Commentary

Revision of "Medical Use of Byproduct Material:" The Nuclear Regulatory Commission's 10 CFR Part 35

On April 1, 1987, with the publication in the *Federal Register* of the new Title 10 of the Code of Federal Regulations, Part 35 (10 CFR 35), 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 will feel their effect in the reasonably near future as their various states come into "agreement" with the attitudes and interpretations of the NRC.

> ***Technical Note:*** *The purpose of this paper is to alert all nuclear medicine technologists to these changes so that they will be prepared to deal with them in their practice settings. The changes are intended to simplify the methodologies that are used to satisfy regulatory requirements.*
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> *During the five-year process of revising the regulations, the NRC as always, provided ample opportunity for input from the nuclear medicine community. The Society of Nuclear Medicine (SNM) and the Technologist Section participated in this process on behalf of the membership through discussion of the issues by their respective Government Relations Committees and other concerned members of the Society. Verbal as well as written comment was provided to the NRC through the Society/ACNP Washington representative. The Society and the Section endeavor to keep the membership involved and informed (see* J Nucl Med *1987;28:151-153) of such activities. This article is provided at the request of the Technologist Section Government Relations Committee as a benefit for the membership.*

By way of preamble, the changes in the regulations that will be addressed in the following subject material immediately affect only those licenses that contain conditions or statements that are not in conflict with these regulations. If a condition of your license says something different from the new regulations on some particular subject, the condition of the present license applies. This present condition will continue to apply until such time as the NRC license is amended for that particular item, or renewed in its entirety.

> ***Technical Note.*** *In other words, if an NRC license for a given institution currently states something other than what the new regulations require, change is not necessary until the license is renewed or amended. For example, if the license for Hospital X currently states that the Radiation Safety Committee meets semi-annually, the frequency would not have to be changed to quarterly until the license is renewed in its entirety or amended for that particular item.*

For reasons of clarity, the important parts of this revision of 10 CFR 35 will be addressed in the same sequence as they appear in the published 10 CFR 35.

It is suggested that the reader refer to the new 10 CFR 35 and his own license as the items within the article are read.

TITLE 10 CFR 35 REGULATORY CHANGES

Amendment Versus Notification Versus Ministerial Changes

The first noticeable change is that it is no longer necessary to notify the NRC of all changes. "Amendments" are necessary for any significant change in the status of the license *prior* to the change, but the NRC now allows "notifications" within 30 days *after* some event as well as "ministerial changes" with no notification but adequate documentation.

Notifications are required for discontinuation of a licensed user, the radiation safety officer (RSO) or the teletherapy physicist, or a name change. Mailing address changes of licensees also apply.

Ministerial changes (minor changes in radiation safety procedures that are not potentially important to safety) are allowed without the need for a license amendment, provided a safety review is made, appropriate records are kept, and affected members of the Radiation Safety Committee (RSC) sign off on them. Examples of such changes are: (a) change in film badge suppliers, (b) a change in the person who calibrates survey meters, (c) waste disposal procedures, or (d) adoption of a model radiation safety procedure as published in a Regulatory Guide.

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Technical Note. *This change requires more attention to documentation on the part of the licensee. However, this is easier than submitting amendments for every change.*

ALARA Program

The ALARA program, a program designed to keep workers and public doses *as low as reasonably achievable*, is now required whereas in the past such a program was suggested by the NRC. The program must involve management, RSO, and all authorized users. The program would be similar to the previous ALARA concepts of radiation safety: summaries of the program, review of personnel exposures, involvement in continuing education of personnel, and changes in radiation safety procedures.

