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REGULATORY GUIDE

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APPENDIX X

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GUIDANCE ON COMPLYING WITH NEW PART 20 REQUIREMENTS

to Regulatory Guide 10.8, Revision 2,
"Guide for the Preparation of Applications
for Medical Use Programs"

The revision of 10 CFR Part 20, "Standards for Protection Against Radiation" (§§ 20.1001–20.2401) changes a number of the requirements for medical use programs. The major change in the revised Part 20 is to incorporate newer national and international concepts on radiation protection, including the application of a risk-based approach to the establishment of radiation protection limits. Included are the adoption of the "effective dose" concept, specification of occupational dose limits as the sum of internal and external dose, and use of annual limits on intake (ALIs) and derived air concentrations (DACs) as a means for regulating the ingestion and inhalation of radionuclides. The adoption of the effective dose concept and the application of the occupational dose limit to the sum of the internal and external doses change the methodology to be used for evaluating, controlling, and recording radiation doses. In addition to the changes to the dose methodology, there are other differences between the provisions of 10 CFR 20.1–20.601 and the provisions of 10 CFR 20.1001–20.2401.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses or license renewals and for evaluating compliance with 10 CFR 20.1001–20.2401.

Regulatory Guide 10.8 was prepared under the provisions of 10 CFR 20.1–20.601 and 10 CFR Part 35. This new appendix discusses the major differences introduced by the revised 10 CFR Part 20 that modify the guidance previously provided by the NRC for the conduct of medical use programs.

Any information collection activities mentioned in this appendix are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014.

The following are the major areas of medical use programs affected by the revised Part 20.

1. RADIATION PROTECTION PROGRAMS

(See Appendix G to Regulatory Guide 10.8)

In the revised Part 20, 10 CFR 20.1101 requires each licensee to develop, document, and implement a radiation protection program appropriate to the scope and extent of the activities conducted and to review at least annually the program content and its

implementation. Further, 10 CFR 20.1101 requires that each licensee use engineering controls and procedures to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). In addition, 10 CFR 20.2102 provides the recordkeeping requirements for radiation protection programs.

The requirements in 10 CFR 20.1101 are consistent with the requirements for control of occupational exposures in 10 CFR Parts 33 and 35. Radiation protection programs that have been established under the requirements of 10 CFR Parts 33 and 35 will be considered to be acceptable to meet the occupational ALARA requirements of the revised 10 CFR Part 20 when the program activities are limited to external occupational exposures. However, licensees who handle unsealed radioactive materials that may cause internal exposure to members of the public will need to supplement their ALARA programs to address potential internal as well as external doses to members of the general public from effluents to unrestricted areas. Additional guidance is being developed on this, and it will be addressed in a separate regulatory guide. Licensees should establish ALARA goals or objectives for effluents.

In developing an ALARA radiation protection program, licensees should design the program based on the size of the licensed facility, the potential hazards associated with radiation exposure, the potential intake of radioactive material, and the physical characteristics of the radionuclides (i.e., solid, liquid, or gas). For example, the magnitude of an ALARA program for a large research hospital would be expected to be considerably more comprehensive in scope than a radiation protection program for a private practice physician. The program should include the mechanisms for periodic (at least annually) review of performance, as well as actions to be taken when ALARA goals or objectives are not met.

The revised 10 CFR Part 20 does not require that a numerical cost-benefit analysis (quantitative approach) be used to demonstrate ALARA. However, NRC encourages medical licensees to use quantitative analyses in developing ALARA programs and procedures. If it can be performed readily, licensees should demonstrate through quantitative analysis that the cost and benefits associated with design, engineering controls, and operating procedures have been optimized in accordance with the ALARA principle. If a quantitative analysis cannot be readily performed, licensees should thoroughly evaluate any design or engineering controls that may need to be changed to keep operating procedures ALARA.

Examples of the type of ALARA optimization considerations appropriate to the conduct of medical use programs are presented in the National Council on Radiation Protection and Measurement (NCRP) Report No. 107, "Implementation of the Principle of As Low As Is Reasonably Achievable (ALARA) for Medical and Dental Personnel,"* December 31, 1990. This NCRP report provides specific hypothetical examples of optimization decisions in implementing ALARA in nuclear medicine and radiation oncology.

