain the same. It is therefore expected that the licensees will have to revise, if necessary, their emergency dose calculation methodology to classify an emergency and recommend protective actions in order to comply with the revised EPA PAG manual. (Reference: 50.47, EPA PAG manual)

QUESTION 17: Will QA Category 1 requirements discussed in Regulatory Guide 1.26 have to be changed due to offsite dose requirements of 0.5 rem being changed to 0.1 rem in the new Part 20?

ANSWER: The new Part 20 does not change the QA Category 1 requirements. The 0.5 rem bench-mark is for design considerations; therefore, it will likely remain the same. (Reference: 10 CFR 50 Appendix B)

QUESTION 20: Pertaining to question 19 below, will 10 CFR 50 Appendix I and Technical Specifications have to be modified to reflect a total effective dose equivalent (TEDE)?

ANSWER: Appendix I, and the corresponding Technical Specifications, will not have to be modified as a result of the new Part 20; however, the staff is considering whether Appendix I design objectives need to be recast as effective dose equivalent. (References: 10 CFR 50 Appendix I, Reactor Technical Specifications)

Conforming Changes: Reactor Technical Specifications

QUESTION 18: For power reactors, the Technical Specification instantaneous release rate limits are based on old Part 20 doses and concentrations (relative to an implied 500 mrem/yr limit). Will changes in the Technical Specifications and ODCMs be required as a result of the explicit 100-mrem/yr limit in the new Part 20?

ANSWER: The instantaneous release rate limits for airborne releases will not be changed because they are imposed on licensees as a control to ensure that licensees meet Appendix I requirements. However, the instantaneous release rates for liquid effluents, to the extent that they directly reference Appendix B concentration values, will need to be changed. The corresponding bases and certain alarm set-points will have to be changed by license amendment. (Reference: Reactor Technical Specifications)

QUESTION 19: Current computer codes, such as LADTAP and GASPAR, calculate individual organ doses for comparison against individual organ dose limits in 10 CFR 50 Appendix I and/or Technical Specifications. Will the codes have to be modified to convert whole body and organ doses to effective dose equivalents?

ANSWER: Appendix I is not changed by the new Part 20. Therefore, until Appendix I is changed, licensees must continue to show compliance with technical specifications based on Appendix I and expressed in terms of organ and whole body doses. (Reference: Reactor Technical Specifications)

QUESTION 52: Since the technical specification "exemptions" for nuclear power reactors already apply to locking of high radiation areas, does this "exemption" continue to apply pursuant to 10 CFR 20.1008(d) if a 45-cm

(18-inch) survey distance is specified (i. technical specifications) versus the rule's 30-cm distance (10 CFR 20.1601(a))?

ANSWER: The provisions of power reactor technical specifications for control of high radiation areas are not "exemptions" from the regulations. They are alternative methods of control provided in accordance with the provisions of 10 CFR 20.203(c)(5). Under the new Part 20 these technical specifications will continue to apply to the control of high radiation areas (but not very high radiation areas) until they are changed. These technical specifications refer to a high radiation area as defined in Part 20. When new Part 20 is implemented, the new definition of a high radiation area, using the 30-cm distance, will apply. Thus to determine the boundaries of the high radiation area, the 30-cm (12-in.) distance will be used. However, within the boundaries of that area the less-restrictive 45-cm (18-in.) distance specified in the technical specifications will be used to determine whether the radiation exposure is less than, equal to, or greater than 1,000 mR/h, the exposure rate used in the technical specifications to define the degree of control required. Changes in the technical specifications to be proposed by the NRC staff will include a change from 45 cm to 30 cm for the specified distance. (References: 20.1601, 20.1602, Reactor Technical Specifications)

QUESTION 61: Will the annual reports that are required by power reactor technical specifications (reports that tabulate occupational exposures greater than 100 mrem/yr according to work and job functions) still be required after the new Part 20 is implemented.

ANSWER: Yes. There are no plans to change this requirement of the Technical Specifications. However, the reports on occupational exposures required by the old Part 20 in 10 CFR 20.407 (statistical summary reports) and 10 CFR 20.403 (termination reports), will no longer be required. These statistical summary and termination reports are being replaced by the new "reports of individual monitoring" required by 10 CFR 20.2206. (Reference: Reactor Technical Specifications, 20.2206)

Conforming Changes: Regulatory Guides

QUESTION 21: Is it time to update Regulatory Guide 1.109 and its corresponding codes due to the updated dose conversion factors in the new Part 20?

ANSWER: Perhaps, but such an update could only be a partial update at this time. The full updating could only occur if and when Appendix I is recast as an effective dose equivalent. The evaluation of whether Appendix I should be changed is currently underway. (Reference: Regulatory Guides)

ENCLOSURE 1

SECOND SET OF QUESTIONS AND ANSWERS ON THE NEW PART 20

Following are questions concerning the new 10 CFR Part 20 (10 CFR Part 20 Sections 20.1001 - 20.2401) and its implementation. These questions and answers have been compiled primarily for use in training NRC Regional inspection staff members, but they are being made publicly available for information of interested organizations and individuals and to encourage communications between the public and the NRC staff concerning this new rule. Additional questions and answers are being compiled and will be made publicly available at a later date.

The questions included here were provided by individuals and organizations outside the NRC and by individual NRC staff members. Answers to these questions have been prepared by, and reviewed by, NRC staff members in the NRC Offices of Nuclear Regulatory Research, Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, Governmental and Public Affairs (State Programs), and the five NRC Regional Offices. The questions and answers also have been reviewed by attorneys in the NRC Office of the General Counsel.

Additional information about the questions and answers follows:

- Questions and answers are arranged in the order of appearance in Part 20 of the section of Part 20 to which the question appears to be most closely related. Questions on Part 20 itself are followed by questions concerning conforming changes to other parts of the regulations and to regulatory guides.

- The questions are not in numerical order because the number assigned to each question is merely an identifying (accession) number that is being used in an internal NRC data base. This number has no relationship to the subject of the question.

- Unless otherwise indicated in an answer, a reference to a Federal Register volume and page number (e.g., 56 FR 23377) refers to a page number in the May 21, 1991 edition of the Federal Register which contained the new Part 20, and related information, on pages 23360-23474.

10 CFR 20.1003 Definitions

QUESTION 66: This question concerns restricted area limitations. At some sites for nuclear power plants the restricted area has been defined as the site boundary. In some areas routine public access was available with the understanding that, should the need arise, public use of these areas could be prohibited. Examples of this type of access include fishing, visitor centers, and farming. This type of use now appears to fall within the intent of the definition of controlled area and therefore, a new restricted area boundary located somewhat nearer the plant must be defined, in places where such uses exist.

The next physical boundary is a single fenced area, roughly corresponding to the security definition of owner controlled area. Station parking is

routinely within this area and access is provided through openings in the single fence which are not continuously guarded. These openings are posted, "No Trespassing." The direct questions involved are:

a. Can this area (single fenced area) qualify as the restricted area boundary?
b. If so, are postings sufficient or would guards be required?
c. If postings are sufficient, what is the acceptable wording for such a posting?

ANSWER: a. Yes, access to this area could be limited so as to meet the definition of a restricted area. However, it should be recognized that the dose received by an individual in a restricted area is an occupational dose that is subject to the occupational dose limits in Subpart C of the new Part 20 (or to the occupational dose limits of 10 CFR 20.101 in the old Part 20) and the requirements in 10 CFR 19.12 on instructions to workers. (See definitions of "restricted area" and "occupational dose.")

b. Although neither posting nor guards are required specifically, access to a restricted area must, by definition, be controlled. In the situation described in the question, access control could be accomplished by posting or use of guards

c. See answer to b. above.

NOTE: This answer also applies to research and test reactors, fuel fabrication plants, and major radioactive materials processors insofar as the conditions described in the question for nuclear power plants apply to these other facilities.

(References: 10 CFR 20.1003, 20.1201, 20.1206, 20.1207, 20.1208, 19.12)

QUESTION 67: This question concerns water approaches to nuclear sites. Several sites for nuclear power plants include portions of navigable lakes or rivers within their licensed exclusion areas. Obviously, the utility does not own these areas. Would such boundaries as defined in our licenses qualify as restricted areas, controlled areas, or unrestricted areas?

ANSWER: The licensee cannot limit access to navigable lakes or rivers (that the licensee does not own); therefore, these bodies of water cannot be part of a restricted area or controlled area and must be considered to be unrestricted areas. However, for the dose calculations for airborne effluents that are required by reactor technical specifications and that are related to 10 CFR 50 Appendix I, doses are not required to be calculated over such bodies of water. (Reference: 10 CFR 20.1003)

QUESTION 74: Dose rates are used to establish posting requirements for radiation areas, high radiation areas, and very high radiation areas. 10 CFR 20.1601(a)(1), "control of access to high radiation areas," refers to a "deep-dose equivalent" in describing when a control device should be provided to reduce radiation doses below 0.1 rem in one hour, thus implying that the "dose equivalent" in the definition of a "high radiation area" is the "deep dose equivalent" [at a tissue depth of 1 cm (1000 mg/cm^2)]. Are the "dose

equivalent" in the definitions of "radiation area" and "high radiation area" and the "dose" in the definition of "very high radiation area" all considered to be at a tissue depth of 1 cm (1000 mg/cm^2)?

ANSWER: Yes. See question 57, also. (References: 10 CFR 20.1003, 20.1601)

10 CFR 20.1004 Units of Radiation Dose

QUESTION 73: Table 1004(b).2 does not include an entry for "cold" neutrons, (e.g., 7 x 10^{-9} MeV neutrons) which are used in experiments at some research reactor facilities. What values of the quality factor, Q, and the fluence per unit dose equivalent should be used for "cold" neutrons?

ANSWER: The values for "thermal neutrons" should be used until the use of other values is approved by the NRC. (Reference: 10 CFR 20.1004 Table 1004(b).2)

10 CFR 20.1008 Implementation

QUESTION 65: The following question concerns OMB approval of the information collection requirements of the new Part 20. Section 20.1008 indicates that licensees shall implement the provisions of all sections of new Part 20 on or before January 1, 1993 and that if a licensee chooses to implement new Part 20 before then, the licensee shall implement all provisions of new Part 20 not otherwise exempted by subsection 20.1008(d). However, section 20.1009 says that the information collection requirements of the new Part 20 will not become effective until OMB approves them. Does this mean that before OMB approval is obtained, a licensee can implement all of the provisions of the new Part 20 except the information c lection requirements?

ANSWER: OMB approval of the information collection requirements of new Part 20 was obtained on January 24, 1992, with the exception of NRC Forms 4 and 5. OMB approval for these forms is expected in the future. (References: 10 CFR 20.1008, 20.1009)

10 CFR 20.1201 Occupational Dose Limits for Adults

QUESTION 31: Are students and volunteers subject to the occupational dose limits? For example, nuclear medicine students, or "candy stripers" that transport nuclear medicine patients or perform volunteer work in a nuclear medicine department.

ANSWER: Occupational dose is defined in new Part 20 as "the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation..." In the question above, the individual's assigned duties do involve exposure to radiation as a necessary feature of those duties; therefore, the students and volunteer are subject to the occupational dose limits. (Reference: 10 CFR 20.1003, 20.1201)

QUESTION 77: Representatives of the nuclear power industry are concerned that the additional terms provided in the revised rule to describe the "real estate" in and around commercial power plants seems to be overlapping. This could lead to confusion. Access to these various areas may also affect the category to which individuals working within these areas are assigned. At nuclear power plants, either the "protected area" or "radiation controlled area" may serve as the "restricted area." Although workers granted unescorted access entering the "protected area" may not be directly monitored for radiation exposure, they must be considered as "occupationally exposed." At least minimal "radiation worker" training is required for these workers consistent with the regulations. "Controlled areas" would typically extend to the "site boundary" or "owner controlled area." Does the NRC staff have any comments on this matter?

ANSWER: Each licensee should carefully document how the licensees local "area" terms correspond to the area terms in 10 CFR Part 20 (restricted, controlled, and unrestricted areas). Under both old and new Part 20, anyone who enters a restricted area is subject to the occupational dose limits and must receive appropriate instructions in accordance with 10 CFR 19.12. Workers can also be occupationally exposed (and, therefore, subject to the occupational dose limits) in controlled and unrestricted areas (i.e., areas outside restricted areas) depending (in accordance with the definition of "occupational dose") on the nature of the work they are doing and regardless of the area they are in outside a "restricted area." (References: 10 CFR 20.1003, 20.1201).

10 CFR 20.1202 Compliance with Requirements for Summation of External and Internal Dose

QUESTION 86: Does the term "per unit intake" in Footnote 1 to §20.1202 refer to one event, or to the entire monitoring period?

ANSWER: The term "per unit intake" does not, by itself, refer to any particular time period. However, §20.1202, to which Footnote 1 refers, provides a comparison to an annual limit, thus, in context, the time period of concern in this footnote is the "year" as defined in 10 CFR 20.1003. (Reference: 10 CFR 20.1202 Footnote 1)

10 CFR 20.1204 Determination of Internal Exposure

QUESTION 76: The Department of Energy (DOE) does not assign a 50-year dose commitment in the year of intake for its workers exposed to internally deposited radioactive material. The internal dose is assigned on an annual basis. Will commercial nuclear power plant licensees be required to assess internal 50-year dose commitment for workers coming from DOE facilities? Some radionuclides encountered at DOE facilities may be beyond the normal assessment methods of commercial nuclear power plants.

ANSWER: The statement that DOE does not assign a 50-year dose commitment in the year of intake is not correct. Although the DOE dose limits are applied to the dose actually received in a year, DOE facilities are required by DOE Order 5480.11 to generate and maintain individual occupational dose records

that include "committed effective dose equivalent from intakes occurring during the year" and "committed dose equivalent to organ and tissue of concern from intakes occurring during the year." DOE Order 5480.11 also requires that records of exposure be made available to the worker upon request of the worker. See related question number 6. (References: 10 CFR 20.1204, DOE Order DOE 5480.11).

QUESTION 83: If a worker who has been exposed to internal sources under Department of Energy Order 5480.11 comes to work at an NRC-licensed facility, will the worker's committed and committed effective dose equivalents need to be calculated for a fifty-year period by the licensee? DOE Order 5480.11 only requires a one-year dose commitment calculation.

ANSWER: See answer to Question 76. DOE Order 5480.11 requires DOE facilities to generate and maintain records of occupational dose including (a) committed effective dose equivalent and (b) committed dose equivalent to organ or tissues of concern, in addition to records of (c) annual effective dose equivalent and (d) annual dose equivalent to organ or tissue of concern. (Reference: 10 CFR 20.1204, 20.2104, DOE Order 5480.11)

10 CFR 20.1206 Planned Special Exposures

QUESTION 63: Must doses received in excess of the limits that were in effect before implementation of the new Part 20 be subtracted from the 25-rem lifetime allowance for planned special exposures to obtain the total remaining dose available for planned special exposures?

ANSWER: Yes. See 10 CFR 20.1206(e), which limits the dose from all planned special exposures and all doses in excess of the limits to five times the annual dose limits in §20.1201(a) during the individual's lifetime.

The following discussion applies to individuals who worked at facilities of NRC licensees. It does not necessarily apply to individuals who worked at other facilities.

The "25-rem lifetime allowance" in the question is five times the annual limit (5 rem) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). Before implementation of the new Part 20 there were separate limits for internal and external exposure. For purposes of complying with "the 25 rem lifetime allowance," a previous intake, in units of MPC-hours, in excess of the old Part 20 limit may be converted to a committed effective dose equivalent, in units of rems, by multiplying by a factor of (1.25 rem/520 MPC-h). Previous whole-body exposures, in units of rem, in excess of the old Part 20 limit may be assumed to be equal to the deep dose equivalent component of the TEDE (in units of rem). For example, if, under the old Part 20, a worker had received a whole-body dose that was 4 rem greater than the applicable limit and had also received an intake that was 100 MPC-hours greater than the applicable limit, the TEDE available for planned special exposures of that worker under the new Part 20 would be [25 - 4 - (100)(1.25/520)] rem, or 20.8 rem.

Although the question refers only to "the 25-rem lifetime allowance" on the

TEDE, the 10 CFR 20.1206(e)(2) lifetime limit (five times the annual limit) also applies to previous over-exposures involving the lens of the eye, the skin, and the extremities. For purposes of complying with 10 CFR 20.1206(e)(2), previous exposures to the lens of the eye in excess of the old Part 20 limits may be assumed to be equal to the previous overexposures to the whole body (because the limit for the whole body applied to the lens of the eye) and a previous overexposure to the skin of the whole body or to an extremity may be assumed to be equal to a corresponding overexposure to the skin of the whole body or to a hand, forearm, foot or ankle, respectively, except that overexposures resulting from beta radiation from hot particles on or near the skin need not be included in the overexposures to the skin or extremities.

Note: For all future planned special exposures, the lifetime limit is applicable to each annual limit listed in 10 CFR 20.1201(a). (References: 10 CFR 20.1201, 20.1206, 20.2104, Technical Specifications)

QUESTION 109: (a) Can a cardiologist who performs both nuclear cardiology and cardiac catheterizations use a planned special exposure (PSE) to perform an emergency cardiac catheterization on the last day of the licensee's monitoring year if his annual exposure as of December 30 is 4.9 rem? It is expected that he will receive greater than 100 mrem during the procedure. (b) Could the same cardiologist perform multiple cardiac catheterizations as PSEs routinely during November and December if his annual exposure as of October 31 is 4.9 rem?

