COMMENTARY

The Impact of New NRC PART 20 Regulations

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Objective: The Nuclear Regulatory Commission (NRC) has instituted new regulations, effective January 1, 1994 as an outgrowth of publications 26 (1977) and 30 (1979) of the International Commission on Radiological Protection (ICRP). The objective is to determine how to apply these regulations to a routine nuclear medicine department.
Methods: Since these new 10 CFR Part 20 regulations apply to all radiation workers (medical, nuclear power, etc.), it was necessary to delineate those regulations that would uniquely apply to nuclear medicine occupational workers.
Results: Modification of existing procedures were evaluated and changed to correlate with the new regulations. Data collection is suggested to prove compliance.
Conclusion: The changes required to satisfy the new regulations are reasonably easy to implement. Allowances for the use of realistic values, rather than past pessimistic assumptions, has made these new regulatory limits, which appear to be more stringent, actually easier for compliance.
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On April 1, 1987, with the publication in the Federal Register of the new Title 10 of the Code of Federal Regulations, Part 35 (10CFR35), many of the regulations dealing with the *medical* use of byproduct material were revised. Some of these regulations had an immediate effect on nuclear medicine departments in states governed by the Nuclear Regulatory Commission (NRC). Other nuclear medicine departments have since felt their effect as their respective states have come into agreement with the attitudes and interpretations of the NRC.

On January 27, 1992, another major change in the thinking of the NRC was instituted with the implementation of the Quality Management Program (QMP). This was an attempt to reduce the number of misadministrations, both diagnostic as well as therapeutic, in the practice of nuclear medicine. In the process, the definition of misadministrations was restated.

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A more recent development is the revision of Title 10 of the Code of Federal Regulations, Part 20 (10CFR20). This revision is an outgrowth of the efforts of the International Commission on Radiological Protection (ICRP) through their documents, publications 26 (*1*) and 30 (*2*) and affects *all* radiation workers, not just *medical* radiation workers, as is the case with 10CFR35 (*3*). This document changes the philosophy by which radiation protection is viewed. In the past, radiation protection concerns were simply those of the maximum radiation dose to the critical organ, or to the whole body. The concerns of the new Part 20 are to concentrate not just on the limiting of radiation for the reduction of nonstochastic effects, but also relates these exposures to risks of stochastic effects. It attempts to limit the frequency of stochastic effects to no greater than fatality risks incurred by the nonoccupationally exposed population in what are considered as relatively "safe" occupations. These changes have an impact upon the nuclear medicine community.

DISCUSSION

Title 10, Code of Federal Regulations, Part 20 (10CFR20)

Effective January 1, 1994, Part 20 (10CFR20) was put into effect for all radiation workers, whether they be medical personnel, nuclear reactor workers or whatever. This discussion will reflect on those salient features as they apply to medical applications, but not necessarily at the exclusion of other radiation workers.

New Exposure Limits

The new exposure limits take into consideration the 1977 concepts of stochastic and nonstochastic types of radiation health effects. The exposure limits are identified in 20.1201. These limits are shown in Table 1. These new exposure limits use new terminology which encompass the philosophies of ICRP 26 and 30. The definitions of these new terms are as follows:

DE: Dose equivalent = absorbed dose(D) × quality factor(Q) × modifying factor(N) (Q and N = 1 for gamma, x and beta; therefore, in nuclear medicine, DE = D).

TABLE 1
NRC Dose-Limiting Recommendations: 1994

Occupational exposure (annual)		
Whichever is more limiting:		
TEDE (stochastic), or	5 rem	(50 mSv)
Sum of DDE and CDE to any organ/tissue except lens of the eye (non-stochastic)	50 rem	(500 mSv)
Eye dose equivalent (EDE)	15 rem	(150 mSv)
Shallow dose equivalent (SDE) to skin/extremity	50 rem	(500 mSv)
Minors (occupational)	10% of above	10% of above
Public exposures		
TEDE (annual)	0.1 rem	(1 mSv)
Dose in unrestricted area (in any one hour)	2 mrem/hr	(.02 mSv/hr)
Embryo-fetus exposures		
Total dose (if pregnancy declared)	0.5 rem	(5 mSv)
Dose limit for remainder of pregnancy if dose >0.5 rem or within 0.05 rem (0.5 mSv) of that dose at time of declaration	0.05 rem	(0.5 mSv)
Planned special occupational exposure		
In any year	As in occupational exposure	As in occupational exposure
In individual's lifetime	5 × occupational exposure	5 × occupational exposure

DDE: Deep dose equivalent = DE at 1 cm (an external dose).