Technical Note. *This is really nothing new, since most licenses have already incorporated the ALARA program in their licenses.*

Radiation Safety Officer (RSO)

Considerable emphasis is placed on the RSO in relationship to authority and responsibility. Through this officer, licensees shall be able to ensure that radiation safety procedures are being performed. The RSO will therefore investigate all overexposures, accidents, losses, misadministrations, or other excursions from good radiation safety. It is the RSO's responsibility to maintain a procedure file on all matters relating to the byproduct material program from receipt to final disposition. This also includes performance checks on survey equipment as well as inservice education. The RSO will review the radiation safety program in its entirety with management once per year. New responsibilities are given to the RSO by way of establishing personnel exposure investigational levels, action levels for area surveys and for wipe test analyses. If not in a medical institution, the RSO is also responsible for approving minor changes in the radiation safety procedures that are not potentially important to safety. Most importantly, the licensee will provide the RSO with sufficient freedom and authority to take corrective actions when a radiation safety problem is identified.

The RSO is also responsible for the accuracy and completeness of other tasks demonstrated by the requirements for his signature on key documents. This does not mean that the RSO performs the tasks, but rather that the record has been reviewed by a responsible individual with special training and experience. Documents requiring the signature of the RSO are as follows:

1. Sealed source inventory.
2. Sealed source leak test.
3. Survey of sealed source storage area.
4. Dose calibrator linearity.
5. Dose calibrator accuracy.
6. Dose calibrator geometry.

Technical Note. *This change demands more paperwork on the part of the RSO, but it also gives the necessary authority to the RSO to enforce the requirements of the license. Previously, the authority was unclear and it was difficult for the RSO to take action, unless the RSC provided strong support. The change is certainly welcomed by all RSOs.*

Radiation Safety Committee (RSC)

Changes in the RSC include membership that must now consist of at least three individuals, two of whom must be the RSO and the management's representative. If either of these latter members are absent, the RSC may not conduct official business. Additionally, committee membership must include an authorized user of each type of test permitted by the license and a nursing service representative.

Technical Note. *The additional inclusion of the chief nuclear medicine technologist to the RSC is to be encouraged. In many instances, the chief technologist is the single individual most aware of radiation safety protocols and breaches of same. Technologists are the "front line" radiation workers, and therefore may have a practical approach to problems that may not be obvious to other members.*

A quorum of at least one-half of the Committee's membership must be present and the minutes must show those members that are both absent and present. The minutes must be provided to each member promptly.

Technical Note. *Previously, there were no specific requirements regarding the minutes. This is now another area where attention to detail and documentation is important.*

Supervision

The term "supervision" has long been a problem in interpreting the conditions of the NRC license. The biggest problem occurs in the instance of a license listing one single authorized user who wishes to go on vacation. The "visiting authorized user" clause was added to circumvent some of this problem, but the supervision clause precluded a physician from using one of his "trainees." It was necessary to utilize a physician at another institution who was equally licensed but the vacationing physician perhaps had no knowledge of his level of expertise. The current interpretation of supervision is that the receipt, possession, use (to include prescription, administration, interpretation, and follow-up for individual clinical procedures) or transfer of byproduct material by any individual is permitted provided that individual is periodically reviewed by the authorized user, has been instructed in radiation safety practices, and follows the procedure for good radiation safety as established by the RSO. The licensee is the individual that is ultimately responsible for the acts and omissions of this supervised individual.

Visiting Authorized User

This condition, which was stipulated on the license before the revision of Part 35 is now a section of Part 35. Requirements

regarding a visiting authorized user remain the same. The visiting authorized user can be used for sixty days a year provided permission is granted, a copy of his license is on hand, and the clinical procedures are those for which he is licensed.

Misadministrations

Changes in misadministrations reporting requirements involve only those of a diagnostic nature. Regulations regarding therapy misadministrations remain unchanged. The definitions of a misadministration (both diagnostic and therapeutic) remain unchanged, (see "definitions" section of 10 CFR 35), but the requirement to report a diagnostic misadministration is different. A diagnostic misadiminstration must first satisfy the definition of a misadministration (wrong patient, wrong radionuclide or radiopharmaceutical, wrong route of administration, wrong diagnostic dosage by 50%, or wrong total therapy dosage or dose by 10%). If the definition is met, the RSO must investigate and determine if in fact it is reportable. A reportable misadministration involves the use of byproduct material that was not intended for medical use (e.g., reagent grade radiochemical), administration of a diagnostic dosage five-fold different from that which was intended, or administration of a byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 mrem (dosimetry tables in package inserts can be used for this calculation). This calculation should rule out ~ 50% of what were previously termed reportable diagnostic misadministrations. The diagnostic misadministration report must be made within 15 days to the referring physician and the appropriate NRC office. A special NRC form is available for this purpose.