ANSWER: (a) Yes, provided all administrative requirements of 10 CFR 20.1206 are met. (Note, although NRC is not regulating non-byproduct material, NRC still has regulatory authority since the occupational dose has been defined to include exposure from "licensed and unlicensed sources of radiation.") (Reference: 20.1003 and 20.1206) (b) No. 10 CFR 20.1206(a) requires that a PSE be authorized ". . . only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical." Performing routine occupational tasks for two months is not an exceptional situation, so the condition in 10 CFR 20.1206(a) is not met. In short, PSEs cannot be used as a general mechanism to increase the annual dose limit from 5 rem to 10 rem TEDE, for normal situations. Note: The regulations do not prohibit the cardiologist from performing the procedures. If the cardiologist's exposure exceeds the annual limit, it should be treated as an overexposure rather than a PSE. (Reference: 10 CFR 20.1003 and 20.1206)

QUESTION 110: Can a radiography licensee consider an individual's exposure, received during a source retrieval, as a planned special exposure if an approved generic procedure for source retrieval is on file? Assume that this procedure addresses all the administrative and recordkeeping requirements of 10 CFR 20.1206.

ANSWER: Yes, provided it is an exceptional situation when alternatives that might avoid higher exposures are unavailable or are impractical. (Reference 10 CFR 20.1206)

10 CFR 20.1208 Dose to an Embryo/Fetus

QUESTION 84: Can a female worker legally declare pregnancy if she does not yet have documented medical proof?

ANSWER: Yes. The new Part 20 does not require a woman to have "documented medical proof" of pregnancy before declaring pregnancy. (References: 10 CFR 20.1003, 20.1208).

10 CFR 20.1302 Compliance with Dose Limits for Individual Members of the Public

QUESTION 68: This question concerns demonstration of compliance with the dose limits for individual members of the public. Section 20.1302(b) in the revised 10 CFR Part 20 permits the licensee to demonstrate compliance by:

(1) "Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(2) Demonstrating that --
  (i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to §§ 20.1001 - 20.2401; and

  (ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year."

Option (1) above would require the utility to demonstrate compliance within the 100 mrem in a year specified in Section 20.1301 and the limits to a member of the public specified in 40 CFR 190. This option allows for the use of occupancy factors. However, the 10 CFR Part 2 Appendix C - General Statement of Policy and Procedure for NRC Enforcement Actions Conforming Amendments, provides an example of a Severity IV violation based on option '2' above which does not account for occupancy factors.

It can be interpreted that the enforcement examples have been written more conservatively than the rule revision. This unnecessary restriction could severely limit availability of power, particularly at BWRs operating with hydrogen water chemistry, without a corresponding reduction in actual dose to the public. It is requested that these examples of violations be clarified to ensure consistency with the regulation.

ANSWER: The enforcement examples in question are consistent with the corresponding regulations. "Option 2" [10 CFR 20.1301(b)(2)] does not allow for use of occupancy factors other than unity. 10 CFR 20.1302(b)(2)(i) concerns effluent concentrations, which do not involve occupancy, and 10 CFR 20.1302(b)(2)(ii) involves the assumption that an individual is continually present in the area or, in other, words, 10 CFR 20.1302(b)(2)(ii) requires the assumption of an occupancy factor of 1.0. (Reference: 10 CFR 20.1302)

QUESTION 69: This question concerns radioactive effluent concentrations. 10 CFR 20.1302(b)(2) addresses the annual average concentrations, and limits on these concentrations, as they apply to members of the public. The changes published as conforming amendments to Part 2 uniformly address violations to these effluent limits as instantaneous values. While it is clear that significant instantaneous concentrations of these limits constitute a concern to public safety, the description that any release in concentrations above the limits of Appendix B, Table 2 constitutes a Severity Level IV Violation and an instantaneous release exceeding twice the limit of this table constituting a Severity Level III Violation are not consistent with the intent of the rule. It is requested that the descriptions of violations be clarified with respect to the clear intent of the rule that the limits of Appendix B, Table 2 apply to annual average limits.

ANSWER: The examples in the enforcement policy concerning release of radioactive materials to an unrestricted area at concentrations in excess of the limits for members of the public should be understood to refer to the annual average concentrations and not the instantaneous concentrations. There is no requirement in 10 CFR Part 20 based on the instantaneous concentrations (although technical specifications for power reactors do contain such requirements); thus there can be no violation of a Part 20 requirement involving instantaneous concentrations and, therefore, the question of the severity level of the violation, and the examples used for these severity levels, are not relevant. Nevertheless, the subject examples will be clarified in a future revision of the enforcement policy to make it clear that the subject examples refer to the statement concerning annual average concentrations in 10 CFR 20.1302(b)(2)(i). (References: 10 CFR 20.1302(b))

QUESTION 72: Will certain materials licensees (such as teletherapy and brachytherapy licensees) be required to conduct environmental monitoring in unrestricted areas to demonstrate compliance with the new dose limit for individual members of the public?

ANSWER: Yes. The licensee must demonstrate compliance with 10 CFR 20.1301. Licensees must perform radiation surveys in areas adjacent to locations where radioactive materials are used or stored. It is unlikely, however, that a licensee will need to perform effluent or environmental monitoring if it is only licensed for teletherapy and/or brachytherapy. (References: 10 CFR 20.1302, Byproduct Material licenses (medical))

10 CFR 20.1502 Conditions Requiring Individual Monitoring

QUESTION 114: A licensee is required to provide individual monitoring for each occupationally exposed individual who is likely to receive, in a year, a dose in excess of 10% of the applicable limits in 10 CFR 20.1201, 20.1207, or 20.1208. Must a licensee account for the exposure that an individual may receive at another licensee's faci ty, if that worker transfers to another licensed facility during the monitoring year, when determining if it is likely that the individual may exceed 10% of the limits? In addition, if a new employee already has an exposure in excess of 10% of the limits when they start work at the new employer, must the new employer automatically monitor the employee?

ANSWER: No. The licensee is only responsible for evaluating the potential for exposure at its facility. If the licensee makes an evaluation that the dose will not exceed the 10% threshold, the licensee need not record or monitor the dose. If the licensee opts to measure the dose, although its preliminary evaluation shows that it is not necessary and finds that the threshold has been exceeded, it must reevaluate its program and provide monitoring as required. In addition the licensee will need to reconsider the requirements to sum internal and external doses. (Reference: 10 CFR 20.1502)

QUESTION 75: Representatives of the nuclear power industry have expressed a concern regarding 10 CFR 20.1502, which requires licensees to monitor individual internal or external doses for each individual likely to exceed 10% of the applicable annual limit. Licensees are required to maintain records of individuals for whom monitoring was required under §20.1502 [§20.2106(a)]. The handling of internal doses at less than 10% of the limit is of particular interest. Since a licensee cannot predict future exposures at other licensee facilities during the remainder of the year, a question arises regarding summing of doses at these small fractions of the limit if a worker transfers to another licensees during the year. The following procedures have been suggested regarding reporting of internal doses at nuclear power plants that are less than 10% of the limit.

1. At nuclear power plants, an entrance bioassay is typically performed for all incoming radiation workers. Upon departure from the facility, an exit bioassay is typically performed. If no net internal contamination is detectable in the exit bioassay, no internal dose assessment is required. If internal contamination is detected, an assessment will undoubtedly be made. Any positive result above the LLD is available for reporting.

2. Respiratory protection programs are required under §20.1703, to monitor workers to assess intake. Air sampling results and bioassay measurements are acceptable methods to perform this monitoring, with the results used to perform an intake assessment.

3. Therefore, if a worker is monitored for potential internal exposure, data regarding the results of such monitoring will be available and must be recorded. Since these records are available, positive results, above LLD, should be reported to subsequent licensees, even if there is no reason to expect the worker will exceed 10% of the annual internal committed effective dose equivalent limit.

Does the NRC have any objections to this procedure?

ANSWER: No. This procedure for nuclear power plants goes beyond the requirements of the new Part 20 for monitoring, recording, and reporting internal doses to workers. See answer to Question 114. (For example, routine entrance and exit bioassays for all workers are not required by Part 20). However, the procedure is not inconsistent with the Part 20 requirements. (References: 10 CFR 20.1502, 20.2106)

QUESTION 81 (a) Is a licensee required to provide instruction on the procedures for declaring her pregnancy to an occupationally exposed woman if

she does not enter a restricted area? (b) Is it necessary to monitor all (occupationally exposed) declared pregnant women?

ANSWER: (a) There are no provisions in the revised Part 20, or in Part 19, to provide instruction on declarations of pregnancy to women who are occupationally exposed but do not enter a restricted area. It is suggested that the licensee, in accordance with good radiation practice, provide instruction on this topic to all occupationally exposed individuals, regardless of where they receive exposure. (b) No. Only declared pregnant women who are likely to receive in one year from sources external to the body a dose in excess of 0.05 rem (20.1502(a)(2)) or who are likely to receive in one year a committed effective dose equivalent in excess of 0.05 rem from occupational intakes (20.1502(b)(2)). (Reference: 10 CFR 20.1502)

QUESTION 82: Will workers who enter a restricted area and have been determined to require monitoring under §20.1502(a) require monitoring in the controlled area (outside the restricted area)?

ANSWER: Yes, if the workers receive "occupational dose(s)" in the controlled area. (References: 10 CFR 20.1003, 20.1502).

10 CFR 20.1701 Use of Process or other Engineering Controls

QUESTION 90: Can a licensee require its workers to routinely take potassium iodide (KI) when handling large quantities of radioiodine and take credit for the reduction in occupational dose that results from the use of the KI?

ANSWER: No. Requiring the use of KI for this purpose is neither a "process or engineering control...to control the concentration of [radioiodine] in air" (10 CFR 20.1701). Furthermore, because KI blocks uptakes (not intakes), the use of KI for thyroidal blocking cannot be considered to be among the "other controls" required by 10 CFR 20.1702 for limiting intakes. The following cautionary note in NRC Information Notice 88-15 (4/18/88) continues to be applicable under the New Part 20:

> "It is important to stress that the use of potassium iodide is not a substitute for preventive measures; e.g., proper handling techniques, control measures, and emergency procedures that protect the individual from exposure to radioactive material."

A licensee should optimize design and engineering controls, as well as operating procedures, as a means of ensuring that doses from airborne radioiodine are ALARA. However, in situations where KI has been administered following a suspected intake, the licensee may take credit for the protection if bioassays support the effectiveness of the KI in blocking the thyroid.

Finally, although licensees are not authorized to require their employees to routinely take KI when working with radioiodine, nothing in NRC regulations prohibits an individual from taking KI on a purely voluntary basis; however, the NRC does not recommend the voluntary use of KI in this manner.

10 CFR 20.1703 Use of Individual Respiratory Protection Equipment

QUESTION 78: Under §20.1703(d), licensees must notify the NRC Regional Director at least 30 days prior to first using respiratory protection equipment pursuant to §20.1703(a) or (b). All current respiratory protection programs have been documented under the provisions of §20.103(g) which contains equivalent language. Do licensees need to "re-notify" NRC if such notification has already taken place under the "old" Part 20?

ANSWER: Licensees do not need to "re-notify" NRC if such notification has taken place under the old Part 20. (Reference: 10 CFR 20.1703(d)).

10 CFR 20.1902 Posting Requirements

QUESTION 85: In §20.1902, posting of areas is based upon "dose equivalent." Is this "deep," "shallow," "lens of eye," "total effective" or some combination of the above?

ANSWER: These posting requirements are based on the deep dose equivalent for "radiation areas" and "high radiation areas" and the absorbed dose at a tissue depth of 1 cm (1000 mg/cm^2) for "very high radiation areas." See answer to Question 74. (Reference: 10 CFR 20.1003, 20.1902)

QUESTION 27: Do licensees have to post controlled areas (outside the restricted area) as airborne radioactivity areas if derived air concentrations (DAC) are exceeded?

ANSWER: Yes, if the airborne radioactivity is indoors. If the airborne radioactivity is outdoors, the answer depends on the particular situation. In certain situations the licensee may need to identify and delineate an outdoor airborne radioactivity area. For example posting would be required in a small area, accessible to workers, in the immediate vicinity of a vent on the outside of a building, exhausting air containing concentrations of radioactive materials in excess of the DACs specified in Appendix B to 10 CFR Part 20. (References: 10 CFR 20.1003, 20.1902)

QUESTION 53: (a) When a package is properly labeled for transport, shipping papers are still in effect, and a transporter has accepted responsibility for control of the package, do posting and labeling requirements remain in effect while the package is on licensee property outside of the radiologically controlled area?

(b) Does the shipment have to be posted in the protected area?

(c) Does the shipment have to be posted within the owner-controlled area?

(d) Once the transporter has taken control of a package and shipping papers are in effect, is the shipment exempt from posting?

ANSWER: The answer to all four questions is that the posting requirements remain in effect until the transporter has actually taken possession of the package and is starting to transport it. Following are additional responses to three of the four specific questions:

(a) 10 CFR 20.1905(d) exempts this package from the labeling requirements of 10 CFR 20.1904(a).

(b) Whether or not the package is in a "protected area," as defined in 10 CFR 73.2, is not relevant to any requirements in 10 CFR Part 20.

(c) Whether or not the package is in an "owner-controlled area" (or "controlled area" as defined in 10 CFR Part 20) is not relevant to the posting requirements of 10 CFR 20.1902(e).

(References: 10 CFR 20.1902(e), 20.1903, 20.1904(a), 20.1905(d))

10 CFR 20.1906 Procedures for Opening and Receiving Packages

QUESTION 108: Can the surveys of radiographic exposure devices performed under 10 CFR 34.43(b) and (c) be used to show compliance with 10 CFR 20.1906(f)? If so, is it sufficient to document the survey once, to satisfy both requirements?

ANSWER: The survey performed to show compliance with 10 CFR 34.43(c) can be used to show compliance with 10 CFR 20.1906(f). It is sufficient to document the survey results one time.

The survey performed to show compliance with 20 CFR 34.43(b) cannot be used to show compliance with 10 CFR 29.1906(f). The purpose of the survey performed under 10 CFR 20.1906(f) is to ensure that the radioactive source is still properly lodged in its shield after transport. (Reference: 10 CFR 20.1906(f), 34.43(b), and 34.43(c)).

Appendix B

QUESTION 71: The "Class" column of 10 CFR 20 Appendix B covers inhalation, but does not refer to ingestion. When there are two ALIs for ingestion, how do these relate to the "Class," since they really were based upon the f_1 value for gut absorption? (Note: The f_1 value is the fractional uptake from the small intestine to blood).

ANSWER: The ALIs for ingestion do not relate to the "Class," which refers to the retention time in the pulmonary region of the lung. There are two situations for which there are two ALIs for ingestion. One is when the ALI is determined by the non-stochastic dose to an organ. In this case, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses (for example, see ingestion ALI for beryllium-10). The other case (and the case presumably in question) is when different f_1 values were used to calculate the ingestion ALIs. For example, see the entry for cobalt-60, for which the ingestion ALIs are 500 (on the first line) and 200 (on the second line). These ingestion ALI values have no relationship to the corresponding "Class" on the same line (W on the first line and Y on the second line). Rather, as explained in Federal Guidance Report No. 11, these different ingestion ALIs are based on two different f_1 values: f_1 =

0.05 for ALI = 500, and f_1 = 0.3 for ALI = 200. As shown in Federal Guidance Report No. 11, Table 3, f_1 = 0.05 for "oxides, hydroxides and trace inorganic," and f_1 = 0.3 for "organic complexed and other inorganics." For inhalation of cobalt-60, f_1 = 0.05 for both "oxides, hydroxides, halides and nitrates" (class Y), and "all others" (class W).

The following information on Federal Guidance Report No. 11 is provided for those not familiar with this document: The title of this report is "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors of Inhalation, Submersion and Ingestion." The report is subtitled "Derived Guides for Control of Occupational Exposure and Exposure-to-Dose Conversion Factors for General Application, Based on 1987 Federal Radiation Protection Guidance." The report was published by the U.S. Environmental Protection Agency (EPA) as report number EPA-520/1-88-020 on September 1, 1988. The ALI and DAC values in this report are used in Appendix B of the new Part 20.
(References: 10 CFR 20 Appendix B, Federal Guidance Report No. 11).

Reactor Technical Specifications and Materials Licenses

QUESTION 22: Alarm setpoints for many radiation monitors are based on 10 CFR 20 Appendix B concentrations. Will these new changes require numerous ODCM changes, setpoint change requests, and procedure changes?

ANSWER: Separate answers are provided for reactor and materials licensees because these answers are somewhat different.

Reactor Licensees: Alarm setpoints for airborne effluent monitors are not likely to change. These monitors are typically set up to detect an effluent concentration which would yield a whole body dose rate of 500 mrem/y or a thyroid dose rate of 1500 mrem/y (or fraction thereof) in an unrestricted area on an instantaneous basis, as required by the Technical Specifications. Since other limiting conditions are also contained in Technical Specifications to restrict annual doses to the public to much smaller values than those implied above, and since short-term operational flexibility is necessary, it is unlikely that changes would need to be made in the alarm setpoints for airborne effluent monitors.

Alarm setpoints for waterborne effluent monitors are likely to require change, since they are based on 10 CFR 20 Appendix B concentrations, as required by the Technical Specifications. Because Appendix B concentration values differ for many radionuclides between the new and old versions of Part 20, liquid effluent monitor alarm setpoints may have to be changed.