2. INTERNAL DOSE METHODOLOGY

The revised 10 CFR Part 20 incorporates the new dose methodology system developed by the International Commission on Radiological Protection (ICRP), which specifies radiation dose limits in terms of an "equivalent" whole body dose, taken to be the sum of individual organ committed doses weighted by the risk of biological effect for each of the organs irradiated. This effective dose equivalent concept is used to control the stochastic biological effects of exposure to ionizing radiation. Nonstochastic, or threshold, biological effects are avoided by establishing dose limits for the committed dose received by an individual organ and for the exposure to the skin and to the lens of the eye (see 10 CFR 20.1201).

2.1 Units and Terms for Internal Exposure

The revised 10 CFR Part 20 uses the "special" units of dose and activity and presents the corresponding values for the international system (SI). Records and reports required under the revised Part 20 are to be maintained using the "special" units.

The following table provides the conversions between the two systems of measurement:

Special Units	
(Activity) curie (Ci)	= 3.7×10^{10} disintegrations per second (3.7×10^{10} Bq)
(Absorbed dose) rad	= 100 ergs/gram (0.01 Gy)
(Dose equivalent) rem	= Quality factor x rad (0.01 Sv)
SI Units	
(Activity) becquerel (Bq)	= 1 disintegration per second (2.7×10^{-11} Ci)
(Absorbed dose) gray (Gy)	= 1 joule/kg (100 rads)
(Dose equivalent) sievert (Sv)	= Quality factor x grays (100 rems)

In addition, the revised Part 20 introduces new terms for radionuclide intakes by means of inhalation and ingestion, e.g., derived air concentration (DAC).

*NCRP reports can be purchased by writing to NCRP Publications, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814.

For a few radionuclides (e.g., noble gases such as xenon), the terms apply to exposures from submersion.

The new term DAC is used, in broad terms, similar to the way in which the maximum permissible concentration (MPC) is used in Appendix B, Table I, Column 1, to 10 CFR 20.1–20.601 and 20.103. Exposure to airborne radioactivity at a level of 1 DAC for 1 year (2000 hours) would result in either a committed effective dose equivalent of 5 rems (50 mSv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. In order to show compliance with the occupational dose limit of 5 rems (50 mSv), a facility must consider the contributions of internal and external doses prior to calculating ventilation and gas clearance time.

Appendix O to this Regulatory Guide 10.8 provides model procedures for calculating worker doses from concentrations of gases in work areas and for calculating spilled gas clearance times. The procedure states that the MPC values for the radionuclide of interest should be used in the calculations. To implement the revised Part 20, the DAC value for the radionuclide of interest, in conjunction with the contribution of external dose, must be used instead of the MPC value. For example, consider the following simplified approach to determining required ventilation rates in an area where xenon-133 procedures will be performed:

Example

A new room is being designed in an existing nuclear medicine department where xenon-133 ventilation studies will be performed. You are asked to calculate the minimum ventilation rates required to maintain compliance with the occupational dose limits.

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.

2. Modify the DAC value for xenon-133 to allow for the estimated annual external exposure.

   A simplified method is to subtract the estimated external dose from the occupational dose limit of 5 rems (50 mSv) and divide this number by 5 rems. This yields the fraction of the dose limit of 5 rems that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in Appendix B to 10 CFR §§ 20.1001–20.2401 in Table 1, Column 3.

   The annual external dose is 2 rems. The listed DAC value for xenon-133 is 1E–4 μCi/ml. The modified DAC value should be based on 3 rems that could still be incurred from internal exposure.

   $$\text{DAC (modified)} = \frac{3 \text{ rems}}{5 \text{ rems}} \times 1\text{E}{-4}\mu\text{Ci/ml}$$
   $$= 6\text{E}{-5}\mu\text{Ci/ml}$$

3. Calculate the minimum ventilation rates for the room using the procedure provided in Appendix O to this Regulatory Guide 10.8. In place of the MPC value stipulated in Appendix O, use the modified DAC value. In the example provided above, the modified DAC value (6E–5 μCi/ml) would be used instead of the MPC value for xenon-133.

The discussion and example presented in this section do not specifically address ALARA and the monitoring thresholds for internal doses as it relates to the summation of internal and external dose. However, it should be noted that modifications to ventilation rates can be a means to maintaining exposures ALARA. In addition, increased ventilation rates may negate the requirement to monitor internal dose and, as such, may eliminate the necessity to sum internal and external dose to show compliance with the occupational dose limits.