> ***Technical Note.*** *The previous requirements called for a report of any misadministration that satisfied the definition within 10 days after the end of the calendar quarter in which the event occurred.*

A therapy misadministration report must be made by telephone within 24 hr to the NRC Regional Compliance Office, the referring physician, and the patient (or guardian) and in writing within 15 days to the same individuals.

> ***Technical Note.*** *The NRC is particularly concerned about misadministrations of ^{131}I sodium iodide for thyroid imaging and/or therapy. In the Federal Register (October 1987), a notice of proposed rulemaking (NPR) and an advanced notice of proposed rules (ANPR) were published by the NRC, which both seek to establish quality assurance procedures relating to the use of ^{131}I sodium iodide for therapy and diagnosis. These announcements are the response to an NRC study of 27 therapy misadministrations reported between November 1980 and July 1984. Six of these were radiopharmaceutical misadministrations reported as the wrong radiopharmaceutical (2), the wrong dosage (3), or the wrong patient (1). The rest were teletherapy and brachytherapy misadministrations. The incidents of misadministrations in nuclear medicine are very small (1 in 18,750), and in the Society's opinion do not warrant substantive regulatory change.*

Sources for Radioactive Material

The practice of assisting a nearby hospital (not on your NRC license) by sending them an unused patient dose has been eliminated by the regulation that a licensee may use only byproduct material from a licensed manufacturer or distributor of these materials. This has always been a condition of the NRC license but few hospitals adhered to it. It is now a part of the NRC regulations.

Dose Calibrator

Several changes in dose calibrator requirements have surfaced through the revision of Part 35. A dose calibrator is required (even in those instances where only unit dosages are obtained from a radiopharmacy) to measure the amount of activity administered. Since it is a measuring device, it must be periodically checked for: 1)constancy (daily); 2) accuracy (annually) with at least two long-lived sealed sources; 3) linearity (quarterly) throughout the range of its use between the highest dosage administered and 10 μCi; and 4) geometry (upon installation). All values cannot exceed 10% with mathematical corrections for geometry or linearity errors, and repair or replacement of the dose calibrator is required for accuracy or constancy error greater than 100%.

> ***Technical Note.*** *For some, this is an added requirement, while for others, it is current practice. Technologists should determine in discussion with the RSO, whether their procedures are appropriate.*

Survey Meters

Survey meters must continue to be calibrated through all scales up to 1,000 mrem/hr, with two readings on each scale. A change in the regulations stipulated that an exposure rate from a dedicated check source must be determined at the time of calibration. Further, the licensee will verfiy calibration by measuring the same check source upon receipt. This requires use of a long-lived radionuclide check source with each instrument. Another significant change allows a point to be considered calibrated if the exposure rate differs from the calculated exposure rate by not more than 20%. It is necessary now to attach a correction chart or graph to the instrument showing these results.

> ***Technical Note.*** *This is an added requirement which means that a check source must be purchased for each survey meter and shipped with it at calibration time. Furthermore it is an added record keeping requirement.*

Radiopharmaceutical Dosages

The licensee must now measure each dosage containing more than 10 μCi of a photon emitting radionuclide before medical use. This suggests that it is no longer necessary to

measure ^{32}P since it is a pure beta emitter. Furthermore, the licensee must measure each dosage of 10 μCi or less to verify that the dosage is in fact less than 10 μCi. This makes it necessary to measure blood volume syringes and Schillings test capsules.