For reactors, the extent of staff involvement and licensee efforts in adjusting and documenting alarm setpoints will depend on whether the licensee has implemented NRR Generic Letter 89-01. (References: 10 CFR 20 Appendix B, Reactor Technical Specifications, NRR Generic Letter 89-01)

Materials Licensees: Area monitor alarm setpoints for most materials licensees that are currently required to conduct continuous air monitoring will in all likelihood require change. This is especially true for those

facilities that handle significant quantities of source and special nuclear material since the new DACs for these types of material are lower or more restrictive than the old MPCs. It should be noted that for commonly occurring thorium-232 (Th-232) and uranium 238 (U-238) in the oxide (insoluble) form, the DACs are lower than the MPCs by factors of 30 and 5, respectively. Similarly, alarm setpoints for both airborne and waterborne releases for most materials licensees would have to be modified. It should also be noted that for airborne releases, the allowable concentrations for insoluble Th-232 and U-238 have been reduced by factors of about 170 and 80, respectively. For waterborne releases, the allowable release concentrations for soluble Th-232 and U-238 have been reduced by factors of about 70 and 130, respectively. For these reasons, it is anticipated that numerous procedural changes will have to be made for licensees handling significant quantities of source and special nuclear material.

QUESTION 79: Many existing reactor Technical Specifications require commercial power plant licensees to provide statistical personnel dose summary to NRC annually. The old Part 20 contained provisions for such reports, but no corresponding requirement carried over to the revised rule. Why?

ANSWER: The statement above confuses Technical Specification requirements with Part 20 Requirements.

Under the old Part 20, power reactor licensees (and other licensees) were required, by Part 20, to submit both annual "statistical summary" reports (in accordance with 10 CFR 20.407) and "termination" reports (in accordance with 10 CFR 20.408). In addition to these two Part 20 reporting requirements, power reactor licensees are required by their Technical Specifications to submit annual reports that include a tabulation of workers receiving exposures greater than 100 mrem/y and their associated collective dose according to work and job functions.

Under the new Part 20, the statistical summary and termination reports of the old Part 20 are eliminated and replaced by a new annual report on the results of individual monitoring of occupational exposure (10 CFR 20.2206). The new Part 20 has no effect on the annual report required by Technical Specifications. There are no plans to change this reporting requirement in the Technical Specifications. (References: 10 CFR 20.2206, Reactor Technical Specifications)

Regulatory Guides

QUESTION 12: How will the new Regulatory Guides be used in determining acceptability of a licensee's implementation of the new Part 20?

ANSWER: In determining the acceptability of a licensee's implementation of the new Part 20, new regulatory guides will be used in the same way existing guides have been used in determining acceptability of a licensee's implementation of the old Part 20 in cases in which there is no licensee commitment to the guide in a license application. As stated in virtually every guide, Regulatory Guides are not regulations and compliance with them is not required, unless the guide has been made a specific condition of a license (a common practice for materials licensees who are licensed by NRC's Offfice

of Nuclear Material Safety and Safeguards). Also, as indicated in every guide, alternatives to methods described in the guide may be acceptable. (Reference: Regulatory Guides)

Other Questions

QUESTION 87: Will the numbering sequence of the new regulation be revised once the "old" Part 20 expires?

ANSWER: No. (Reference: None)

QUESTION 88: Will each NRC region hold orientation meetings for licensees on the new regulation? When and where might these occur?

ANSWER: There are no plans to hold such orientation meetings. However, the NRC is providing "orientation" information by publishing Regulatory Guides and the new vs. old Part 20 comparison in NUREG-1446, by making documented questions and answers on new Part 20 publicly available, by publishing information in the NMSS Newsletter, and by NRC staff participation in [illegible] meetings concerning new Part 20. (Reference: None)

QUESTION 89: Is it possible to obtain copies of revised NRC "inspection modules" for inspection for compliance with the new regulation? How may these be obtained?

ANSWER: All "inspection modules" (inspection procedures in the NRC Inspection Manual) are available from the NRC Public Document Room, 2120 L Street N.W., Lower Level, Washington, DC 20555; Telephone (202) 634-3273. Inspection procedures have not yet been revised to reflect the new Part 20, but will be revised during 1992. (Reference: None)

Corrections and Revisions to First Set of Questions
and Answers on New Part 20 (12/6/91)

10 CFR 20.1003 Definitions

QUESTION 4: The word "without" was inadvertently omitted from the definition of "technologically enhanced natural radiation sources" in the parenthetical note in the question. The corrected definition is as follows: Technologically enhanced natural radiation sources have been defined as "truly natural sources of radiation ... which would not occur without (or would be increased by) some technological activity not expressly designed to produce radiation."

10 CFR 20.1101 Radiation Protection Programs

ANSWER TO QUESTION 62: In the next to last sentence, "responsably" should be "reasonably".

10 CFR 20.1201 Occupational Dose for Adults

ANSWER TO QUESTION 6: The words "If the worker is to be monitored" should be deleted from the second sentence of the answer. Given that the licensee knows that the worker has already received 5 rems committed effective dose equivalent, the corrected answer is as follows: Previous occupational exposures, even those received at an unlicensed DOE facility, count against the limit. The worker could not be allowed further radiation exposure for the year (except a planned special exposure).

ANSWER TO QUESTION 34: In the references, "20.1301" should be "20.1201".

10 CFR 20.1502 Conditions Requiring Individual Monitoring of Internal and External Occupational Dose

ANSWER TO QUESTION 54: The answer originally provided should be deleted and replaced by the following answer:

> A "Note" in the statement of considerations (56 FR 23377, column 2) says that "... the concentrations to be used for evaluating monitoring thresholds are those of the ambient atmosphere before credit is taken for requirement." That note is a conservative assumption that is appropriate if there will be no "further verification" that the assigned respiratory protection factors actually will be achieved. However, if the "surveys and bioassays, as appropriate," required by 10 CFR 20.1703(a)(3)(ii), include reasonable measures to verify that the expected degree of respiratory protection will be achieved, "the concentrations to be used for evaluating monitoring thresholds" may be those that include credit for the protection factors when respirators are to be used. At nuclear power plants, measures to verify that the expected degree of respiratory protection has been achieved include (but

are not limited to) measurements of nasal smears from workers who have used respirators and whole body counting, relatively soon after a job, of one or more workers among a group of workers who wore respiratory protective equipment while working on the job, and periodic whole-body counting (e.g., annually) of all workers who wear respiratory protective equipment. (Reference: 10 CFR 20.1502(b), 20.1703)

ENCLOSURE 1

THIRD SET OF QUESTIONS AND ANSWERS ON THE NEW PART 20

Following are questions concerning the new 10 CFR Part 20 (10 CFR Part 20 Sections 20.1001 - 20.2401) and its implementation. These questions and answers have been compiled primarily for use in training NRC regional inspection staff members, but they are being made publicly available for information of interested organizations and individuals and to encourage communications between the public and the NRC staff concerning this new rule. Additional questions and answers are being compiled and will be made publicly available at a later date.

The questions included here were provided by individuals and organizations outside the NRC and by individual NRC staff members. Answers to these questions have been prepared by, and reviewed by, NRC staff members in the NRC Offices of Nuclear Regulatory Research, Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, and the five NRC Regional Offices. The questions and answers also have been reviewed by attorneys in the NRC Office of the General Counsel.

Additional information about the questions and answers follows:

- Questions and answers are arranged in the order of appearance in Part 20 of the section of Part 20 to which the question appears to be most closely related. Questions on Part 20 itself are followed by questions concerning conforming changes to other parts of the regulations and to regulatory guides.

- The questions are not in numerical order because the number assigned to each question is merely an identification (accession) number that is being used in an internal NRC data base. This number has no relationship to the subject of the question.

- Unless otherwise indicated in an answer, a reference to a Federal Register volume and page number (e.g., 56 FR 23377) refers to a page number in the May 21, 1991 edition of the Federal Register which contained the new Part 20, and related information, on pages 23360-23474.

Third Set of Questions and Answers on New Part 20

10 CFR 20.1003 Definitions

QUESTION 93: In the definition of individual monitoring devices, is there any reason electronic monitoring devices are not mentioned?

ANSWER: No. The particular devices included in this definition are a few examples, not a comprehensive listing, of such devices. (Reference: 10 CFR 20.1003).

QUESTION 94: Why was the "controlled area" defined?

ANSWER: The "controlled area," which is not defined or used in the old Part 20, was defined and used in the new Part 20 to provide regulatory recognition of the existence of such areas and to clarify their regulatory status within the context of 10 CFR Part 20. In a related change, in new Part 20, occupational dose limits no longer apply only in restricted areas, and lower (public) dose limits no longer apply to everyone outside a restricted area. Thus, under the old Part 20, an individual who receives an occupational dose in a controlled area is subject to the same (low) dose limit as a member of the public in that same area. Under the new Part 20, an individual who receives an occupational dose in a controlled area is subject to the occupational dose limits, but a member of the public in the same controlled area is subject to the (lower) dose limits for members of the public. (Reference: 10 CFR 20.1003).

QUESTION 96: (a) The roentgen (R) is not defined or used in the new Part 20; however, many survey instruments and computer records show dose rates in terms of "mR/h" or "R/h." Will these survey instrument face pieces and computer forms have to be changed when new Part 20 is implemented? (b) Most radiation instrumentation is currently calibrated in units of roentgens rather than rads. A roentgen of x- or gamma-radiation in the energy range of 0.1 - 3 MeV produces 0.96 rad in tissue. Will these instruments need to be recalibrated to account for this difference.

ANSWER: (a) No. The survey instruments will not need to be changed. However, 10 CFR 20.2101 requires that the rad and rem (including multiples and subdivisions) be used for records required by Part 20; therefore, records of these survey instrument readings should be in units of rad or rem. For purposes of these records, it may be assumed that one roentgen equals one rem, or a more accurate conversion factor may be used. (b) No. (References: 10 CFR 20.1003, 20.2101).

10 CFR 20.1101 Radiation Protection Programs

QUESTION 99: The following questions concern the relationship of emergency plans for nuclear power plants to 10 CFR 20.1001 ("Purpose") and 10 CFR 20.1101, "Radiation Protection Programs." (a) To what extent do the radiation protection programs need to be established such that during emergency

conditions, the new 10 CFR 20 can be complied with? (b) For example, in order to comply with the new EPA "Manual of Protective Actions For Nuclear Incidents" October 15, 1991, do germanium counting systems need to be established such as to be able to analyze air samples for iodines and particulates, and computer programs to calculate CEDE, so that CEDE can be added to external dose to get TEDE? (c) Do emergency survey/plume chase teams need to wear breathing zone air samplers?

ANSWER: (a) In general, the new Part 20 contains no new requirements that would make changes necessary in existing radiation protection programs as they relate to emergency conditions. 10 CFR 20.1001 includes the sentence, "However nothing in this part shall be construed as limiting actions that may be necessary to protect public health and safety," and the intent of this sentence is discussed in the statement of considerations (56 FR 23365, first column). NRC requirements concerning emergencies at NRC-licensed facilities (i.e., nuclear power plants and fuel-cycle licensees) are contained in 10 CFR Parts 30, 40, 50, and 70, and no conforming changes to these requirements were needed as a result of the new Part 20. (b) and (c) See answer to (a). With regard to the offsite emergency workers such as fire fighters, law enforcement officers, civil defense workers and environmental field team members, the EPA manual provides guidance given in Table 2-2 titled "Guidance on Dose Limits for Workers Performing Emergency Services." In addition to the refinements in the dose limits, the revised EPA Manual uses the CEDE and the TEDE concept. There are no changes necessary with respect to the monitoring of the external exposure levels of these workers in the early phase of an accident except as noted in the referenced table. The question is, therefore, how to account for the inhalation dose of offsite emergency workers to prevent them from exceeding their limits. Due to the urgency of offsite response in the early phase of an accident, it will not be practical to set up air samplers at numerous locations and analyze those samples in a timely manner. Air samples and radiation measurements taken by the field monitoring teams will be valuable to determine the dose to emergency workers after the fact, but will be of little value during the actual performance of emergency tasks, since some form of real time exposure rate indication is needed. To create this real time indication, a correction factor can be developed that when multiplied by the emergency worker's dosimeter reading can provide a conservative estimate of the inhalation dose. The NRC and FEMA are currently investigating this issue. After appropriate review the NRC and FEMA will provide guidance for offsite agencies to use. (References: 10 CFR 20.1001, 20.1101)

QUESTION 118: 10 CFR 20.1101(c) requires that each licensee "periodically (at least annually) review the radiation program content and implementation." A nuclear power plant has many reviews and audits (including quality assurance audits) of various aspects of their radiation protection programs during a year and reviews are on a schedule that covers all phases of the program on a 2-3-year review cycle. Is this acceptable to the NRC?

ANSWER: Yes, provided that the combination of these reviews and audits covers program content and implementation. Reviews and audits at nuclear power plants should incorporate the following features to assess procedural compliance, technical performance, implementation, and effectiveness of the

facility radiation protection program.

- Radiation protection supervisory reviews

  Onsite radiation protection supervisors should periodically perform and document reviews of the effectiveness of the radiation protection staff in such areas as radiological work practices, work monitoring, procedural compliance, and survey adequacy.

- Quality assurance audits

  Quality assurance audits should be performed by the onsite auditing group. Personnel in the auditing group should have sufficient radiation protection training or experience so they can determine whether radiation protection functions are being performed as required. The quality assurance program audits should meet the requirements of Appendix B to 10 CFR Part 50.

- Corporate or contract audits

  Offsite (corporate or contract) audits and evaluations should be performed to determine whether the radiation protection program complies with the regulations and other requirements and whether plant-wide objectives are being met as well as to identify needed program improvements. (Reference: 10 CFR 20.1101)

10 CFR 20.1201 Occupational Dose Limits for Adults

QUESTION 97: 10 CFR 20.1201(b) refers to "doses received during accidents, emergencies, and ..." Is there any difference between an "accident" and an "emergency"?

ANSWER: Yes. An accident is an unexpected and undesirable event. An emergency is a situation or occurrence of a serious nature, developing suddenly and unexpectedly, and demanding immediate action. Thus an accident usually results in an emergency, but it is possible to have an emergency without an accident (e.g., action taken in an emergency may prevent an accident). In either case, licensees must account for doses received in excess of the annual limits in either an accident or an emergency, or both, in accordance with 10 CFR 20.1201(b). (Reference: 10 CFR 20.1201(b)).

QUESTION 100: (a) Is any special TLD monitoring of eye dose equivalent required? (b) Do TLDs for eye dose measurement need to be physically located near the eye?

ANSWER: (a) Individual monitoring of the dose equivalent to the lens of the eye is required if the eye dose is likely to exceed, in a year, 1.5 rem (10% of 15 rem) for an adult or 0.15 rem (10% of 1.5 rem) for a minor. Licensees may use any form of monitoring that is capable of measuring these doses. (b) The answer to this question depends on the conditions of exposure. In most cases a licensee will not have to physically place a TLD near the eye.

However, there may be unusual exposure situations (such as exposure of the eye to a narrow beam of radiation) that would make it necessary to place a dosimeter near the eye. [Note: See answers to related questions 45 and 46.] (References: 10 CFR 20.1003, 20.1201, 20.1502).

QUESTION 123: In 10 CFR 20.1201(a)(1) does "annual limit" for dose(s) mean the limit on doses received in a "year" as defined in 10 CFR 20.1003?

ANSWER: Yes. (References: 10 CFR 20.1201, 20.1003)

10 CFR 20.1202 Compliance with Requirements for Summation of External and Internal Doses

QUESTION 101: 10 CFR 20.1202(d) requires licensees to evaluate and, to the extent practical, account for intakes through wounds or skin absorption. What type of "evaluation" is appropriate for determining absorption through the skin from skin contamination, and at what "practical level" should it be accounted for? For what nuclides, using what criteria can absorption be neglected under a certain threshold, such as less than 10K, 100K of skin contamination?

ANSWER: The requirement to evaluate and account for intakes through wounds or skin absorption is not new. The old Part 20 has a similar requirements [10 CFR 20.103(a)(1)]. Therefore, the "type of evaluation" that has been used before, if adequate, can continue to be used. The statement in the old Part 20 (10 CFR 20.103, footnote 4) that such intakes should "be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances" continues to be appropriate guidance for the new Part 20. (Reference: 10 CFR 20.1202(d)).

10 CFR 20.1204 Determination of Internal Exposure

QUESTION 121: 10 CFR 20.1204(g) provides that when a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in section 20.1201 and if certain other conditions are met. How can a licensee both disregard certain radionuclides and use the total activity?

ANSWER: The term "total activity" in this section refers to "gross activity" measurements that are correlated with other measurements of individual radionuclides. For example, "gross beta" measurements of air samples might be used for determining intakes of a mixture of beta-emitting radionuclides when (a) gamma-ray spectrometry of representative air samples has identified radionuclides that account for more than 70% of the activity in the air samples (i.e, the percentage of radionuclides disregarded does not exceed 30%) and (b) the concentration of any radionuclide disregarded is less than 10% of its DAC. (Reference: 10 CFR 20.1204)

10 CFR 20.1208 Dose to an Embryo/Fetus

QUESTION 120: Would a licensee be found to be in noncompliance with the limit for the dose to an embryo/fetus if, at the time the woman declared her pregnancy, the dose to the embryo/fetus exceeded 0.5 rem and the embryo/fetus subsequently received more than 0.05 rem from licensed material that was in the body of the woman before she declared her pregnancy.