2.2 Occupational Dose Limits

In 10 CFR 20.101, the quarterly occupational dose limit of 1.25 rems (5 rems in a year) applies only to whole body exposures to external radiation (10 CFR 20.101). If the licensee has a dose history and a worker's cumulative dose is less than 5(age-18) rems, the worker could be allowed under certain circumstances to receive occupational exposure in excess of the 10 CFR 20.101(a) limit up to 3 rems per quarter (10 CFR 20.102(b)). In addition to the 5-rem annual total for occupational external exposure, 10 CFR 20.103 specifies a separate limit to apply to exposures to concentrations of radioactive materials in air in restricted areas (10 CFR 20.103 and Column 1, Table 1, of Appendix B to §§ 20.1–20.601).

The revised Part 20 applies the 5-rem (50-mSv) occupational dose limit as a whole body "effective" dose. This limit is the sum of the deep-dose equivalent from external sources and the committed effective dose equivalent to the organs exposed from the internal uptake of radionuclides, expressed as the total effective dose equivalent (10 CFR 20.1201). Additional guidance is provided in Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Doses," on the methods to be used for determining these dose equivalents. Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," provides guidance on reporting the dose data on NRC Forms 4 and 5. The revised Part 20 no longer contains provisions for an age proration 5(N–18).

2.3 Effective Dose Equivalent

The effective dose equivalent concept described above makes it possible to combine both the internal and external doses in assessing the overall risk of health effects to an individual. Prior to the revision of Part 20, the activity concentration limits for intakes of a single radionuclide (in Appendix B to §§ 20.1–20.601) were based on controlling the dose to the organ receiving the highest dose ("critical organ"). These concentration limits, however, were treated separately from the dose limits for external exposure. The revised 10 CFR Part 20 dose methodology evaluates the doses to all major body organs, multiplies these doses by the appropriate organ weighting factors, and then sums the organ-weighted doses to obtain a whole body risk-weighted "effective dose." The ALIs and DACs in Appendix B to §§ 20.1001–20.2401, therefore, reflect the doses to all principal organs that are irradiated, not just the one organ that receives the highest dose, as was done previously.

3. DECLARED PREGNANT WOMEN
[Embryo/Fetus Dose Limits]
(See 10 CFR 20.1003 and 20.1208)

The revised Part 20 uses the term "declared pregnant woman" to mean a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

For declared pregnant women, the NRC limits the dose to the embryo/fetus to 0.5 rem (5 mSv) over the entire pregnancy. In addition, the licensee is required to make an effort to avoid substantial variation above a uniform monthly exposure rate (0.05 rem/month) (0.5 mSv/month). Declared pregnant women are not allowed to receive planned special exposures that involve whole body doses or maternal intakes that could result in exceeding the embryo/fetus dose limit. The radiation protection program should make provisions for instructing women workers about the special need to protect the embryo/fetus and to encourage them to promptly notify their employer if they become pregnant. Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus," contains guidance on evaluating the dose to the embryo/fetus.

4. LEVELS IN UNRESTRICTED AREAS
(See 10 CFR 20.1301 and 20.1302)

The revised Part 20 uses the following terms with regard to areas with or without radiological restrictions:

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 mrem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

"Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted to 2 mrem (20 μSv) in any 1 hour from external sources and to 100 mrem (1 mSv) in a year total effective dose equivalent for individual members of the public. Depending on how the licensee's hospital areas are controlled and monitored, hallway areas outside patient therapy rooms and diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

5. NVLAP PROCESSORS
(See 10 CFR 20.1501)

Personnel dosimeters that require processing to determine the dose to compare to the 10 CFR Part 20 dose limits must be processed and evaluated by a dosimetry processor that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

6. CONTROL OF LABORATORIES
(See 10 CFR 20.1101, 20.1702, 20.1801, 20.1802, and 20.1902)

Access to laboratories using radionuclides, as well as the work practices in these laboratories, need to be controlled. Controlling access to radionuclide laboratories is accomplished by posting the entrance door and locking all accessible entrances to the laboratory when an authorized user, or an individual under the supervision of an authorized user, is not present. An acceptable alternative is to provide lockable storage facilities within the laboratory. In 10 CFR 20.1902(e), posting is required for each area or room in which there is used or stored a quantity of licensed material exceeding 10 times the quantity in Appendix

C to §§ 20.1001–20.2401. Some of the Appendix C quantities are changed. Appendix I to Revision 2 of Regulatory Guide 10.8 provides model rules for safe use of radiopharmaceuticals that can be used for radionuclide laboratories, and Appendix J provides model spill procedures.