> ***Technical Note.*** *Technologists need to pay attention to this change to insure that the procedures are instituted or a violation will occur.*

Sealed Sources

The licensee in possession of sealed sources must leak test the source every 6 mo. Leakage is defined as a wipe sample with more than 0.005 μCi of removable radioactivity. This procedure is not required on the materials of less than 30 days half-life, gases, less than 100 μCi of beta or gamma emitting radionuclides, or less than 10 μCi of alpha emitting radionuclides; sources stored and not being used; and seeds of ^{192}Ir encased in nylon ribbon. Quarterly inventories of all sealed sources must be performed. Quarterly surveys of storage areas of sealed sources must be performed.

Syringe Shields and Labels

The licensee must identify the contents of a syringe or the syringe shield by showing at least one of the following:

1. Radiopharmaceutical name.
2. Clinical procedure.
3. Patient name.

Syringe shields are required when preparing a radiopharmaceutical kit or when administering a radiopharmaceutical by injection, unless the use of the shield is contraindicated for that patient. It is not necessary to use a syringe shield for drawing up a dosage. In the case of vials, the vial must be kept in the vial radiation shield and the shield must be labeled to show the radiopharmaceutical name. Color coding alone is no longer adequate.

> ***Technical Note.*** *It is not current practice in many institutions to label syringes or shields. Technologists must again adopt new procedures to insure compliance.*

Surveys

Ambient Radiation Exposure Rate. A licensee shall survey with a radiation detection instrument, at the end of each day of use, all areas where radiopharmaceuticals are routinely prepared for use or administered. This should include the stress lab area. Furthermore, a survey should be made each week of all areas where radiopharmaceuticals or their waste are stored. The survey instrument must be able to detect dose rates as low as 0.1 mR/hr with the licensee (with the assistance of the RSO) establishing appropriate trigger levels for decontamination. The RSO must be notified immediately should a trigger level be exceeded.

Contamination. A licensee shall wipe test all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored once each week. A system must be available to detect a wipe sample of 2,000 dpm with the licensee (through the assistance of the RSO) establishing appropriate trigger levels. Immediate RSO notification when contamination trigger levels are exceeded is required. NRC Regulatory Guide 8.28 could be used in establishing such trigger levels. There is one trigger level that is not left to the option of the licensee or RSO—decontamination of the ^{131}I therapy patient room. The maximum permissible level here has been stipulated by the NRC to be 200 dpm/100 cm^2.

Release of Therapy Patients

NRC regulations now allow the release of any patient administered a radiopharmaceutical (diagnostic or therapeutic) when the measured dose rate from the patient is less than 5 mR/hr at a distance of one meter *or* the activity in the patient is less than 30 mCi. In instances where greater than 30 mCi of ^{99m}Tc is utilized in a diagnostic procedure, the first condition of 5 mR/hr at one meter may be used since it would require ~ 80 mCi of ^{99m}Tc to receive a meter reading of 5 mR/hr at one meter. Furthermore, this new regulation suggests that at these same levels, radiation safety practices can be discontinued even in the event that a patient would be required to remain in the hospital for some reason other than the radiation dose. In the latter instance, the patient would be allowed to be moved from the private room.

> ***Technical Note.*** *In the past, patients were released if the activity in the patient was less than 30 mCi. However, if hospitalization of the patient was required after the radioactivity had decayed to the 30 mCi level, it was the recommended practice (NCRP 37) to maintain the radiation safety program until patient dose rates reached 1.8 mR/hr at one meter.*

Storage of Volatiles and Gases

No fume hood is required if the radiopharmaceuticals and/or radioactive gases are stored in the shipper's shipping container. It is necessary, however, to store a multi-dose container in a fume hood after drawing the first dosage from it.

Decay In Storage

Within the last couple of years, because licensees forgot to request the approval to decay short-lived radionuclides in storage, this condition was automatically placed on any licenses submitted for amendment and/or renewal. It is now a part of the revision of the new Part 35. The licensee may now decay in storage any byproduct material with a physical half-life of less than 65 days before disposal into ordinary trash provided it is held for a minimum of ten half-lives *and* there is no measurable radiation coming from the waste package. This means that if the decay-in-storage method is used, the radionuclide must remain in storage for ten physical half-lives. While this is not particularly burdensome for some radionuclides, ^{125}I poses a serious problem to the RIA laboratories. Using this method of disposal, the RIA laboratory would necessarily hold the RIA vials and/or liquid for 600 days. In an ordinary RIA laboratory, this may represent

an insurmountable storage problem.