ANSWER: No. The intent of 10 CFR 20.1208(d) is that the licensee should not be in violation of the limit for the embryo/fetus as a result of doses received by the embryo/fetus before the woman declared her pregnancy or doses received as a result of intakes before that declaration was made. (Reference: 10 CFR 20.1208)

10 CFR 20.1301 Dose Limits for Individual Members of the Public

QUESTION 105: How should demonstration be made of compliance with the 2 mrem in an hour limit [10 CFR 20.1301(a)(2)]? Is it adequate, for a nuclear power plant, to demonstrate compliance by having effluent control (trip) systems that prevent effluent releases from exceeding the limits on the instantaneous release rates, and by performing periodic surveys during radioactive material storage and movements?

ANSWER: The 2 mrem in an hour limit is not new; it appears in the old Part 20 in 10 CFR 20.105(b)(1). Therefore, methods for complying with this limit that have been acceptable in the past will continue to be acceptable under the new Part 20. The 2 mrem in an hour limit applies to doses in an unrestricted area from radiation sources located either inside or outside of that unrestricted area. Therefore, compliance can be achieved by a reasonable combination of appropriate controls, surveys, and monitoring of sources, and potential sources. Such controls, surveys and monitoring are not necessarily limited to the "effluent control trip system" and "periodic surveys during radioactive material storage and movements" that are stated in the question. For example, controls and surveys related to increased turbine shine at BWRs as a result of hydrogen water chemistry must be included. (Reference: 10 CFR 20.1301)

QUESTION 106: (a) Are there no limits on airborne radioactivity concentrations in the controlled area, other than de facto limits for public dose to keep dose rates less than 2 mrem in an hour? (b) Would stack effluents creating temporary airborne radioactivity concentrations greater than DAC levels in the controlled areas be allowed, as long as the public dose criteria of 10 CFR 20.1301 are met? (c) It appears that these areas would not need to be "posted" or controlled, since there are not any 10 CFR Part 20 airborne radioactivity concentration limits for controlled areas. Is this correct?

ANSWER: (a) There are no limits on concentrations of airborne radioactive materials in controlled areas that are expressed in terms of concentrations. However, both the occupational dose limits (for individuals who receive an occupational dose in a controlled area) and the dose limits for an individual member of the public (when in a controlled area) indirectly limit the

concentrations of radioactive material in controlled areas. Note that for members of the public the 100 mrem in a year limit applies. The 2 mrem in an hour limit does not apply in a controlled area. This limit applies only in an unrestricted area. (b) Yes. (c) There may be "airborne radioactivity areas" within controlled areas that need to be posted. See answer to question #27. (Reference: 10 CFR 20.1301, 20.1201)

QUESTION 111: Section 20.105(a) of 10 CFR Part 20 provides for Commission authorization of radiation levels in unrestricted areas based on a criterion of 500 millirems in one year to an individual in such areas. Does such an authorization for radiation levels in an unrestricted area that could result in a dose to a member of the public in excess of 100 millirems in a year continue under 10 CFR 20.1301(c)? In other words is this considered an "exemption" as covered in 10 CFR 20.1008(d)?

ANSWER: No and No. The nature of the information requested under 20.1301(c) is different from that requested under 20.105(a) in that 20.1301(c) requires a demonstration of need for the proposed dose limit and procedures for maintaining doses ALARA. It may be appropriate for an applicant to refer to information submitted under 20.105(a) as part of an application submitted under 10.1301(c). (References: 10 CFR 20.1301(c), 20.1008(d), and 20.105(a))

QUESTION 125: 10 CFR 20.1301(a)(2) requires that the "dose" in any unrestricted area from external sources not exceed 2 mrem in any one hour. Which of the many "doses" in new Part 20 is "the dose" in §20.1301(a)(2).

ANSWER: The "dose" from external sources in 10 CFR 20.1301(a)(2) means the deep dose equivalent or the eye dose equivalent or the shallow dose equivalent. See definitions of these dose terms in 10 CFR 20.1003. (References: 10 CFR 20.1301, 20.1003).

10 CFR 20.1302 Compliance with Dose Limits for Individual Members of the Public

QUESTION 102: Under 10 CFR 20.1302(b)(2)(ii), (a) do the words, "If an individual were continually present in an unrestricted area," mean that under these provisions it should be assumed a hypothetical individual is there, or (b) should occupancy studies be made in applying this section?

ANSWER: (a) Yes. (b) No. Supplemental response: Although this question came from a nuclear power plant, it seems unlikely that a nuclear power plant would choose to use this option [10 CFR 20.1302(b)(2)], with its conservative assumptions, to demonstrate compliance with the annual dose limit in 10 CFR 20.1301(a)(1). It seems more likely that a nuclear power plant would prefer to use the option of 10 CFR 20.1302(b)(1) which does not involve the conservative assumptions (effluent concentrations "at the boundary of the unrestricted area" and an "individual...continuously present in an unrestricted area"). Nuclear power plants and other uranium fuel cycle facilities must meet the more restrictive public dose limits of 40 CFR 190. As noted in the statement of considerations (56 FR 23374, third column), demonstration of compliance with the limits of 40 CFR 190 will be considered

to demonstrate compliance with the 0.1-rem annual limit of 10 CFR 20.1301(a)(1) for most facilities. This demonstration of compliance would be consistent with the option of 10 CFR 20.1302(b)(1). See related question and answer #68. (Reference: 10 CFR 20.1302).

QUESTION 103: 10 CFR 20.1302(b)(2)(ii) refers to "the dose from external sources." (a) What are "external sources"? (b) Are both (1) shine from the facility or from stored contaminated materials and sources, as well as (2) cloud shine from effluents to be included?

ANSWER: (a) "External sources" are radiation sources outside the body. (b) Yes. (Reference: 10 CFR 20.1302).

QUESTION 104: 10 CFR 20.1302 provides two options for demonstrating compliance with the annual dose limit, in 10 CFR 20.1301, for members of the public. How does 10 CFR 20.1302(b)(2), the second option, provide demonstration of compliance with the annual dose limit for members of the public who are in a controlled area?

ANSWER: It doesn't. This second option applies to members of the public in unrestricted areas and a controlled area is not an unrestricted area. However, it would be acceptable to demonstrate compliance with the annual dose limit for members of the public in a controlled area [10 CFR 20.1301(a) and (b)] by applying the effluent concentration criteria of 10 CFR 20.1302(b)(2)(i) and the external dose criterion of 10 CFR 20.1302(b)(2)(ii) to the controlled area, rather than to the restricted area. (References: 10 CFR 20.1003, 20.1302).

10 CFR 20.1502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

QUESTION 98: The following questions concern the requirements of 10 CFR 20.1502 as applied to nuclear power plants.

(a) Since the nuclear power industry has had few (if any) intakes approaching the 10% criteria for adding internal and external doses, is the historical record of intakes plus the establishment of a corporate (licensee) policy to limit intakes to less than 10% of an ALI sufficient to exclude a nuclear power licensee from the requirements for "monitoring" intakes (10 CFR 20.1502) and adding internal and external (except for specific intake instances)?

(b) Will the apparent new practice of minimizing TEDE and allowing some intakes invalidate this historical basis and essentially require nuclear power licensees to "monitor" intakes?

(c) In determining whether a worker is likely to exceed the 10% criteria, on what basis are projections to be made of the future intake of contract workers (for the remainder of the year after they leave our site)?

ANSWER: (a) Yes, assuming that the conditions of exposure are not expected to change to the extent that they are outside the bounds of that historical record and that procedures will be put into effect to implement the policy. (However, "surveys", in accordance with 10 CFR 20.1501(a), would still be needed.) (b) Not likely. However, the resulting potential increase in intakes will need to be considered in determining whether or not workers are likely to receive intakes in excess of 10% of an ALI. The historical record should be useful in evaluating this potential increase. (c) Such projections are not required. As indicated in draft Regulatory Guide DG-8010 ("Criteria for Monitoring and Methods for Summation of Internal and External Occupational Doses"), each licensee makes the determination independently; doses that may have been received, or that may be received in the future, at another licensee's facility are not included in the determination of the monitoring requirement. (Reference: 10 CFR 20.1502).

QUESTION 114: A licensee is required to provide individual monitoring for each occupationally exposed individual who is likely to receive, in a year, a dose in excess of 10% of the applicable limits in 10 CFR 20.1201, 20.1207, or 20.1208. Must a licensee account for the exposure that an individual may receive at another licensee's facility, if that worker transfers to another licensed facility during the monitoring year, when determining if it is likely that the individual may exceed 10% of the limits? In addition, if a new employee already has an exposure in excess of 10% of the limits when they start work at the new employer, must the new employer automatically monitor the employee?

ANSWER: No. The licensee is only responsible for evaluating the potential for exposure at its facility. If the licensee makes an evaluation that the dose will not exceed the 10% threshold, the licensee need not record or monitor the dose. If the licensee opts to measure the dose, although their preliminary evaluation shows that it is not necessary and finds that the threshold has been exceeded, it must reevaluate its program and provide monitoring as required. In addition the licensee will need to reconsider the requirements to sum internal and external doses. (Reference: 10 CFR 20.1502)

10 CFR 20.1602 Control of Access to Very High Radiation Areas

QUESTION 92: At power reactor facilities, when the reactor is at power, very high radiation areas (due to neutron and N-16 gamma radiation fields) can exist inside the primary containment. At some facilities, these areas inside containment are not readily locked, without substantial plant modifications to make them lockable. In recognition of this situation, the following controls are planned to meet the requirements of 10 CFR 20.1602 as it relates to a PWR or de-inerted BWR containment at power: When the reactor is at power and entry is not required, the primary containment access hatch (and any other access way) will be locked and posted as a very high radiation area. The key control access and special radiation work permit for entry will be in accordance with, or provide protection equivalent to, the guidance in draft Regulatory Guide DG-8006. When the reactor is at power, and entry is required, a qualified (in accordance with the applicable ANSI standard)

radiation protection technician will accompany and provide continuous job coverage to each (small) group of workers assigned to perform a particular task (e.g., surveillance).

Do the preceding controls meet the intent of 10 CFR 20.1602?

ANSWER: Yes. The controls outlined are an example of one way (but not the only way) to comply with 10 CFR 20.1602 in this situation. (References: 10 CFR 20.1003, 20.1602).

10 CFR 20.1701 Use of Process and Other Engineering Controls

QUESTION 115: The words, "e.g., containment or ventilation," have been added to 10 CFR 20.1701. Does this mean that increased emphasis is being placed on glove bags to do valve replacements, repacks, etc. at nuclear power plants?

ANSWER: No. These words were added simply to provide examples of "process or other engineering controls." (Reference: 10 CFR 20.1701)

10 CFR 20.1703 Use of Individual Respiratory Protective Equipment

QUESTION 91: As long as no credit is taken for the protection provided by the respiratory protection equipment, the old Part 20, in 10 CFR 20.103(c), allows licensees to use this equipment without meeting the requirements of 10 CFR 20.103(c)(1) through 20.103(c)(4), inclusive. Has this "loophole" in the old Part 20 been closed in the new Part 20?

ANSWER: Yes. 10 CFR 20.1703(a), which contains requirements similar to those in 10 CFR 20.103(c), imposes these requirements "if a licensee uses respiratory protection equipment to limit intakes," regardless of whether or not the licensee makes "allowance for this use of respiratory protective equipment in estimating exposures of individuals..." (Reference: 10 CFR 20.1703)

QUESTION 124: Do the requirements of 10 CFR 20.1703(a) apply to respiratory protection equipment that is to be used only in emergencies?

ANSWER: Yes, if that equipment is to be used to limit intakes of radioactive material. (Reference: 10 CFR 20.1703)

10 CFR 20.2101 Records, General Provisions

QUESTION 116: 10 CFR 20.2101(b) requires the licensee to make a clear distinction among the dose quantities entered on the records and gives examples of the following different dose quantities: total effective dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, committed effective dose equivalent. Does this mean (for example) that the dose rates measured during surveys of external radiation fields must be recorded in terms of one of these dose quantities or (as another example)

that the results of air sampling must be recorded in terms of one of these quantities?

ANSWER: No. The examples given refer to dose quantities used for doses to individuals, not to dose (or activity) quantities used in surveys of areas. (Reference: 10 CFR 20.2101)

QUESTION 117: Does the requirement of 10 CFR 20.2101(a) to use the unit curie (for activity) mean that it will not be permissible to record the results of contamination surveys in units of disintegrations per minute (dpm) or mrad smearable?

ANSWER: No. The 10 CFR 20.2101(a) requirement as it applies to units of activity (curies) is intended to apply to records of quantities of material directly related to the explicit requirements of Part 20 (e.g., storage and control, posting and labeling, waste disposal, concentrations in air, and individual intakes of radioactive material). It is not intended to apply to surveys for contamination. (Note: There are requirements in 10 CFR 35.70(h), which applies to medical licensees, to record the results of surveys for removable contamination as disintegrations per minute per 100 square centimeters.) (Reference: 10 CFR 20.2101)

10 CFR 20.2104 Determination of Prior Occupational Dose

QUESTION 113: If an NRC licensee employs an individual formerly employed at a DOE lab and that individual's DOE lab dose record shows a CEDE of more than 5 rems (but within DOE limits) must the NRC licensee consider this an overexposure and reduce this individual's planned special exposure allowance accordingly?

ANSWER: No. The "limits" referenced in 20.2104(a)(2) and 20.1206(e) are the limits in effect and applicable to the individual at the time of the exposure. It should be noted that if the 5 rem CEDE was received during the current year, this individual would not be allowed any further exposure for the balance of the year. (References: 20.2104 and 20.1206(e)).

10 CFR 20.2105 Records of Planned Special Exposures

QUESTION 112: A licensee authorizes a "planned special exposure" in accordance with 10 CFR 20.1206 and the doses to the involved individuals are fortuitously much lower than anticipated. In retrospect, a planned special exposure authorization was unnecessary. May the doses be assigned as "routine" doses on the Form 5 rather than recorded as planned special exposure doses?

ANSWER: No. Following a planned special exposure, the individual doses must be recorded in accordance with 10 CFR 20.2105 (no matter how small) and may not be recorded as routine doses on the Form 5. (References: 10 CFR 20.1206 and 20.2105).

10 CFR 20.2203 Reports of Exposures, Radiation Levels, etc.

QUESTION 122: The conforming amendment to 10 CFR 50.73(a)(2) states that reports submitted in accordance with 10 CFR 50.73(a)(2)(viii) also meet the effluent release reporting requirements of 10 CFR 20.2203(a)(3). However, 10 CFR 20.2203(a)(3) requires reporting of concentrations in an unrestricted area of 10 times any applicable limit in Part 20 while 10 CFR 50.73(a)(2)(viii) requires reports of airborne or liquid effluent releases that exceed 20 times the applicable concentration limits in Table 2, Appendix B. Why is the multiple ten in one case and twenty in the other?

ANSWER: The two reporting requirements are consistent in terms of public dose. The annual dose limit for a member of the public is 100 mrem. 10 CFR 20.2203(a)(3) requires reporting above a threshold of ten times this applicable limit, or 1000 mrem. The concentrations in Table 2, Appendix B, correspond to an annual dose of 50 mrem; therefore, the requirement in 10 CFR 50.73(a)(2)(viii) for reporting at 20 times these concentrations corresponds to a reporting threshold in terms of annual dose, of 20 x 50 mrem, or 1000 mrem, which is the same dose threshold as that in 10 CFR 20.2203(a)(3). (References: 10 CFR 20.2203, 50.73)

10 CFR Part 19

QUESTION 95: 10 CFR 19.12 requires training (instruction) of workers who enter a restricted area. Do individuals receiving occupational doses in controlled areas need training?

ANSWER: Yes. They need training, but it is not specifically required by 10 CFR 19.12 since this section addresses only individuals working in or frequenting any portion of a restricted area. The obvious intent of the training (instruction) requirement of Part 19 is that individuals who are permitted to receive occupational doses within the occupational limits will receive appropriate training. Although not explicitly stated in 10 CFR Parts 19 or 20, individuals who are to receive an occupational dose in any area should receive appropriate training. (Reference: 10 CFR 19.12).

ENCLOSURE 2

Question 54 was included in the first set of questions and answers on new Part 20 (12/6/91). A revised answer to Question 54 was included with the second set of questions and answers on new Part 20 (4/17/92). The answer has been revised again. The question and revised answer are as follows:

20.1502 Conditions Requiring Individual Monitoring of Internal and External Occupational Dose

Question 54: Must bioassay be performed for a worker who, without respiratory protection, is likely to receive an intake in excess of the applicable ALI but who is not likely to receive such an intake with respiratory protection?

Answer: A "Note" in the statement of considerations (56 FR 23377, column 2) says that "...the concentrations to be used for evaluating monitoring thresholds are those of the ambient atmosphere before credit is taken for respiratory protective factors." That note is a conservative assumption that is appropriate if there will be no "further verification" that the assigned respiratory protection factors actually will be achieved.

At nuclear power plants, if the "surveys and bioassays, as appropriate," required by 10 CFR 20.1703(a)(3)(ii), include reasonable measures to verify that the expected degree of respiratory protection will be achieved, "the concentrations to be used for evaluating monitoring thresholds" may be those that include credit for the protection factors when respirators are to be used. Measures to verify that the expected degree of respiratory protection has been achieved may include (but are not limited to) measurements of nasal smears from workers who have used respirators and whole body counting, relatively soon after a job, of one or more representative workers among a group of workers who wore respiratory protective equipment while working on the job, and periodic whole-body counting (e.g., annually) of all workers who wear respiratory protective equipment.