SDE: Shallow dose equivalent = DE at 0.007 cm (an external dose).

LDE: Eye dose equivalent = DE at 0.3 cm (an external dose).

CDE: Committed dose equivalent = DE calculated over 50 yr (an internal dose). (Since radionuclides used in nuclear medicine are relatively short-lived, the calculation is usually over the life of the radionuclide.)

TODE: DDE + CDE (nonstochastic dose).

W_T: Weighting factor: converts CDE and/or the DDE to the stochastic risk to the whole body.

EDE: Effective dose equivalent = DDE × W_T. (Since W_T becomes 1.0 for radiation workers in nuclear medicine because of the uniform nature of the radiation, then the terms DDE and EDE are synonymous.) The NRC currently does not permit the use of weighting factors for external exposures.

CEDE: Committed effective dose equivalent = CDE × W_T.

TEDE: DDE + CEDE (stochastic dose).

The relationship of these new terms may be better understood by referring to Figure 1.

Report of Annual Occupational Exposure (19.13(b))

It is necessary to provide an annual dose report to all radiation workers who exceed 10% of the occupational dose limit (Table 1). It is not necessary to have a request for this information from the radiation worker. This regulation is one which may be overlooked because the reader may take comfort in the fact that medical radiation workers are not included in 20.2206 and therefore it would appear that annual reports are unnecessary by exclusion. However, the need to report takes its direction from 19.13(b) which references 20.2106 which references 20.1502. This annual dose report must also include doses that are received by the occupationally exposed person as a result of a second job (moonlighters) provided the exposures are >10% of the occupational dose limit.

Records of Prior Exposure (20.2104)

The licensee is now required to determine the prior occupational exposure of any new employee prior to beginning work if the expected exposure is believed to be >10% of the limit. This may take the form of determining (or estimating) the total occupational radiation dose received during the current year and an attempt to obtain the previous exposure records.

Two Millirem in Any Hour to an Unrestricted Area (20.1301(a))

This limit is not a new concept. It existed in old Part 20; however, the application of the concept has changed in new Part 20. Old Part 20 said that any radiation limits were exempt from radiation coming *from* the patient. New Part 20 said that any radiation limits were exempt from radiation *to* the patient. This provision would have been one of the most difficult to meet in the case of nuclear medicine, even diagnostic nuclear medicine, because this regulation would make every diagnostic nuclear medicine patient a "walking restricted area."

Since a 20-mCi (740 MBq) dosage yields approximately 10 mrem/hr at the surface of the patient, an inpatient would require a private room and outpatients would be required to remain in a special radiation-controlled waiting room until their exposures were reduced to this level, or be hospitalized.

The NRC quickly saw this as a conflict with their previously published patient release criteria (10CFR35.75) and