7. POSTING AND CONTROLLING ACCESS TO PATIENT ROOMS
(See 10 CFR 20.1903(b))

When patients have received therapeutic administrations of radionuclides or therapeutic applications of sealed sources, the criteria for exceptions to posting requirements specified in 10 CFR 20.1903 will likely be exceeded. Dose rates from therapy patients can often exceed 5 mrem (50 μSv) per hour at 1 meter from the patient. Under these conditions, the entrance to the patient's room must be posted and access to the area controlled. Access can be controlled by routine surveillance and by posting instructions for hospital personnel and visitors at the entrance to the patient's room. Examples of such instructions can be found in Exhibit 17 of this Regulatory Guide 10.8. Systems such as remote TV surveillance, electronic eye, or personnel entry detection devices are considered acceptable for monitoring personnel access to the patient's room.

Note that 10 CFR 20.1903 allows exceptions to the posting requirements if specific conditions are met. Licensees should review 10 CFR 20.1902 and 1903 for posting requirements since some of the posting language has changed.

8. EXEMPTIONS TO LABELING REQUIREMENTS
(See 10 CFR 20.1905)

Licensees are not required to label containers holding licensed material in quantities less than the quantities listed in Appendix C to §§ 20.1001–20.2401. For iodine-125, carbon-14, and sulfur-35, the quantities below which labeling is not required are 1 μCi, 1000 μCi, and 100 μCi, respectively. In addition, licensees are not required to label containers holding licensed material in concentrations less than those specified in Table 3 of Appendix B to 20.1001–20.2401. For iodine-125, carbon-14, and sulfur-35, the exemption concentrations are 2×10^{-5} μCi/ml, 3×10^{-4} μCi/ml, and 1×10^{-3} μCi/ml, respectively.

9. PROCEDURES FOR RECEIVING AND OPENING PACKAGES
(See 10 CFR 20.1906(c) and 20.1906(d))

In the revised Part 20, 10 CFR 20.1906 modifies the Type A package quantity limits affecting package opening procedures, monitoring required for radioactive contamination on external surfaces of a package, and surface contamination levels requiring notification of the NRC as follows: Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 10 CFR 71.4 and Appendix A to Part 71 (e.g., more than 20 curies of molybdenum-99; 100 curies of technetium-99m; 10 curies of iodine-131, cesium-137, or iridium-192; or more than 70 curies of iodine-125). All shipping packages received, known to contain radioactive material, must be monitored for radioactive contamination and radiation levels if the package is labeled according to U.S. Department of Transportation rules (i.e., labeled with White I, Yellow II, or Yellow III) as containing radioactive material or if there is evidence of damage to the package. Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours, or within 3 hours from the beginning of the next working day if received after working hours, in accordance with the requirements of 10 CFR 20.1906. The NRC Regional Office and the final delivery carrier must be notified immediately if removable contamination exceeds the limits of 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47. Note that these Appendix X procedures for receiving and opening packages do not exempt packages containing less than Type A quantities of radioactive material from removable contamination surveys as does 10 CFR 20.205(b) and Appendix L to this Regulatory Guide 10.8. Therefore, it may be necessary for a licensee to revise current package opening procedures to reflect the changes in the revised Part 20.

10. EFFLUENT RELEASES TO SEWER

In the revised Part 20, 10 CFR 20.2003 allows licensees, under certain quantity release constraints, to discharge licensed material into sanitary sewers if the material is readily soluble in water or if the material is readily dispersible biological material. Dispersible in this context means able to be distributed as particles, more or less evenly throughout a medium, such as a sewer system. In practical terms, biological material should be divided finely enough so as to mix readily with a water stream and continue to disperse rather than to reconcentrate. This provision of the revised Part 20 allows continuation of the practice of discharging readily dispersible biological materials such as ground-up animal carcasses. The prohibition of the discharge to sanitary sewer systems of nonbiological insoluble materials by § 20.2003 was designed to minimize the accumulation of insoluble material in the sewer system, treatment plant, and in sewage sludge. Licensees should note that the monthly average concentrations of radionuclides allowed to be released to sanitary sewers under

10 CFR 20.2003 and Table 3 of Appendix B to §§ 20.1001–20.2401 are, generally, 10 times more restrictive than the monthly average concentrations that have been allowed to be released into sanitary sewer systems under 10 CFR 20.303(c). In addition, the licensee should note that there are no longer daily concentration limits for release of material to the sanitary sewer as discussed in Appendix R to this Regulatory Guide 10.8.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this Appendix X to Regulatory Guide 10.8. The regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this appendix and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988) is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC, as an enclosure to Part 20.

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