At fuel cycle and materials facilities using large quantities of unsealed radioactive materials, the nature of the operations is such that bioassays are required for workers who, without respiratory protection, are likely to receive an intake in excess of ten percent of the applicable ALIs. Because of the types and quantities of radioactive airborne particulates at fuel cycle and materials licensees, it is advisable to not take credit for respiratory protection factors when determining if monitoring (e.g., bioassay) is required. NRC will consider licensee proposals to allow using respiratory protection factors when determining if internal dose monitoring is required, if the licensee demonstrates a verification method that the respiratory protection factor is actually achieved for all workers wearing respirators. Unless authorized in the license, fuel cycle and materials licensees should understand that the threshold level for monitoring in 10 CFR 20.1502(b) is ten percent of the applicable ALIs without credit for respirators.

(Reference: 10CFR 20.1502(b), 20.1703)

DRAFT

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

Certification of Industrial Radiographers

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed Rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations pertaining to industrial radiography. Licensees would be required to ensure that individuals acting as industrial radiographers, in addition to meeting the existing training and qualification requirements, be certified through a radiation safety certification program by an NRC recognized certifying entity. Certifying entities could be either organizations approved by NRC, or Agreement States with compatible certification programs. The amendment would outline the acceptable organizational elements, certification program elements, written examination elements, and the procedures for organizations to obtain Commission approval to act as a certifier. The certification program and written examination program elements would be matters of compatibility for Agreement State programs. These requirements stem from the Commission's ongoing efforts to improve safety in industrial radiography. The proposed requirements are intended to provide independent assurance that individuals acting as radiographers have a satisfactory

knowledge of radiation safety principals and NRC's regulations applicable to industrial radiography, to place greater responsibility on individual radiographers, and to reduce radiation exposures to both radiography workers and the public. The proposed amendments would affect persons licensed to perform industrial radiography.

DATES: The comment period expires _____ (90 days after the publication date). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Mail written comments to: The Secretary of the Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 2120 L Street, NW, (Lower Level), Washington, DC, between 7:30 a.m. and 4:15 p.m. Federal Government workdays.

Copies of comments received and documents referenced in this proposed rule may be examined at the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: J. Bruce Carrico, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 504-2634.

SUPPLEMENTARY INFORMATION:

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I. Background

Industrial radiography is a form of non-destructive testing that uses radiation either from x-ray devices or from byproduct material sources (principally iridium-192 and cobalt-60) to examine the internal structure of materials. The NRC regulates only devices containing byproduct material sources. Most such radiography operations involve projecting a radioactive source out of its shielded position within an exposure device or "camera;" however, some devices, such as the so called "pipeliner," use a shutter to allow the radiation beam to exit from a shielded position within the device. The majority of radiography devices are designed to be "portable" or "mobile," which allows the exposure device to be transported to a field site where a item may be examined. Some devices, used in shielded facilities, are permanently fixed (although portable and mobile devices are also used) and the items to be examined must be brought into the facility. The radioactive sources used in portable radiography devices may contain up to 200 curies of iridium-192 or 100 curies of cobalt-60; devices at fixed facilities can contain sources of several hundred curies. Industrial radiography involves significant radiation levels; a 200 curie iridium-192 source will produce gamma dose rates of 96 rem per hour at 1 meter; and near surface gamma dose rates of approximately 960,000 rem per hour (or 16,000 rem per minute) at 1 centimeter.

The procedure for conducting radiographic operations using a portable device at a field site is straightforward. First, a restricted work area is set up around the item to be examined. High radiation area signs and

radiation area signs are posted. Radiation area signs are generally posted at the restricted area boundary. Ropes or other similar barriers are often used to help further establish and define the boundaries. The portable exposure device is connected to a drive cable used to push the sealed source and a guide tube to assure the source reaches the correct position. After ensuring that the restricted area is free of personnel, the radiography camera is unlocked, allowing the radioactive source to move, and the source is pushed by a cable driven by a crank through the guide tube to the item to be examined. Radiation sensitive film will be exposed by radiation passing from the source and through the item to be examined. While the source is unshielded, continuous direct visual surveillance of the high radiation area must be maintained to ensure that no one enters the area. Most procedures also require continuous surveillance of the restricted area. During the first exposure, a radiation survey of the restricted area boundary is conducted to confirm that dose rates are within acceptable limits. A survey of the high radiation area is not expected. At the end of the desired exposure time the source is pulled back into the device by reversing the cranking motion. A survey of the entire circumference of the exposure device and of the guide tube is made to ensure that the source is in the shielded position. The source is secured in the device by locking the camera.

Only qualified radiographers, or radiographers' assistants under the personal supervision of a radiographer, may conduct industrial radiography operations (use exposure devices, sealed sources, or perform required surveys). If an individual acting as a radiographer's assistant (or trainee) conducts any of the above operations, a qualified radiographer must be present

at the site watching the assistant's performance and must be able to give immediate assistance if required. NRC's regulations in paragraph 34.31(a) specifies that a licensee shall not permit any individual to act as a radiographer until such individual has been instructed in the subjects listed in 10 CFR part 34 appendix A of NRC's regulations, and the licensee's operating and emergency procedures; has demonstrated competence in the use of the licensee's radiographic equipment; and has successfully completed a written test and field examination on the subjects covered under that paragraph. NRC's radiography licensing requirements in 10 CFR 34.11, specifies that an applicant for a license will have an adequate program for training radiographers and will submit to the Commission a description of the program, including the licensee's procedures for determining a radiographer's knowledge and understanding of and ability to comply with Commission regulations and licensing requirements, and the operating and emergency procedures of the applicant. Through this process, radiography licensees are allowed to train and designate employees as radiographers. While NRC evaluates each training program, it does not independently assess the level of knowledge of individual radiographers.

Industrial radiography involves the use of higher activity sources than most applications of byproduct material licensed by NRC. Radiation overexposures to radiography workers and occasionally the general public have occurred. These radiation overexposures are a concern to both the NRC and the Agreement States. Industrial radiography performed in the field is of most concern. These types of operations are often only under control of the radiographer and the work is generally performed under time limitations and in

adverse weather and environmental conditions. Radiographers may make errors in following proper procedures and these may lead to radiation overexposures. In many overexposure cases, the required radiation surveys were not made and in some instances assistant radiographers were left to perform the radiography without the direct supervision of the radiographer. NRC and Agreement State investigations indicate that inadequate training is often a major contributing factor to radiography problems. Some individuals have also expressed the opinion that NRC's regulatory scheme does not sufficiently hold the individual radiographer accountable for his/her actions.

II. Radiography Radiation Exposure

Radiography licensees and certain other categories of licensees are required to submit annual reports to NRC showing the total radiation exposure workers receive during the calendar year. All licensees are required to report radiation overexposures to NRC. NRC exposure data for the years 1980 through 1988 indicate that radiography accounted for over 25 percent of all overexposures reported by NRC licensees. Over this same time period, radiography accounted for approximately 46 percent of the overexposures greater than 5 rem to the whole body or 75 rem to the extremities and 25 percent of the overexposures greater than 25 rem to the whole body or 375 rem to the extremities for all overexposures reported to the NRC. However, radiography workers made up only 4 percent of the total population receiving a measurable dose in 1988 and radiography licenses make up only 4 percent of the total number of NRC's non-reactor licensees. In 1988, radiography also

recorded the highest average measurable dose per worker among various categories at 0.47 rem. (The next highest license category was recorded for commercial light water reactors at 0.41 rem.) (1988 is the most recent year for which complete exposure data has been tabulated for all NRC licensees.)

The extreme hazard potential involved in radiography overexposures is shown in cases in foreign countries and in the United States where members of the public have been exposed to lost radiography sources. Individuals have died from the radiation exposure. In Morocco in 1984, a laborer found a disconnected source and took it home. Eight members of his family eventually died from overexposure, and several others received significant doses. In California in 1979, a worker found a lost source, placed it in his hip pocket, and carried it around for about 45 minutes. The individual suffered a severe radiation burn on his right buttock. The individual remains under periodic medical review. Ten other persons were exposed to the source, with two of them developing radiation burns on their fingers.

Even in cases involving only radiography workers, overexposures have caused acute effects such as burns and necrosis of body tissues. Two incidents in 1990, illustrate the damage which may result from radiography overexposures.

In the first incident, a radiographer and assistant radiographer were conducting industrial radiography at an oil refinery (a temporary job site) in Oklahoma. After setting up the radiography equipment, the assistant felt resistance as he attempted to crank the 80 curie iridium-192 source out. He returned the controls to its original position and discussed the situation with the radiographer. The radiographer approached the exposure device with a

survey meter, and then straightened the cables which apparently relieved the stress, and they proceeded to crank out the source without difficulty. When the final exposure was complete, the radiographer removed the film and instructed the assistant to disassemble the tubes and cables from the exposure device. The radiographer failed to conduct the required radiation surveys following the exposures. The assistant removed the 7-foot long source guide tube from the exposure device and draped it around his neck (in a U-shape), coiled the control cables and hung them around his neck, and then gathered his survey instrument and other miscellaneous items and walked back toward the truck. As the assistant was setting the items down and removing the guide tube from his neck, he heard a noise, noted that the radioactive source assembly had fallen from the guide tube to the ground, and so he retreated from the area. Based on instructions from the radiography company owner, the radiographer recovered the source assembly and returned it to the safe storage in the exposure device.

NRC's evaluation of the incident determined that the assistant had the guide tube draped around his neck for approximately 5 minutes. During this time period, or some portion of this time period, the source capsule was located near the individual's left posterior-cervical area of the neck. While it was difficult to determine the assistant's actual exposure, a medical physicist, who first examined the individual, conservatively estimated a dose of 25,000 to 31,000 rem to the local skin area; a 1250-rem dose to the cervical spinal cord; and a whole body dose of approximately 40 rem. Cytogenetic evaluation indicated chromosome irregularities equivalent to a whole body dose of approximately 24 rad. The assistant's failure to wear his

whole-body film badge made the dose assessment an even harder problem. By the evening of the first day, the assistant complained of a burning sensation; however, there was no evidence of localized skin erythema (reddening). A light erythema appeared the next day and disappeared 2 days later. The erythema reappeared after 4 days and, within 3 weeks, developed into a blistered area. As a result of the overexposure and other violations, the licensee was assessed a $7500 civil penalty.

In the second incident, a radiographer and assistant radiographer were also conducting operations at a temporary job site in Oklahoma. The radiography workers were making a series of exposures of a tank at a fabrication shop using a 49.2 curie iridium-192 source. The source guide tube was taped (near the guide tube end-cap) to a stand that was mounted magnetically to the side of the tank and approximately 3 feet above the floor. While the assistant finished setting up for an exposure, the radiographer left the immediate area to load film for the next exposure, thereby leaving the assistant to work by himself. After completing the set-up, the assistant cranked the source out two or three turns when he saw that the magnetic stand had fallen from the side of the tank. When this occurred, the assistant's alarming personnel dosimeter (chirper) alarmed loudly; however, the chirper stopped alarming after the assistant thought he cranked the source back into the exposure device. Although a survey meter was readily available, the assistant failed to use it to perform a survey as he approached the guide tube stand, relying instead only on the chirper. After repositioning the stand, the assistant used his right hand to reposition the guide tube end-cap a specific distance from the tank. Returning to the crank, the assistant

proceeded to complete the exposure but noted that his chirper did not alarm as it normally did when the source was cranked in or out. Because of this, the assistant looked at his pocket dosimeter and found it had been exposed beyond its maximum measuring value. About this time the radiographer returned, the assistant informed the radiographer of the off-scale dosimeter and that the chirper failed to work during the last exposure. Both the radiographer and assistant believed the devices simply malfunctioned due to being bumped or dropped and continued with their work activities.

The incident was not reported to NRC for 2 weeks. The radiographer did not think that an overexposure occurred until the assistant's right hand became red and his fingers began to swell. NRC's evaluation of the incident was that the assistant's right hand was in contact with the guide tube near the source capsule approximately 5 to 10 seconds while repositioning the guide tube end-cap. The dose to the assistant's hand was estimated to be between 1446 rem, for 5 seconds, and 2892 rem for 10 seconds. The morning after the incident, the assistant reported that his hand felt stiff, but was better by the afternoon. By 12 days after the incident, the assistant's hand was showing localized erythema (reddening) and was swollen. Within 4 more days, the individual's middle and index fingers and thumb blistered. The next day an NRC inspector observed the assistant's radiation injuries and noted that the thumb, index, and middle fingers were "severely blistered and swollen." The assistant was also complaining of pain that radiated from his hand up to his elbow. There was some indication from the treating physician that amputation of several fingers may be required. As a result of this incident, the radiographer's failure to properly supervise the assistant, and other

problems, the company's NRC license was terminated and NRC suspended the company's authority to conduct radiographic operations within NRC's jurisdiction under reciprocity for a period of 3 years. (The company office was located in an Agreement State.)

NRC's radiography licensees reported seven additional overexposures during 1990. In one case, an individual's accumulated quarterly occupational exposure exceeded the 3-rem limit, but no incident occurred. The remaining overexposures all resulted from specific incidents. Three of these remaining overexposure incidents caused individuals to receive whole body doses exceeding 1.25 rem but less than 3 rem for the quarter, and one resulted in an individual receiving a 4 rem whole body dose. The last two incidents resulted in individuals receiving considerable extremity doses. The NRC estimated that one individual received 1070 rem to the hand and the other individual received 111 rem to the hand. In each of this cases, the cause of the overexposure can be traced to radiography worker failure to comply with regulatory requirements and conduct surveys or to secure the source in the safe storage position in the exposure device.

III. Inspection and Enforcement Considerations

Partly because the radioactive sources used in radiography can pose significant risk to public and worker health and safety, industrial radiography licensees are among the most frequently inspected of all NRC material licensees. Generally, NRC will inspect each of its radiography licensees at least one time each year. Inspection statistics for NRC

radiography licenses from 1984 through 1990 indicate that many of the more common violations are related to knowledge deficiencies, to activities by unauthorized users, or to radiography worker error. Over this period, NRC conducted 1637 inspections of radiography licensees. Noncompliance was noted in 694 of the inspections, with 1567 different violations of regulatory requirements cited. Although 38 different categories of violations were cited, violations involving 9 categories (training or training records; failure to perform surveys or inadequate records of surveys; failure to use or provide personnel monitoring devices; failure to post restricted, radiation, or high radiation areas; use by unauthorized individuals; failure to maintain utilization records; unsecured or unattended storage of devices; failure to follow operating or emergency procedures; and failure to maintain surveillance of radiographic operations) accounted for 53 percent of the total number of violations. The frequency of noncompliance (within the nine categories) per inspection for licensees authorized to conduct operations at temporary job sites was approximately 46 percent, while the frequency for licensees authorized to conduct operations only at fixed locations was about 33 percent. All violations (20) involving individual exposures in excess of regulatory limits were cited against licensees authorized to conduct operations at temporary job sites.

The purpose of the NRC enforcement program is both to promote and to protect the radiological health and safety of the public, including employee's health and safety, by: (1) Ensuring compliance with NRC regulations and license conditions; (2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety; (3) Deterring future violations

and occurrences of conditions adverse to quality; and (4) Encouraging improvement of licensee and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems. NRC's basic enforcement sanctions are notices of violation, civil penalties (monetary fines), and orders of various types. Penalties may also be imposed for criminal violations of the Atomic Energy Act (referred to the Department of Justice). Civil penalties, orders, and criminal penalties are generally classified as "escalated enforcement actions."

Enforcement data based on inspections of NRC radiography licensees conducted from 1985 through 1990 shows that 80 inspections resulted in escalated enforcement action. The number of escalated enforcement actions averaged about 11 per year for inspections conducted from 1985 through 1989; however, in 1990, 25 inspections resulted in escalated enforcement. Civil penalties totaling about $495,000 were imposed in 40 of the escalated enforcement cases. The escalated enforcement actions for inspections conducted in 1988 and 1989 show that 13 of 20 cases (65 percent) included violations due to performance failure, such as failure to survey or failure to follow the licensee's written procedures. NRC imposed a civil penalty in all but three of these 13 cases.

IV. Previous Regulatory Initiatives

The concept of licensing or certifying radiographers as a means of helping to reduce radiation overexposures in the radiography industry is not new. In July 1964 the Atomic Energy Commission (AEC) directed its staff to

consider whether individual radiographers should be licensed as were individual reactor operators at that time. The staff response was that the increased AEC workload created by either licensing or certification of individual radiographers by the Commission would be very large and was not warranted, but that the Commission could improve radiography safety by encouraging the certification of radiographers by third (independent) parties such as industrial societies and associations. In 1972, the United States General Accounting Office (GAO) called for strengthened training requirements for radiographers.

In June 1977, the Non-Destructive Testing Management Association (NDTMA) filed a petition for rulemaking with the NRC (PRM-34-2) to require NRC registration of individual radiographers, and issuance of a registration card to qualified radiographers which would then be subject to NRC recall or revocation. In response to this petition and a recommendation from the Agreement States, an Advance Notice of Proposed Rulemaking (ANPRM) on certification of industrial radiographers by an NRC-approved third-party was published in the Federal Register on May 4, 1981 (47 FR 19152). Public meetings in connection with the ANPRM were also held at four different locations in 1982. Comments received from these public meetings and the ANPRM indicated that most commenters believed that a certification program would not significantly reduce the number of overexposure incidents to personnel and that the costs associated with such a program would exceed the benefits. However, the Agreement States continued to recommend that the NRC go forward with the development of a radiographer testing program to assure the adequacy of radiographer training so that only qualified individuals perform

radiography. Although some organizations expressed interest in acting as independent certifiers, none of these organizations came forth with an acceptable proposal for radiographer certification.