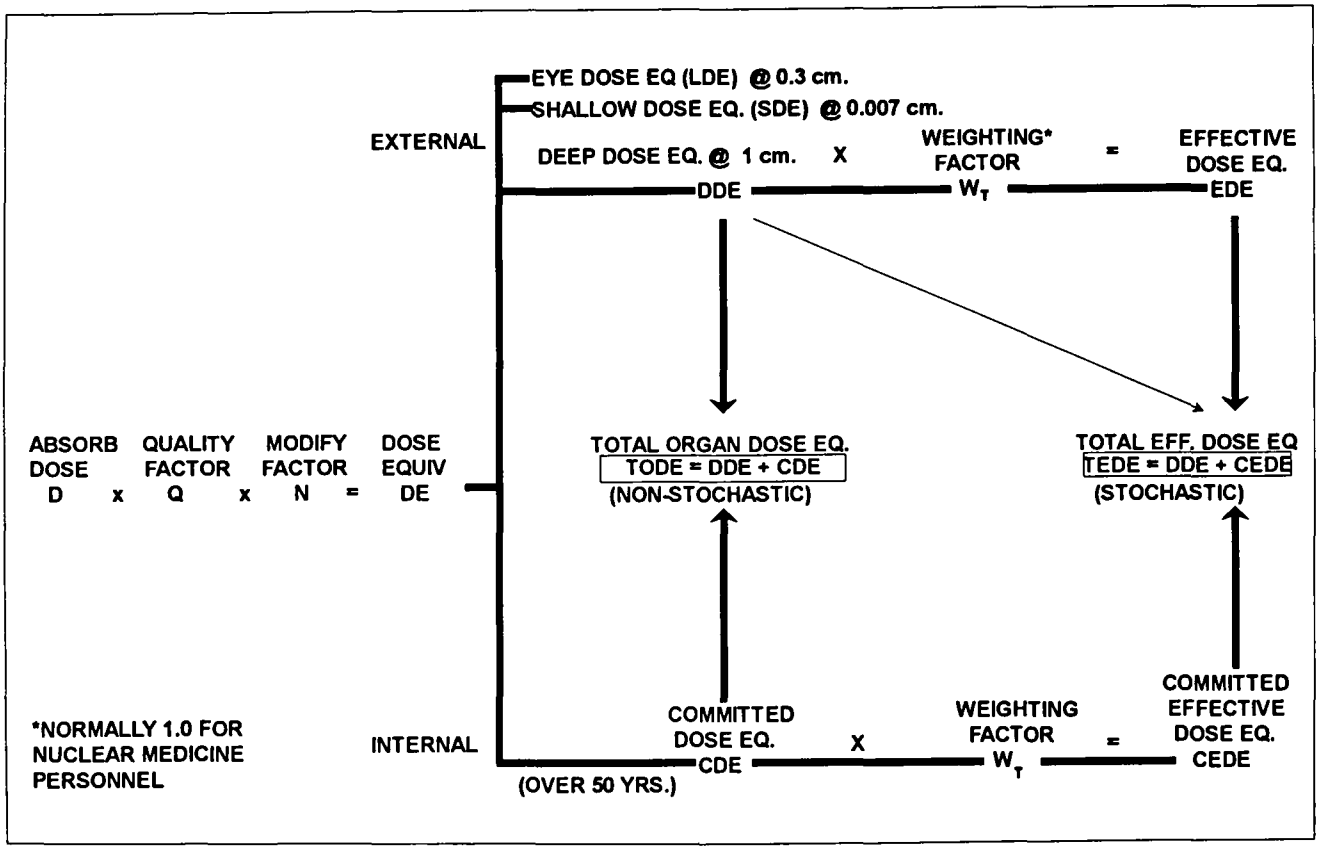

FIGURE 1. Personnel monitoring terms flow chart.

ruled that since 35.75 is more specific, then 35.75 would take precedence (*4*). Therefore, the 2 mrem in any 1 hr regulation does not apply to radiation from a patient if the patient has been released from radiation control; 35.75 indicates that that release can be anytime that the radiation from the patient is less than 30 mCi in the patient or <5 mrem/hr at 1 m (for ^{99m}Tc, this is approximately 80 mCi). This interpretation is also being considered for revision.

One-Hundred Millirems Per Year to Members of the General Public (20.1301)

This limit in new Part 20 is a reduction of the limits in old Part 20 (500 mrem/yr) by a factor of 5. It is an outgrowth of the more recent calculations of the Japanese bomb survivors, where it was determined that the radiobiological effects of the atomic bomb was a result of radiation exposures that were less than originally believed. This value of 100 mrem per year must now be applied to any *unrestricted* area where members of the general public would be likely to remain for some period of time. Areas such as waiting rooms, lounges, secretarial areas and patient rooms would fall into this area of concern.

One important departure from old Part 20 is the fact that one can use *realistic* values such as times of occupancy to calculate anticipated exposures to radiation. In the past, it was necessary to use the most pessimistic (and therefore, usually *unrealistic*) values to determine the need for additional radiation protection measures. This limit does not apply to *restricted* areas such that if members of the general public were to enter a restricted area (e.g., a radiopharmaceutical therapy patient's hospital room), they would assume the risk associated with that of a medical radiation worker, and therefore their dose limit under those conditions would increase to 5000 mrem/yr. At the time of this writing, this interpretation is being challenged with a proposal to limit the dose to the general public (even in these situations) to the 100 mrem limit (*5*). ALARA concerns also dictate that the 100-mrem limit would apply in these situations.