Should the decay in storage program be adopted, upon disposal the labels must be removed or obliterated prior to final disposal into the ordinary trash. In order to determine generator background levels, the generators would have to be removed from their protective radiation shielding.

Licensure

One of the main changes in the new 10 CFR Part 35 is the redefinition of licensure "groups." In the past, there were six groups; three for diagnostic uses and three for therapeutic uses. With the revision of Part 35, there are still six groups, now called "types of use" that are as follows:

a. 10 CFR 35.100 is comprised of the well established laboratory techniques (identical to General License under old 10 CFR 35.31 and the old Group I);
b. 10 CFR 35.200 includes all diagnostic imaging techniques to include xenon gas plus generators and kits (a combination of the old Groups II and III);
c. 10 CFR 35.300 includes all radiopharmaceutical therapy, whether hospitalized or not (a combination of the old Groups IV and V);
d. 10 CFR 35.400 deals with brachytherapy (similar to the old Group VI but excludes those therapeutic sources that were used for diagnostic purposes such as bone mineral analyzer sources);
e. 10 CFR 35.500 which includes those sealed sources that are used for diagnosis (they have their own type of use now); and
f. 10 CFR 35.600 which includes the use of a sealed source in a teletherapy unit such as ^{60}Co or ^{137}Cs.

Given licensure for any radiopharmaceutical types of use, a licensee may use any byproduct material within those groups provided the FDA has accepted a "Notice Of Claimed Investigational Exemption For A New Drug" (IND) or approved a "New Drug Application" (NDA). For diagnostic clinical procedures, it is no longer necessary to follow the package inserts in the use of radiopharmaceuticals. It is felt by the NRC that to be restricted to the package insert for diagnostic radiopharmaceuticals may have an adverse impact on the public health and safety because it prevents physicians from performing diagnostic clinical procedures needed by their patients.

Technical Note. *This is a welcomed change that has been requested for years.*

However, if a licensee alters a chemical form of a radiopharmaceutical then the modified radiopharmaceutical would be a new radiopharmaceutical and would require approval by the FDA. For this reason, it would not be authorized for use. This new regulation eliminates the need to file for an IND when the physician would like to use an approved radiopharmaceutical in a different form (xenon gas versus xenon dissolved in saline), a different route of administration (intravenous versus the hepatic artery), or a different dosage. The only restriction is the change of the chemical form.

Type of Use—35.100

This type of use carries with it the requirement that the licensee must possess a survey meter capable of detecting dose rates from 0.1 mR/hr to 100 mR/hr. It is also important to note that the general license for in vivo studies has been eliminated and is now included under this type of use. The general license for in vitro uses that is in 10 CFR 31.11 remains intact.

Type of Use—35.200

This new type of use carries with it the need to evaluate the ^{99}Mo concentration such that the licensee may not administer to humans a radiopharmaceutical containing more than 0.15 μCi of ^{99}Mo per 1 mCi of ^{99m}Tc. The licensee that elutes the generator must make this measurement. If prepared radiopharmaceuticals are purchased, there is no need to make this measurement and/or keep records of it. The NRC is now in concert with the molybdenum specifications of the *U.S. Pharmacopoeia.* The licensee authorized for this type of use must have in its possession two survey instruments; 1) a portable radiation *detection* survey instrument (e.g., Geiger-Mueller or crystal survey meter) capable of measuring 0.1 mR/hr to 100 mR/hr and 2) a portable radiation *measurement* survey instrument (e.g., ionization type survey meter) capable of measuring dose rates from 1 mR/hr to 1,000 mR/hr.