As a result of the comments received and an analysis of the costs involved, the NRC staff requested withdrawal of the ANPRM and the Commission approved this recommendation in November 1985. In making its recommendation to the Commission, the staff developed estimated costs for a hypothetical certification program. The hypothetical program had an examiner travel to each licensee's facility and administer a written examination and a field test (practical) to each radiographer. Radiographers would be recertified annually. Costs were based on the number of NRC radiography licensees at that time, and the annual cost to the industry was estimated to be approximately $658,000 (in 1985 dollars). The annual cost for a "large" licensee (greater than 300 employees) was estimated to be approximately $27,500.

NRC withdrawal of the 1982 ANPRM on Certification placed the option of an examination program to evaluate the training of industrial radiographers solely on the States. Consequently, the State of Texas formally committed to the concept of a State agency-administered examination as a means of verifying adequate radiation safety training. In the early 1980's, the Industrial Radiography Committee of the Texas Advisory Board decided to revise part 31, "Radiation Safety Requirements for Industrial Radiographic Operations," of the Texas regulations. The Committee determined that the Bureau of Radiation Control would establish and administer a testing program which would include State-wide written examination and reexamination of radiographers (including those working under reciprocity) and the issuance of identification cards to

demonstrate successful completion of the examination. As a result, section 31.20 of the Texas regulations now provides that, in order for an individual to perform radiography operations, he/she must satisfactorily complete a State-administered examination and possess a valid, State-issued identification card.

Texas initiated its radiographer testing program in January 1987. In January 1988, the new regulations went into effect and all individuals acting as radiographers in the State had to meet the new requirements. As of May 1991, Texas has tested a total of 3340 individuals and has issued a total of 2549 identification cards. Texas has seen an overall failure rate of about 22 percent for its examination program. While it is hard to attribute benefit to any one factor, Texas radiography overexposure data indicates a drop in both the number and severity of overexposures since the program was implemented.

The Atomic Energy Control Board (AECB) of Canada has, since 1983, required individuals who independently operate radiography devices to complete an AECB examination. In January 1991, the AECB was charging a $235 (Canadian) fee to sit for the examination. While the AECB indicates it believes the examination program has improved safety in the industry, it has not seen a significant drop in the number of radiography overexposures. However, the AECB has noted a decrease in the severity of the overexposures.

On December 17, 1986, the NRC published for public comment the report of its Materials Safety Regulation Review Study Group (51 FR 45122). This report recommended, among other things, that NRC or Agreement States certify industrial radiographers through some form of third-party (independent)

certification. In 1988, the General Accounting Office called for the NRC to adopt this recommendation.

In 1987, the American Society for Nondestructive Testing (ASNT), recognizing the need for a qualified certifying organization, formed a task group to develop an ASNT radiographer certification program for Industrial Radiography Radiation Safety Personnel (IRRSP). NRC encouraged ASNT's efforts. In February 1988, ASNT presented a draft proposal to the NRC for consideration as a certifying organization. Several subsequent drafts of the ASNT program were submitted for NRC's review, and in July 1989 the NRC concluded that the certification program would help to assure that individuals performing radiographer duties have an acceptable knowledge of radiation safety practices and principals, and meet minimum regulatory requirements for assessing training and experience.

Based on this conclusion, in 1989 the NRC published for comment a proposed rule that would permit certification of industrial radiographers under the ASNT program in lieu of an existing requirement applicable to radiographer license applicants. In 1991, NRC formally recognized the industry-sponsored industrial radiographer radiation safety certification program. On March 19, 1991, NRC published in the Federal Register (56 FR 11504), a final amendment to the requirements in section 34.11 which allows license applicants and existing licensees the option to affirm that individuals acting as radiographers will be certified in radiation safety by the ASNT prior to commencing duties as radiographers. License applicants may use ASNT certification in lieu of the portion of the current licensing requirement that specifies submission of descriptions of planned initial

radiation safety training and qualification procedures. In addition, the amendment permits existing NRC radiography licensees to substitute the ASNT examination for the licensee's radiation safety examination and to substitute ASNT certification for procedures used for verifying the training and testing of experienced radiographers as described in license applications.

V. The ASNT-IRRSP Certification Program

The ASNT-IRRSP Certification Program, which is a program for certifying industrial radiographers, was approved by its Board of Directors in March of 1990. The program, which currently includes use of a written examination developed by the State of Texas, has been reviewed extensively by NRC headquarters and regional staff. The ASNT program will offer certification for both isotope and x-ray users. This rule, however, applies only to isotope radiography.

ASNT application requirements for industrial radiographer certification specify the documentation of a candidate's completion of 40 hours of classroom training in radiation safety topics specified by the ASNT (which includes those topics listed in appendix A of 10 CFR part 34); documentation of 520 hours of direct hands-on experience with radiography sources and devices under the control of an NRC or Agreement State licensee; and proof of successful completion of a practical examination on safety procedures administered by an ASNT recognized institution. Recognized institutions are generally the candidates' employers, who are licensed by the NRC or Agreement States for the use of radiography sources.

On ASNT's approval of a certification application, a candidate radiographer is then eligible to take the State of Texas written examination. The examination is administered by the ASNT or the Conference of Radiation Control Program Directors (CRCPD), and is sent to the State of Texas for grading and the results forwarded to the ASNT. The examination covers fundamental radiation safety principals outlined in appendix A of part 34, pertinent Federal and State regulations, basic radiographic equipment operation, general operating and emergency procedures, radiation detection instrumentation, and radiation safety procedures applicable to industrial radiography. In addition, the candidate is required to sign an acknowledgement that he/she will abide by the ASNT Rules of Conduct which ASNT considers necessary to maintain the integrity of the ASNT/IRRSP Certification Program. Upon successful completion of the required examinations and other requirements, the candidate for certification is provided with a wallet card identifying him/her as an ASNT certified radiographer.

ASNT certification is valid for 3 years unless suspended or revoked for cause. Renewal of certification may be accomplished both with or without reexamination. A candidate for renewal without reexamination must document continued active permanent employment in radiography for at least 24 of the last 36 months. In addition, the candidate must document at least 8 hours of annual classroom refresher training covering basic radiation safety principals, equipment operations, emergency procedures, new safety regulations, license requirements and other pertinent information. If these criteria are not met the candidate must retake the examination.

As described above, the ASNT-IRRSP program requires certified individuals to abide by certain Rules of Conduct. The Rules of Conduct require that certified individuals comply with NRC and/or Agreement State regulations, the employer's radiation safety and operating and emergency procedures, and to act in a professional manner in matters pertaining to industrial radiography or to the ASNT-IRRSP certification.

The program also contains complaint and hearing procedures. Upon receipt of a written allegation of unauthorized practice by an ASNT-IRRSP individual, a formal complaint is prepared and distributed to the IRRSP Ethics Subcommittee. Should the subcommittee not dismiss the allegation for insufficiency or other reason, a formal hearing that includes all interested parties may be held. Should the ASNT-IRRSP Ethics Subcommittee determine that an unauthorized practice has been committed, the committee can take the following actions, based upon one of three severity levels specified in the ASNT certification program:

Severity Level I--A severity level I violation is grounds for revocation of certification for a minimum of 1 year and surrender of the certification card to ASNT.

Severity Level II--A severity level II violation may result in suspension of certification for 30 to 180 days and surrender of the certification card to ASNT for the duration of the suspension.

Severity Level III--Violations in this category shall result in a formal reprimand that describes the nature of the violation and any subsequent action which may result if the violation is repeated.

More detailed information regarding the ASNT-IRRSP certification program is available from the American Society for Nondestructive Testing, Inc., 4153 Arlingate Plaza, P.O. Box 28518, Columbus, Ohio 43228-0518.

ASNT is currently implementing its certification program. The program is expected to be capable of certifying all eligible radiographers within 2 to 3 years. The NRC and ASNT have entered into an agreement on the exchange of information. ASNT will share with the NRC, and with the Agreement States through the NRC, an up-to-date list of radiographers certified through the ASNT program. ASNT will also inform the NRC of radiographers who have been reprimanded or whose certification has been suspended, revoked or otherwise affected, and will provide the NRC with information concerning the basis for the ASNT action. Also, the ASNT will refer to the NRC allegations of unsafe practices that it receives from complainants concerning certified radiographers. Allegations about radiographers working in Agreement States will be referred to the appropriate Agreement State. The NRC will review as appropriate those allegations referred to it and will inform the ASNT of the results of such reviews and on any regulatory action taken. Further, if the NRC takes enforcement action directly affecting an ASNT certified radiographer, the NRC will provide appropriate information to the ASNT so that ASNT can consider appropriate action relating to the radiographer's ASNT certification.

VI. Agreement State Compatibility

According to available information, NRC estimates that there are 739 radiography licensees and 12,000 individuals acting as radiographers nationwide. The NRC currently administers 237 licenses authorizing industrial radiography and estimates that NRC licensees employ 4223 radiographers. Therefore, it is estimated that around 500 radiography licensees are located in the Agreement States, and these licensees employ over 7000 radiographers. Consequently, the Agreement States must play an important role to achieve improved radiation safety performance by industrial radiographers on a national level.

NRC's principal objective in amending 10 CFR part 34 to require certification of industrial radiographers is to provide greater assurance that individuals acting as radiographers, through the completion of an independently developed and administered examination, have an acceptable knowledge, understanding, and appreciation of the hazards and dangers of radiation and of applicable radiation safety practices and principals, and have obtained appropriate training and experience. Other important objectives include holding individual radiographers more responsible for their actions, and ensuring the viability of the national-level industrial radiographer certification concept.

The Commission is considering making the amendments a matter of compatibility for the Agreement States. The States participated, through the CRCPD, in the development of ASNT's radiographer certification program. Several States commented on this issue in the voluntary certification

rulemaking. The Agreement States were also invited to participate in the development of this rule as part of a public meeting held May 14, 1991, and a public workshop held May 27th and 28th, 1992. Their comments were considered both in the development of ASNT's program and this rule. Most Agreement States have indicated agreement with the certification concept and the verification aspects of this proposed rule. However, some States have expressed a desire to have their own in-state radiographer testing and certification program rather than solely participate in an independent certification program conducted by an NRC approved organization.

As previously discussed, NRC's principal rulemaking objective is provide greater assurance of radiographers' radiation safety knowledge and qualifications through completion of an independently developed and administered examination and independent verification of training and experience. While NRC strongly supports independent organization certification, an in-state radiographer testing and certification program accomplishes the same principal objective. Therefore, the NRC staff has suggested that these amendments be categorized in part as Division 1 and in part as Division 2 level of compatibility. A Division 1 level of compatibility requires that the States address provisions in NRC regulations relating to basic principals of radiation safety and regulatory functions using essentially the same identical language. For those States that wish to develop certification programs, sections II and III of proposed appendix B will be a Division 1 matter of compatibility. The remainder of the proposed rule will be a Division 2 matter of compatibility. This level of compatibility requires that the States address provisions in NRC regulations

relating to basic principals of radiation safety and regulatory functions without necessarily using the same identical language. States may also adopt requirements more restrictive than NRC rules under this level of compatibility. NRC will expect the States to adopt regulations requiring individuals to be certified in radiation safety by an approved certifying entity. The States are not necessarily expected to incorporate the provisions of proposed appendix B that apply to independent certifiers. The Commission would appreciate comments on these suggestions.

VII. Public Comments

A. ASNT Rulemaking

The proposed rule on voluntary certification of radiographers (54 FR 47089, November 9, 1989), specifically solicited comments on two issues:

1. The provision to provide license applicants the option to affirm that all of their active radiographers would be certified in radiation safety by the ASNT; and

2. The costs and benefits of radiation safety certification for use by the Commission in its consideration of a planned subsequent rulemaking that would require radiographer certification.

In a majority of the 52 responses received, the commenters did not comment on the first issue but directed their comments to the second issue involving mandatory certification. While the proposed rule did not state

that, if there were mandatory certification, the ASNT would be the only certifying organization, most commenters assumed this would be the case, with the result that many comments included criticism directed toward the ASNT and provided little discussion of the major issues associated with requiring radiographer certification. However, several questions were raised regarding mandatorycertification. The final rulemaking on voluntary certification (56 FR 11504) indicated that NRC would consider these comments in any rule mandating radiographer certification. The following is a summary of the comments made on this issue:

1. The criteria that other certifiers would have to satisfy should be identified.

NRC Response: The proposed rule will identify, in a new appendix to part 34, the criteria that organizations will have to meet in order to be acceptable to NRC. In addition, the new appendix will also outline the acceptable certification program elements, written examination elements, and the procedures for obtaining Commission approval to act as an independent certifying organization. The certification program and written examination elements would also apply to any Agreement State that wishes to conduct its own certification program.

2. Will ASNT-certified radiographers have to be recertified in Texas or in other States that develop their own programs? Who will decide whether there will be reciprocity among the various certification programs?

NRC Response: Traditionally, regulatory compatibility between the NRC and the Agreement States has depended on the issue. For some regulatory items, NRC has expected strict compatibility of the regulatory language, while

with other items, the States develop different regulatory language to accomplish the same end. Many of NRC's regulations are not a matter of compatibility, and the States do not have to incorporate these regulations. In some cases, the States implement more restrictive regulations than the NRC. The State of Texas radiographer testing program is an example of a more restrictive regulation. Under the proposed criteria, the NRC would be able to accept an individual State program only if certain content criteria for the program outlined in proposed appendix B are met. The NRC has supported the concept of a national certification program, in part, in the hope that reciprocity issues would be simplified. However, the NRC does not oppose an Agreement State imposing additional criteria, such as State-issued identification cards, in order for a individual to act as radiographer in that State.

3. If there are multiple certification programs, who will have the authority to decertify individual radiographers for cause?

NRC Response: Although the proposed rule allows for multiple certification programs, the NRC is not aware of any other private organization which meets the criteria of the proposed rule expressing any interest in becoming an independent certifying organization. The NRC, the States, and ASNT have agreed, in concept, to recognize regulatory actions taken against a certified individual by other jurisdictions.

4. Since the NRC does not regulate x-rays, who will certify x-ray radiographers in States that do not have their own certification program?

NRC Response: Both the Agreement and non-Agreement States are aware, through their involvement with the CRCPD, that ASNT's program includes

certification provisions for x-ray radiographers. Individual States will decide if they wish to take advantage of this provision through some sort of regulatory action.

5. Unless there is a national certification program with reciprocity among all States, revoking a radiographer's certification in any particular State will be ineffective in preventing him/her from working in another State.

NRC Response: NRC agrees with this comment. This is one of the reasons why NRC has supported the national certification concept.

6. Rules that are to become matters of compatibility should be developed in close cooperation with the States through a joint rulemaking effort.

NRC Response: The NRC has considered the States' comments in preparing this proposed rule. At a public meeting held May 14, 1991 in Wichita, Kansas, where many State representatives were present, NRC discussed, at a very early stage, its concepts for a certification rulemaking. The radiographer certification concept was also discussed in depth at a public workshop held May 27 and 28, 1992 in Mobile, Alabama. Many State representatives made comments at the public meeting and workshop, and NRC's response to these comments is provided in the following sections. The Agreement States were also invited to participate in the development of ASNT's program, and also on this proposed rule package. It is important to note that NRC does not intend to make the entire rule a matter of Division 1 compatibility. Instead, NRC will only expect the Agreement States to require individuals acting as radiographers in their States to be certified in radiation safety by an approved certifying entity. Of course, the NRC will

expect the Agreement States to continue to incorporate the existing criteria for radiographers specified in part 34, which has long been a matter of compatibility, as part of their regulatory requirements. Under this degree of compatibility Agreement States will have the option to take advantage of the NRC approved national certification program or to develop their own certification program. However, it is anticipated that recognition between all programs will occur.

7. NRC should form a task force to develop procedures to handle reciprocal recognition of the training and experience criteria established by various entities for certification of industrial radiographers.

NRC Response: The NRC is working with a CRCPD subcommittee to ensure that the procedures the commenter suggests are developed.

B. Public Meeting

On May 14, 1991, NRC held a public meeting in Wichita, Kansas to discuss this and three other proposed rules the NRC staff was developing at that time. In order to facilitate early Agreement State participation in certain rulemakings as directed by the Commission, NRC staff arranged the meeting in conjunction with the 1991 annual meeting of the Conference of Radiation Program Directors, Inc. However, comments from both the Agreement and non-agreement States, and members of the public were welcome. Announcement of the meeting was handled in the same manner as is customary for noticing a meeting with a licensee, and a letter of invitation was sent to each of the States.

NRC staff made brief presentations explaining the proposed rule changes, and then received comments and questions from members of the audience. A transcript was made of the meeting. The presentation on radiographer certification received a total of 21 questions and comments from 6 individuals. While written comments were also invited, no written comments were submitted. The following is a discussion of the comments received:

1. One element, NRC described, which must be included for a certification program to be deemed acceptable, concerned a "practical examination administered by an NRC or Agreement State licensee." Could this be worded so that it would apply to the radiographer's current employer?

Another commenter raised a similar question concerning the concept of a certification program including a requirement for completion of a practical examination and how this might apply to the specific equipment a given licensee would have.

NRC Response: The intention for including this provision as an element for an acceptable certification program was to ensure that individuals meet all necessary training and experience prerequisites the NRC normally expects. The proposed rule would not relieve a licensee of its responsibility to ensure that its radiographers are properly trained and knowledgeable in the licensee's operating and emergency procedures or how to operate and use the licensee's equipment. NRC will continue to expect licensees to administer practical examinations to all individuals acting as radiographers.

2. A question was raised about the appropriateness of setting the educational criteria for the written examination at the ninth grade level.