Another concern is that of ^{60}Co teletherapy units. All such units (and they are growing fewer in number each year) were protected with high-density concrete and/or lead walls to limit the exposure to the general public to 500 mrem/yr. The new requirement applies to these units as well. It is believed by the NRC that since these teletherapy units were built according to the specification of NCRP Report 49 (*6*), which most agree uses very conservative assumptions, and that with the use of more realistic values, retro-fitting of these units will not be necessary. This remains to be seen. If this is not the case, then these units will have to be retro-fitted to satisfy these new radiation limits. At the time of this writing, this ruling is also being challenged in light of the tremendous additional cost that would be incurred by hospitals in this era of hospital cost-containment.

A further concern is any radionuclide storage area. Should there be a common wall between the "hot" lab or a patient waiting area and a secretarial area, it will be necessary to

prove using realistic values that the secretary (if a nonradiation worker) is below the 100 mrem/yr limit throughout her annual working experience. The 100 mrem/yr for 2000 hr work experience limit yields an average of 0.05 mrem/hr above background. A survey of the secretarial workplace should not yield greater than these levels. A better averaging device might be to provide a TLD (ring) badge to the secretary for a period of one quarter, or place that badge on the wall common to the secretary for the same amount of time.

ALIs and DACs

ALIs (annual limit on intake) and DACs (derived air concentrations) have been instituted to take the place of the maximum permissible body burden (MPBB) and maximum permissible concentrations (MPC), respectively. One ALI is defined as the activity of a radionuclide which, if inhaled or ingested by reference man, will result in a dose equal to the occupational dose limit, either stochastic or nonstochastic, whichever is reached first (e.g., the nonstochastic ALI value for ^{131}I = 50 μCi). Tables of ALIs for radionuclides exist in Part 20. One DAC is defined as that concentration of radionuclide in air which when breathed by reference man for a work year would result in an intake of one ALI. Tables of DAC limits for radionuclides exist in Part 20.

Bioassays

Bioassays will be continued in the same fashion as practiced under old Part 20. The only difference is that there is some relaxation of the bioassay limits using the NRC's Regulatory Guide 8.9 (*7*), rather than the old Regulatory Guide 8.20. For instance, the new ^{131}I limits in Regulatory Guide 8.9 suggest an *evaluation level* when any thyroid measurement exceeds 0.133 μCi (2% of ALI limit). An *investigation level* is reached when the thyroid measurement exceeds 0.665 μCi (10% ALI). These values are based on an ALI value of 50 μCi (1.85 MBq), and a thyroid intake retention factor (IRF) for ^{131}I at 24 hr of 0.133 (NUREG 4884) according to the following calculation:

Evaluation level:

50 μCi (ALI limit) × 0.133 (IRF) × 0.02 = 0.133 μCi uptake,

Investigation level:

50 μCi (ALI limit) × 0.133 (IRF) × 0.1 = 0.665 μCi uptake.

If any single uptake measurement exceeds 0.133 μCi (4.92 kBq), the RSO will investigate (Level I). Repeat measurements should be made to verify measurements and obtain a better measure of the intake. If any single measurement exceeds 0.665 μCi (24.6 kBq), the RSO should institute a thorough investigation (Level II). Multiple measurements over several days should be performed. Air sampling and surveys should also be evaluated and compared to the bioassay. Preventative actions should be taken if confirmed. Certainly, individuals should be removed from iodine handling prior to reaching a total uptake of 6 μCi (222 kBq) for the year since this would indicate approaching the limit of one ALI.

Pregnancy of a Radiation Worker (20.1208 and 20.2106(e))

The licensee should develop a pregnancy policy at least to the extent that these new Part 20 regulations are addressed. One of the most significant changes is the limit on the dose to the embryo/fetus of a declared pregnant worker. To invoke this limit, the pregnant worker must declare her pregnancy in writing and include the approximate date of conception (20.2106(e)). These records should be maintained in a separate file for reasons of privacy. Without this declaration, the licensee is not required to limit the fetal exposure to less than what any other radiation worker receives.

Regulations in 20.1208 state that the licensee must ensure that the dose to the embryo/fetus of a declared pregnant radiation worker must not exceed 500 mrem (5 mSv) during the entire pregnancy. An attempt must be made to avoid substantial variation above a uniform monthly exposure rate to that pregnant worker. If the dose to the embryo/fetus at the time of the declaration is found to exceed 500 mrem (5 mSv) or is within 50 mrem (0.5 mSv) of the limit, the dose for the remainder of the pregnancy period must not exceed 50 mrem (0.5 mSv). This regulation may infringe on the mother's right to work, which is in violation of her constitutional rights (*7*). To avoid any problems along these lines, the NRC has allowed the mother the right to "undeclare" her pregnancy, at which time the institution is absolved of all responsibilities for radiation protection of the embryo/fetus. (This right of undeclaration is not found in any section of the CFR; however, it is found in the NRC's set 7 of questions and answers regarding Part 20) (*9*).

Receipt of Shipments

Part 20 has always addressed the receipt of radioactive shipments regarding the need to wipe-test and survey the external surfaces of certain shipments. New Part 20 is similar to its predecessor in that it retains the requirement to survey only those radioactive shipments containing >Type A quantities (which are usually >10 Ci). Be aware that this requirement may be overruled through a license condition (e.g., acceptance of Appendix L of NRC Regulatory Guide 10.8, a licensing guide (*10*). New Part 20 departs from old Part 20 in that it requires the wipe-testing of *all* shipments of radioactive materials containing a radioactive label (White I, Yellow II or Yellow III). The limits of removable contamination have been made more stringent: from 220 dpm/cm^2 (or 66,000 dpm/300 cm^2) to 22 dpm/cm^2 (or 6600 dpm/300 cm^2), a change by one order of magnitude. This new limit is the same as the limit for *shipment* of radioactive materials.

Monitoring of Gaseous Effluent

The limits for gaseous effluent have been completely changed in accordance with ICRP 26 and 30. The NRC has defined new effluent concentration limits. These new limits

have changed the values for 767 radionuclides, 65% of which are less restrictive, 26% more restrictive and 9% unchanged. If it can be shown by calculation or actual measurement that a nuclear medicine department can fall within <20% of the limits for all radionuclides in use, then there is no need to monitor gaseous effluent. This should not be difficult for the routine nuclear medicine department. Xenon-133 should certainly not be a problem, especially since the effluent concentration limits are less stringent. It may, however, be a problem for the institution that utilizes large quantities of ^{131}I. It is incumbent upon the licensee to determine these limits.

Disposal Into Sanitary Sewerage Systems

In accordance with 20.2003, the limits regarding the release of radionuclides into the sanitary sewage system have become, for most radionuclides, much more stringent. Patient excreta continues to be exempt from this limit, however. The daily limit has been discontinued but the yearly limit (1 Ci/yr for all radionuclides, except for ^{3}H and ^{14}C which are 5 Ci/yr and 1 Ci/yr, respectively) remains the same. This method of waste disposal continues to be the most efficient method if the material is soluble or readily dispersible in water. It is incumbent on the licensee, however, to re-evaluate the disposal limits and ascertain that the institution is still within the limits as described in 20.2003. This will probably be an issue only in large institutions and large RIA laboratories.

Placement of Film Badges

The NRC has finally solved the long-standing question, "Where do I wear my film badge?" This simple question has been a source of much discussion over the years. Is the proper position under the lead apron or on the collar? The proper placement of finger badges has been equally disconcerting. Is the proper position on the right hand, the left hand, facing the palm or facing away from the palm? New Part 20 has made it clear. It states that the personnel monitor must be placed near the location expected to receive the highest dose (20.1201(c)). It certainly precludes the wearing of the film badge behind the lead apron (except with the use of a second badge in the case of pregnancy) to evaluate the TEDE for the whole body (the DDE for most nuclear medicine technologists). The whole body includes the head and shoulders which is not covered by the lead apron. Part 20.1201(c) probably precludes the wearing of the finger badge in a position facing away from the palm as well. This regulation would suggest that an evaluation should be made as to where these personnel monitors should be worn.

It is hoped that the above considerations will assist the reader to understand the sections of new Part 20 as they apply to a routine nuclear medicine department. Be aware that it is known by these authors that different agreement states sometimes interpret these regulations differently. It is important that those persons residing in agreement states become familiar with the comparable new regulations in these states, and the unique interpretations within those states.

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