NRC Response: This criteria is the same as the State of Texas used in the development of its examination. NRC understands that Texas concluded this was an appropriate design level for the examination after considering the testing population and a recommendation from an examination development expert. NRC agrees with Texas's conclusion. This provision is only intended to ensure that the language and construction of the written examination questions and answers are likely to be understood by an individual who has obtained at least a ninth grade education. It does not reflect on the subject matter.

3. A question was raised about how examinations would be designed, and how often questions would be rotated within the examinations.

NRC Response: ASNT's certification program currently uses examinations prepared by the State of Texas. Before a question/answer is "officially" used on a Texas-prepared examination, the question/answer is subject to a series of tests to assure its validity. Texas has developed questions and answers in several different categories. When preparing an examination, Texas will randomly select a number of questions from each category. Texas also prepares a "new" examination at least every other month. Individuals are prohibited from taking the same unique examination. Through these methods, Texas is able to rotate the examination questions and answers. Similar provisions would be necessary for NRC to find any written certification examination acceptable.

4. Some concern was expressed about legal ramifications should a private organization revoke an individual's certification independent of NRC or State action.

Similarly, one commenter saw potential difficulties regarding enforcement actions, especially if a jurisdiction took a particular enforcement action and the independent certifier did not agree with that action. The commenter also indicated that the independent certifier should be concerned about this possibility and the litigation which might result.

NRC Response: ASNT's certification program includes provisions where ASNT could revoke an individual's certification independent of NRC or State action; however, as a practical matter, ASNT might only take such action if the NRC or a State first took similar enforcement action against the individual. ASNT's program also includes provisions where it could impose lesser sanctions, such as requiring retraining. ASNT might impose these lesser sanctions independent of an NRC or State enforcement action involving the individual. (Although such actions would probably be based on NRC or State inspection records.) In reviewing the ASNT program, both NRC's legal staff and ASNT's legal representative insisted on ensuring that individuals are provided due process, including hearing rights, and such provisions are part of ASNT's certification program. NRC would not have recently revised its regulations to "recognize" voluntary ASNT certification if it believed these issues were of concern. However, the proposed rule will include "due process" as a criteria that must be met for a program to be found acceptable.

5. A commenter noted that while ASNT's procedures would prohibit a proctor being from a company undergoing testing, the proctor could be from a company that was a wholly-owned subsidiary, a fact which seemed inappropriate to the commenter.

NRC Response: As the commenter noted, ASNT's procedures would not allow the proctor administering an examination to be from the same company as any of the individuals taking the examination. ASNT and NRC are also developing procedures which would provide for periodic regulatory oversight of the program, including actual observation at testing sites. In addition, Texas has insisted on strict security arrangements for use of its examinations. An acceptable certifying program would have to include similar security provisions. NRC believes these provisions should provide adequate safeguards for ensuring the integrity of the examination process; however, NRC has added language to the proposed rule to also indicate that the proctors cannot be employees of the same company as candidates or have other financial interest in the company.

6. A commenter stated that he believed that the program should include provisions to allow the State or NRC to remove a certified individual's certification identification card.

NRC Response: ASNT and NRC staff have considered such a provision. The general consensus was that NRC inspectors should not attempt to physically remove an individual's certification identification card. However, NRC staff noted that NRC's enforcement procedures allow NRC to issue immediately effective orders which might prohibit an individual from involvement with radiographic operations. Some Agreement States may consider regulations which enable the State to remove an individual's certification identification card. It was also agreed that ASNT should consider revising its IRRSP program so that an NRC or State order would automatically suspend an individual's ASNT certification. The proposed rule would require licensees to verify and

document an individual's certification status prior to allowing that individual to act as a radiographer. These procedures would essentially accomplish what the commenter suggested.

7. One commenter noted that ASNT's program does not contain separate requirements for a radiographer who may be providing on-the-job training to new employees (radiographer assistants).

NRC Response: ASNT designed its program to complement NRC's and most States' current industrial radiography licensing and regulatory programs. NRC's regulations do not require that individuals who provide on-the-job training, meet additional training or experience criteria beyond that expected for radiographers. The ASNT program is intended to apply only to individuals acting as radiographers. The commenter's concern is outside of the scope of ASNT's program and the radiographer certification concept. A State may impose additional requirements for individuals providing on-the-job training if the State believes this is necessary.

8. One commenter suggested the certification program should include provisions for x-ray radiography.

NRC Response: The ASNT program does include provisions for certifying x-ray radiographers which the States may wish to consider in developing their regulatory programs. However, NRC does not have the authority to regulate x-ray machines; therefore, this rule only applies to byproduct material radiography.

9. One individual indicated that his State was interested in becoming a certifying body and asked, "How is the NRC going to approve us as a partner in the regulatory activity?

NRC Response: The criteria NRC is proposing would specify that, in order to be acceptable to NRC, the certifying organization must be a national organization, such as a society or association, whose membership is likely to participate in, or have an interest in, the fields of industrial radiography or non-destructive testing. The NRC does intend to recognize Agreement State certification programs meeting the appropriate criteria of appendix B.

10. A commenter suggested that, considering the NRC has gone to a full cost recovery program, NRC should evaluate the feasibility of running its own radiographer testing program.

NRC Response: NRC did look at the feasibility of running its own testing program in preparing this rulemaking. A description of this option and the estimated cost are fully described in the draft regulatory analysis prepared in support of the proposed rule. The hypothetical program described in the draft regulatory analysis was patterned after the State of Texas program. The staff estimated that the average annual cost to industry (only NRC licensees considered) would be {$1,389,100}. This option is considerably more expensive than the independent organization option described in the draft regulatory analysis (patterned after ASNT's program) where the average annual cost to the industry (NRC licensees only) was estimated to be {$326,587}.

11. A suggestion was made that the regulatory oversight committee should have access to, and be able to review and audit all organization records relating to the certification program.

NRC Response: Any regulatory oversight program agreed to by NRC would include provisions to accomplish what the commenter suggests.

12. Is it NRC's intent to make approval of independent certifying organizations a reserve function under (10 CFR part) 150, as opposed to being delegated to the Agreement States?

NRC Response: NRC does intend to make approval of certifying organizations a reserve function under 10 CFR part 150.

13. If an Agreement State has requirements which are more stringent in one or more areas than (10 CFR) part 34, would national certification preclude additional testing on these unique State rules? For example, some States require two individuals to be present when radiography is performed.

NRC Response: The written examination required for an acceptable certification program generally will concern radiation safety topics. While the examination would include questions concerning regulatory requirements, NRC does not believe that such significant differences exist between NRC and the Agreement States radiography regulations that this should pose a problem. It should be noted that licensees will continue to be required to test radiographers' knowledge and understanding of the licensees operating and emergency procedures. If a State wishes to incorporate an NRC accepted certification program, but feels that the examination does not adequately cover requirements unique to the State, the State may require its licensees to also test radiographers in these unique requirements.

14. Radiography licenses are typically written in one of two ways, either the license names authorized radiographers or the license specifies that only individuals who have completed a described training course may act as radiographers. Would national certification eliminate the first option?

NRC Response: NRC does not believe that certification should have any impact in this area. NRC has issued very few licenses where the license lists the authorized radiographers. In the cases where it has, NRC has often done this because it has granted the licensee an exemption from the requirements specified in 10 CFR section 34.11(b) which require a license applicant to describe its training and testing programs in order to obtain an NRC license. The individuals who act as radiographers are still expected to meet the training and testing requirements specified in 10 CFR section 34.31. Under the above circumstance, the licensee is expected to provide complete information to NRC which shows that the individuals meet these requirements. If certification is required, then all individuals must be certified - being listed on a license would not relieve the licensee of this requirement.

15. One individual commented about the need for compatibility between NRC and a State's program. He suggested that NRC require a lower level of compatibility, such as Division 3, on this issue to allow the States greater latitude in deciding how radiography problems should be addressed in their jurisdiction. He suggested that an acceptable alternative might be to name individual radiographers on licenses.

NRC Response: NRC does not intend to make participation in the independent organization certification program a matter of compatibility. However, NRC's goal in proposing this rulemaking is to improve safety in industrial radiography by ensuring that individuals acting as radiographers in the United States have a minimally acceptable level of knowledge and understanding of the regulations and radiation safety topics important to this area. NRC proposes to meet this goal by requiring all individuals acting as

radiographers be certified either by an approved certifying organization or through a compatible Agreement State program. Naming radiographers on a license would not meet this goal. Under the proposed concept, the Agreement States will have the option of using the approved organization or having a radiographer certification program. This concept could be viewed as a Division 2 level of compatibility.

16. A commenter expressed concern about private certifying organizations "following through," and stated that only the States should have the authority to re-authorize a problem individual to act as a radiographer.

NRC Response: Because of its interactions with the ASNT committee responsible for the IRRSP program, NRC does not especially share the commenter's concern. The ASNT committee has indicated that its sanctions would be based on enforcement actions taken by NRC or the States. However, the ASNT-IRRSP program does not specifically address this issue. Therefore, NRC will include a criterion that an acceptable independent organization must commit to impose sanctions which will be at least as restrictive as an enforcement action imposed by the Commission. The commenter should note that within its own jurisdiction, a State or NRC imposed order would always be in effect, not withstanding any imposed sanction by an independent organization.

17. One commenter expressed the opinion that, given the fact that ASNT is a radiography society, NRC is helping to create a "self-testing" operation rather than independent testing.

NRC Response: NRC views "independent certifying organization" to mean a organization other than a licensee or the regulatory authority. Given this definition, the ASNT program should not be viewed as a self-testing operation.

However, even if the program is considered to be a form of self-testing, NRC believes that this is an improvement over the current situation where self-testing by the licensee is normal.

18. One individual suggested that NRC should consider a "standards-for-duty" criteria for all licensee personnel, rather than just a code of ethics for radiographers.

NRC Response: The suggestion is outside of the scope of this rulemaking and will not be included as a consideration. NRC currently has a "fitness-for-duty" rule applicable to reactor operations in effect, 10 CFR part 26. NRC is considering proposing new regulations to apply the concept to licensees authorized to possess, use, or transport Category I Material (formula quantity of strategic special nuclear material). Thus far, the Commission has rejected extending the requirement to other material licensees.

19. A commenter suggested that NRC may wish to recognize the Canadian program and allow international reciprocity.

NRC Response: NRC staff has evaluated the Canadian industrial radiography regulations and its radiographer (qualified operator) testing procedures and found significant differences between the Canadian and United States approaches. For example, Canada does not require its radiographers to receive any formal radiation safety training nor complete any on-the-job training. The only criteria Canada appears to impose is that the individual successfully complete the written examination. NRC staff also noted significant differences with Canada's basic radiation protection regulations. In view of these differences, NRC has no reason to believe a Canadian radiographer would have any knowledge of radiography regulations unique to the

United States. There would also be questions concerning jurisdictional authority.

C. Public Workshop

NRC held a public workshop on May 27 and 28, 1992, in Mobile, Alabama to discuss national radiographer certification. Invited to the workshop were representatives from the ASNT, the CRCPD, the Organization of Agreement States, and 17 Agreement States. Representatives from Oklahoma and Canada and several members of the public were also in attendance. The meeting was noticed in the Federal Register (57 FR 20430).

Brief presentations were made by NRC staff and certain invitees concerning recent actions regarding certification. While NRC arranged the meeting to facilitate discussion about national radiographer certification between NRC, ASNT, and the Agreement States, comments from the other parties were also welcome. A transcript was made of the meeting. Numerous comments, questions, and suggestions were raised concerning radiographer certification at the national level. The ensuing is a discussion of the comments received; however, any comments which were addressed in earlier sections of this paper are not repeated here:

1. Can a viable, workable, national program be established which recognizes multiple certification programs? Will NRC recognize a state-administered certification program?

NRC Response: NRC believes that a workable national program that recognizes multiple certification programs can be established. For Agreement

States having certification programs, provided all parties have similar criteria, then all parties should be able to accept the other programs pursuant to reciprocity. The certification programs must include the following four elements: individuals must receive 40 hours training in the subjects listed in 10 CFR part 34 appendix A (or equivalent), pass a written examination, have a minimum period of OJT, complete a practical examination (or equivalent), and there must be verification of training. An acceptable independent certifying organization must meet the following: (a) the group must have expertise in radiography, (b) the certification program must be open to the public, (c) it must be a non-profit organization, (d) it must have a permanent full-time staff. (e) it must have written policies and procedures, and (f) a method for enforcing policies. However, as explained beforehand, NRC does not anticipate that other organizations than ASNT, which meet these criteria, will come forward.

2. We should use a term like "certifying entity" or "certifying body" rather than "third-party."

NRC Response: NRC has incorporated this comment.

3. Would alternative tests developed by an independent certifying organization be acceptable? What criteria should the test (items) meet?

NRC Response: NRC believes that an independently developed examination would be acceptable if it meets certain criteria, including: (1) test questions must be validated, (2) the examination program must have regulatory oversight, (3) there must be test security, and (4) the examination items must not be biased in any way. The criteria that acceptable examinations must meet will be listed in proposed appendix B.

4. What should be the functions of an oversight task group?

NRC Response: NRC strongly believes that there needs to be periodic regulatory oversight of certification programs, and has already initiated efforts with ASNT to develop such a program. Oversight task group activities might include unannounced visits at test sites. For state administered certification programs, it may be reasonable to have the task group conduct similar oversight reviews during the routine state review.

5. How would NRC react to a labor union, for example, that may wish to act as an independent certifier?

NRC Response: NRC would set general criteria, and any organization that meets this criteria theoretically could qualify; however, NRC does not believe it is likely that other organizations are interested. Labor unions would seem to be excluded because of the criterion that the association must be open to participation by the public as well as members. What NRC is looking for in an independent certifying organization is expertise and independence that implies professionalism.

6. Will an individual be allowed to certified by more than one organization at one time?

NRC Response: With similar criteria, all participants should be able to accept other programs pursuant to reciprocity. NRC sees no need for more than one certification if reciprocally recognized; however, some states may require the individual to have a state identification card, which seems acceptable.

7. The following comments are related to enforcement activities: Which safety-related violations will be subject to sanctions? What should the sanctions be? If sanctions differ, will organization A recognize sanctions

imposed by organization B? What will constitute due process? How will violations be documented?

NRC Response: These items are all related to communication mechanics between the various participants, and seem to assume that problems can be expected. A CRCPD committee, which includes NRC representation, has been established to resolve these type of problems, should they occur.

8. Workshop participants seem to be failing to recognize that major corporations have integrity and good training programs.

NRC Response: NRC does recognize that some licensees do a good job; however, for others, this is an high overhead item. NRC believes the certification program is an appropriate attempt to bring independence into the system and require a greater level of assurance of a radiographer's training and background.

VIII. Description of Amendments

Section 34.2

This section provides definitions for various terms used in 10 CFR part 34. NRC proposes adding four new definitions to the section. These definitions would further define the terms "certifying entity," "radiographer certification," "independent certifying organization," and "radiographer certification program."

Section 34.11

Section 34.11 outlines the information license applicants must submit in order for NRC to approve their application and issue an NRC radiography license. Under the proposed revisions, paragraph (b) would be revised to take into account mandatory certification. The requirement in §34.11 for submitting a description of the applicant's initial training and testing program for radiographers on the radiation safety subjects listed in appendix A of 10 CFR part 34 would be deleted. However, the proposed rule would not change the requirements for radiographers' assistants and license applicants would continue to submit descriptions of the periodic retraining and training in operating and emergency procedures. When reviewing a license application, NRC staff will continue to examine how the applicant intends to train prospective radiographers in radiation safety topics. If the license applicant intends to conduct this training in-house, the identity of the individual and his/her qualifications must be set forth in the application. The NRC will also require the applicant to confirm that prospective radiographers will receive approximately 40 hours of formal classroom training in the 10 CFR part 34 appendix A radiation safety topics.

A new paragraph (g) would be added to require license applicants to develop and submit a description of procedures for verifying the certification status of newly-hired radiographers and for ensuring that radiographers' certification status remains active. The proposed rule change would also require that the procedures include provisions for making and maintaining a

record of the certification status verification. These records would have to be maintained for three years.

The requirement for verifying an individual's certification status would only apply to previously certified radiographers a licensee might hire. NRC anticipates that a licensee will know an individual's status if the licensee sends the individual to become certified. The procedures for ensuring that an individual's certification status remains active is applicable to all of a licensee's radiographers.

Section 34.31

This section specifies the minimum training requirements which must be met in order for a licensee to allow an individual to act as a radiographer or a radiographer's assistant. NRC proposes revising paragraph (a)(1) to require that all individuals a licensee allows to act as radiographers be certified through a radiation safety certification program conducted by a certifying entity. Paragraph (a)(1) would also reference a new appendix B NRC proposes to add to 10 CFR part 34. A new paragraph (a)(1)(A) would identify the Commission-approved radiation safety certification programs and independent certifiers and a new paragraph (a)(1)(B) would identify the States which have compatible programs. The requirements in paragraphs (a)(2) and (3), which are applicable to licensee-specific programs, remain unchanged.

NRC also proposes to amend existing paragraph 34.31(c), which requires licensees to maintain training and test records, to require licensees to make and maintain copies of each radiographer's certification document(s). NRC also

proposes to add a new paragraph (d) to this section which will allow licensees to continue to take advantage of the current radiographer qualification program until the final effective rule date (3 years after the effective rule date).

Appendix B

NRC proposes to add a new appendix B to 10 CFR part 34. This appendix would outline the organizational elements, certification program elements, and written examination elements which must be met for an independent certifying organization, and its radiation safety certification program, to be acceptable to NRC. The appendix would also describe how an independent certifying organization would apply to the Commission for approval of its certification program. The certification program elements and written examination elements would also apply to any Agreement State that wishes to develop a compatible certification program.

The appendix would separate the organization elements into two components; one area concerning the organizational structure of the independent certifying organization and the other area concerning the organizational structure of the certification program. NRC is proposing that for an independent certifying organization to be acceptable to NRC, it would have to be a national society or association involved with industrial radiography or non-destructive testing. Membership in the organization must not restricted because of race, age, sex, or national origin, and the certification program must be open to nonmembers. The independent certifying

organization must also have a permanent full-time staff and a set of written organizational ground rules (by-laws, policies, etc.).

For the certification program organizational structure to be acceptable, the independent certifying organization must establish a committee to assist in preparing and implementing certification guidelines and procedures, and establish a committee to review complaints against certified individuals. The independent certifying organization must establish written procedures detailing the certification program, and must also agree to establish procedures with NRC (and other regulatory authorities, if applicable) for exchange of information and periodic certification program review.

In order for a certification program to be acceptable, NRC is proposing that it must include provisions requiring individuals to receive training in part 34 appendix A topics, satisfactorily complete a written examination, provide evidence of satisfactorily completing a practical examination or equivalent, and require a minimum period of job experience. The program would also have to include procedures whereby an individual's certification may be revoked, suspended, or restricted for willful or significant failure to comply with their employer's operating and emergency procedures and the Commission's or an Agreement State's regulations.

The third element of proposed appendix B would concern the written examination. NRC is proposing that, for the written examination to be acceptable, it must be designed to test knowledge and understanding of 10 CFR Part 34, appendix A subjects; it must be validated to test at an educational level equivalent to the ninth grade; and the examination question and answer items must be validated in accordance with accepted practices.

The final element of proposed appendix B would inform organizations wishing to be considered as approved certifiers, what information they must submit for NRC's consideration, and where to send the information.

IX. Implementation

NRC intends to vary the dates on which particular requirements of the rule become effective.

NRC proposes making new appendix B and the amendment to section 34.31(c) effective 30 days after publication of a final rule. While applicable to the rulemaking under consideration, NRC believes that the word changes proposed for section 34.31(c) will also help to clarify what records licensees are allowed to maintain when voluntarily participating in ASNT's certification program as is currently provided under 10 CFR part 34. Proposed appendix B does not impose new requirements on NRC's radiography licensees. Instead, it specifies the criteria an organization wishing to act as an independent certifying organization must meet and describes the procedures an organization must follow in for applying for NRC approval.

NRC anticipates making the remainder of the requirements effective two years after publication as a final rule. This will allow radiography licensees operating in NRC jurisdiction two years to have their employees who act as radiographers certified. ASNT has indicated that two years may be needed in order to completely process the number of individuals subject to certification. ASNT's estimate of two years assumes that individuals would apply for certification in a somewhat orderly fashion. NRC is concerned that

should licensees wait until the "last minute" to have radiographers certified, it may overwhelm the system. Therefore, NRC has considered imposing alternative implementation schedules that might ensure a more orderly process. For example, NRC might require that all NRC licensees, whose institution code (the middle 5 numbers in an NRC license) ends in a even number, have their radiographers certified within one year, while the remainder of licensees would have the full two years.

It should be noted that it is NRC's intention that all individuals acting as radiographers within NRC jurisdiction must be certified by the effective rule date. This includes radiographers employed by Agreement State licensees operating in NRC's jurisdiction under reciprocity pursuant to 10 CFR 150.20. NRC has taken a similar approach with other recent rulemakings involving industrial radiography; for example, the requirements concerning alarm rate meters published as part of the 1990 final rule on radiography equipment applies to all individuals. NRC notes that the State of Texas provides a 90-day grace period for non-Texas licensees operating in that State under reciprocity (TRC 31.90). Apparently, Texas provides this one-time exception for non-Texas licensees who may be unaware of the Texas requirements. Because this proposed rule change will be a matter of compatibility, radiography licensees nationwide should be aware of the rulemaking; therefore, NRC does not believe it necessary to provide Agreement State licensees a similar grace period after the effective rule date. Agreement State licensees operating in NRC's jurisdiction under reciprocity would have the full two years to comply with any final rule.

The NRC requests that persons commenting on the proposed amendments particularly address any anticipated hardships that may result from the proposed implementation schedule. NRC is particularly interested in comments concerning the need for, or suggestions of alternative implementation schedules that would ensure an orderly process.

X. Impact of the Rule

The impact on the radiography industry is expected to be moderate. As detailed in the draft regulatory analysis prepared for this rulemaking, NRC estimates that there are approximately 739 radiography licensees nationwide with about 12,000 individuals employed as radiographers on a full- or part-time basis. Of these numbers, 237 are NRC licensees employing an estimated 4223 individuals as radiographers.

Since ASNT has an approved certification program, ASNT costs have been used in this analysis. ASNT certification costs $95 for ASNT members and $140 for non-members. In its analysis, the NRC estimated the cost of (ASNT) certification per radiographer to be $220. The remainder, about $100, represents the cost of travel and food. The ASNT certification is valid for 3 years. NRC estimated the cost of recertification without examination to be $85, $55 for members and $100 for non-members. NRC also estimates that 20 percent of the individuals taking the examination would fail and retake the examination, and only one-third of the individuals requiring recertification would qualify for recertification without reexamination. Individuals who fail the examination, will be charged $60 to retake the examination. The analysis

assumes that ASNT would certify all 12,000 individuals in the first 3 years, that the radiographer population remains constant, and that one-third of the population would be recertified each year after the third year. Based on these assumptions, the cost to industry is then estimated to be $2,784,000 for 3 years and $725,220 per year thereafter (in 1991 dollars). If only individuals authorized to act as radiographers in NRC's jurisdiction are considered (4223); then the cost is estimated to be $979,680 for 3 years and $255,380 per year thereafter.

The total cost of the proposed action is comprised of the sum of NRC cost, the costs of other government agencies, and industry costs. Anticipated recurring costs to the NRC are not expected to be significant for this action. An estimated one-time cost of 1 1/2 professional staff-year ($125,810) effort will be needed to support this rulemaking activity. The Agreement States would be asked to review and comment on the proposed rule. For the 29 Agreement States the total one-time review effort is estimated at approximately 232 person-hours ($11,140). Should the rulemaking become a final rule and a matter of compatibility, the Agreement States would need to revise their regulations. NRC estimates that each of the 29 States would incur a one-time cost of 1/4 professional staff-year ($608,300) to complete this action. Additional record keeping and procedure preparation costs are also proposed in the rule.

The total cost of this action then would be approximately $7.9 million for 30 years. If only individuals authorized to act as radiographers in NRC's jurisdiction are considered, the cost is estimated to be approximately

$2.5 million for 30 years. All of these costs are further detailed in the draft regulatory analysis prepared in support of this rulemaking.

Of course this assumes that all individuals acting as radiographers would participate in the independent certification program. As proposed, some States may opt to develop their own certification programs. Because NRC is uncertain how many, if any, States may opt for this option, it is difficult to determine how this may impact cost. The State of Texas currently charges individuals $55 to take its examination. Texas charges ASNT $40 for each examination ASNT purchases for use in its program. As an alternative in the draft regulatory analysis, NRC has evaluated the cost of administering a testing program within its jurisdiction. NRC estimated that the average annual cost to NRC's radiography licensees would be $1,389,100, and the total cost would be approximately $13.1 million for 30 years. In order to recoup 100 percent of NRC costs, the analysis indicates NRC would need to charge $760 per examination.

XI. Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(i). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

XII. Paperwork Reduction Act Statement

This proposed rule amends the information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average about 533 hours per year (for 217 NRC licensees and 502 Agreement State licensees involving 5200 individual radiographers) or about 0.72 hours per year per licensee for verifying certification status and copying certification documents. The one-time burden to develop and prepare written procedures is estimated to be about 2956 hours. This burden estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information for completeness. 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 (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019, (3150-0016 and 3150-0001), Office of Management and Budget, Washington, DC 20503.

XIII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis of this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW.(Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from J. Bruce Carrico, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 504-2634.

XIV. Regulatory Flexibility Certification

The NRC has prepared an initial regulatory flexibility analysis of the impact of this proposed rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis, which is set out in appendix A of this document, indicates that the proposed rule could have an annual economic impact of about $1360 for the first three years and about $1010 each year thereafter on each radiography licensee. If only NRC licensees are considered, the proposed rule could have an annual economic impact of about $1480 for the first three years and about $1110 each year thereafter on each radiography licensee.

The NRC has adopted size standards that classify a small entity as one whose gross annual receipts do not exceed $3.5 million over a 3-year period. The NRC believes that about 90 percent or more of the licensees affected by the proposed rule would be classified as small entities. However, the NRC

does not consider these costs to be overburdensome in light of the possible benefits derived.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size in terms of annual income or revenue and number of employees;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a large licensee;

(c) How the proposed regulation could be modified to take into account the licensee's differing needs or capabilities;

(d) The benefits that would be gained or the detriments that would be avoided by the licensee if the proposed regulation were modified as suggested by the commenter; and

(e) How the regulation, as modified, would still adequately protect the public health and safety.

XV. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule and, therefore, that a backfit analysis is not required for this rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

XVI. List of Subjects

Packaging and containers, Criminal penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

XVII. Wording of the Proposed Amendments

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendment to 10 CFR part 34.

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

1. The authority citation for part 34 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 34.32 also issued under sec. 206, 88 Stat. 1246 (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§34.20(a)-(e), 34.21(a) and (b), 34.22, 34.23, 34.24, 34.25(a), (b), and (d), 34.28, 34.29, 34.31(a) and (b), 34.32, 34.33(a), (c), and (d), and (f), 34.41, 34.42, and 34.43(a), (b), and (c) and 34.44 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§34.11(d), 34.25(c) and (d), 34.26, 34.27, 34.28(b), 34.29(c), 34.31(c), 34.33(b) and (e), and 34.43(d) are issued under sec. 161b, 68 Stat. 958, as amended (42 U.S.C. 2201(b)); and §§34.11(d), 34.25(c) and (d), 34.26, 34.27, 34.28(b), 34.29(c), 34.30, 34.31(c), 34.33(b) and (e) and 34.43(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In §34.2, the following definitions are added:

§34.2 Definitions.

* * * * *

"Certifying Entity" means an approved independent certifying organization or an Agreement State with an compatible radiographer certification program.

"Radiographer certification" means the issuance of a document by a certifying entity, to an individual which recognizes that the individual has satisfactorily met certain training, testing and experience criteria.

"Independent certifying organization" means an organization that is financially and corporately independent of any company for whom an individual acts as a radiographer or performs radiography duties, and which is independent of the Commission.

"Radiographer certification program" means a program for certifying radiographers conducted by an independent certifying organization which has been approved by the Commission or conducted by an Agreement State with a compatible program.

3. In §34.11, paragraph (b) is revised and paragraph (g) is added to read as follows:

§34.11 Issuance of specific licenses for use of sealed sources in radiography.

* * * * *

(b) The applicant will have an adequate program for training radiographers and radiographers' assistants, and;

(1) Describe its program for complying with §34.31;

(2) Describe its program for providing periodic and on-the-job training;

[Licenses in effect on (date of publication) are deemed to include the option, for individuals who are certified in radiation safety by an approved certifying entity, to substitute the certification in lieu of the program previously submitted and approved by the Commission to determine a

radiographer's knowledge and understanding of the subjects in appendix A of this part.]

* * * * *

(g) The applicant has established and submits to the Commission a description of its procedures for verifying the certification status of its radiographers and for ensuring that the certification status of individuals acting as radiographers remains active. A record of the certification status verification shall be made and maintained for three years after making the record.

4. In §34.31, new paragraph (d) is added, paragraphs (a)(5) and (a)(6) are deleted, and paragraphs (a) and (c) are revised to read as follows:

§34.31 Training.

(a) * * *

(1) Is certified through a radiation safety certification program by an independent certifying organization approved by the Commission in accordance with the criteria specified in appendix B of this part and identified in paragraph (A) of this section or a compatible Agreement State program identified in paragraph (B) of this section. (Organizations wishing to act as an independent certifying organization must apply to the Commission following the procedures identified in item IV of appendix B of this part.)

(A) The following are approved radiation safety certification programs and independent certifying organizations:

(i) The Certification Program for Industrial Radiography Radiation Safety Personnel of the American Society for Nondestructive Testing, Inc.

(B) The following States have adopted compatible radiation safety certification programs:

(i) (list of States)

(2) * * *

(3) * * *

(4) Has demonstrated understanding of the instructions in paragraphs (a)(2) and (3) by successful completion of a field examination on the subjects covered.

* * * * *

(c) Records of the above training, including radiographer certification documents and copies of written tests and dates of oral tests and field examinations, shall be maintained for three years following the last time an individual acts as an radiographer.

(d) In lieu of meeting the requirement of (a)(1) of this section, the licensee may, until (3 years after the effective rule date), allow an individual to act as a radiographer after the individual has received training in the subjects outlined in appendix A of this part, and demonstrated understanding of those subjects by successful completion of a written examination submitted to and approved by the Commission.

5. A new Appendix B is added to read as follows:

APPENDIX B

I. INDEPENDENT CERTIFYING ORGANIZATION ORGANIZATIONAL ELEMENTS

A. Organizational structure.

1. The independent certifying organization must be an organization, such as a society or association, whose membership is likely to participate in, or have an interest in, the fields of industrial radiography or non-destructive testing.

2. Membership in the independent certifying organization must be available to the general public on the national level, this membership must not restricted because of race, age, sex, or national origin, and its certification program must be open to nonmembers.

3. The independent certifying organization must be an incorporated, not-for-profit, nationally recognized organization, which is involved in setting national standards of practice within its fields of expertise.

4. The independent certifying organization must have a permanent full-time staff, a viable system for financing its operations, and have a policy and decision making review board consisting of members with "impartial interest."

5. The independent certifying organization must have a set of written organizational ground rules (by-laws, policies, etc.) which assure avoidance of conflict of interest, and provide for a system for monitoring and enforcing policies.

B. Certification program organizational structure.

1. The independent certifying organization must establish a committee consisting of members with an "impartial interest" to assist in establishing certification guidelines and procedures, and to assist the staff in implementing the certification program.

2. The independent certifying organization must establish a committee consisting of members with an "impartial interest" to review complaints against certified individuals and to determine appropriate sanctions.

3. The independent certifying organization must establish written procedures detailing all aspects of the certification program, and maintain records on each certified individual and on the administration of the program.

4. The independent certifying organization must agree to establish procedures for exchange of information about certified individuals with the Commission and the Agreement States, and allow these regulatory authorities to periodically review records pertaining to the certification program.

5. The independent certifying organization shall establish procedures ensuring certified individuals "due process."

6. The independent certifying organization must agree to respond to inquiries (by telephone or letter) from members of the public concerning an individual's certification status.

7. The independent certifying organization shall establish procedures to ensure that the individuals proctoring a given examination are not employed by the same company or corporation as any of the examinees or have other financial interest.

8. The independent certifying organization must describe its procedures for choosing examination sites. Examination sites shall be established in close proximity to the examinees and shall be chosen with due consideration for providing an appropriate examination environment (classroom-style seating, adequate space between individuals, little cause for distraction, and consistency from location to location).

II. CERTIFICATION PROGRAM ELEMENTS

A. The program must require individuals to receive training in and satisfactorily complete a written examination covering the topics set forth in Appendix A of this part.

B. The program must require applicants for certification to provide signed documentation that shows the applicant has satisfactorily completed a practical examination (or equivalent) administered by a NRC or Agreement State licensee and that shows the applicant has completed a minimum period of on-the-job training (i.e., a minimum period of job experience).

C. The program must provide procedures for ensuring that specific examination items are protected from disclosure to radiographers and the general public.

D. The program must include procedures whereby an application or certification would be considered null and void if the applicant or certified individual was prohibited from acting as a radiographer by a regulatory agency at the time of making the application.

E. The certification must be valid for a period of not less than 3 years.

F. The program must describe procedures for renewing the certifications and, if the program includes provisions for renewal without examination, the renewal procedures must require evidence of reasonable active permanent employment and annual refresher training.

G. The program must include procedures whereby an individual's certification may be revoked, suspended, or restricted for willful or

significant failure to comply with their employer's operating and emergency procedures and the Commission's or an Agreement State's regulations.

H. The program must provide for automatic suspension of an individual's certification based on Commission or State action prohibiting the individual from acting as a radiographer.

I. The program must ensure that sanctions imposed against certified individuals are at least as severe as any action taken by the Commission or a State.

III. WRITTEN EXAMINATION ELEMENTS

A. The examination must be designed to test an individual's knowledge and understanding of 10 CFR Part 34, Appendix A (or Agreement State equivalent) subjects.

B. The examination must be a multiple-choice format.

C. The examination question and answer items must be normalized to a ninth-grade reading comprehension level.

D. The examination question and answer items must be analyzed for reliability and validity in accordance with accepted practices. The examination items must be tested by at least 50 individuals prior to being used as "official" items. Typical item analysis procedures such as provided in the computer program, "Educational Maintenance System," should be used.

E. Sufficient examination items must be developed so that individual examination items should be used only periodically. The program should include procedures for randomly picking examination items, and for ensuring that it is unlikely that an examinee would retake a unique examination.

IV. CERTIFICATION PROGRAM APPROVAL PROCEDURES

A. Organizations requesting approval by the Commission as independent certifying organizations shall provide complete information to show that its radiation safety certification program and its organization meet the criteria identified in items I. through III. of this appendix.

B. Requests should be sent to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC. 20555.