Aerosols and Gases

Xenon-133 is now included in 35.200 whereas before this utilization was treated separately. It is still necessary to satisfy the conditions and limits for airborne concentrations specified by 20.103 and 20.106. Unfortunately, the NRC included both aerosols and gases in this new regulation. Prior to this time, aerosols were treated not as a gas and therefore positive pressure rooms could be utilized for aerosol studies. By disallowing their use except in negative pressure rooms, it was felt by some that this prevented the use of an important diagnostic modality to the critically ill patients who could not be moved to the nuclear medicine department. In light of this and with the assistance of Mallinckrodt, Inc., a request was made to the NRC to delay application of this regulation to aerosols until such time as a Petition For Rulemaking could be acted upon hopefully in favor of allowing aerosols to be used in rooms other than those with a negative pressure. The NRC responded to this request on March 23, 1987, approximately one week before these new regulations were to be in effect and notified all licensees that the inclusion of aerosols in the conditions of 10 CFR 35.205 be disregarded until further notice. Mallinckrodt, Inc. has filed a Petition For Rulemaking prior to this publication by the NRC and at this writing, no ruling has been made.

Technical Note. *It is appropriate that the NRC review the conditions of use for aerosols. To impose a negative pressure requirement by treating aerosols as a gas would remove a very important diagnostic procedure to patients in intensive care units.*

Type of Use—35.300—Radiopharmaceutical Therapy

This type of use includes radiopharmaceutical therapy for those patients that require hospitalization as well as those that do not. Changes in the regulations are minimal in this type of use. One such change is that visits by individuals under age 18 may be authorized only on a patient by patient basis. As stated before, the patient is allowed to leave the hospital and/or to terminate radiation safety practices at any time that the patient's radiation levels reach 5 mR/hr at one meter or 30 mCi of radioactive material. It is necessary to survey the patient's room following therapy and insure that removable contamination be less than 200 dpm/100 cm^2. It is a further requirement that every individual who helped prepare or administer a dosage of ^{131}I greater than 30 mCi be measured for thyroid burden (in accordance with NRC Regulatory Guide 8.20) within three days after administering the dosage. The licensee must possess both a portable radiation detection survey instrument as well as a portable radiation measurement survey instrument capable of measuring radiation levels as previously described.

Technical Note. *This regulation increases the frequency of bioassays. In the past, those hospitals using capsules were removed from this requirement.*

Type of Use—35.400—Brachytherapy

Changes within this type of use are minimal to include the following:

1. The licensee must maintain the names of the individuals permitted to handle the sources.
2. A very precise inventory describing number of sources removed and number of sources returned must be instituted.
3. Immediately after implanting the sources in a patient, the licensee shall make a radiation survey of the patient and the area used to confirm that no sources have been misplaced.
4. Safety instructions must be provided to all personnel caring for the patient undergoing implant therapy.
5. The patient must be provided with radiation safety guidance that will help to keep radiation dose to household members and the public *as low as reasonably achievable.*
6. The licensee must have both a portable radiation detection survey instrument as well as a radiation measurement survey instrument with the characteristics as described above.

Record Retention

For the first time, the NRC has provided complete guidelines for retention of all records generated in a nuclear medicine department. They are as follows:

Indefinitely:
- Personnel monitoring records
- Bioassay records
- Radiation accident investigation results
- RSC minutes
- Misadministration reports

5 Years:
- Sealed source inventory
- Sealed source leak test

3 Years:
- Patient dose records
- Area surveys (includes brachytherapy)
- Disposal survey records of decay-in-storage radioactive material
- ^{99}Mo assay records
- Survey meter calibration
- Dose calibrator constancy tests
- Dose calibrator linearity tests
- Dose calibrator accuracy tests

Duration of use of dose calibrator: geometry tests

Technical Note. *This is a welcome addition to the regulations. Most licensees have maintained all records indefinitely and the mountains of paper are growing rapidly. Hopefully, the Agreement States will follow suit.*

CONCLUSION

This paper describes changes in the Code of Federal Regulations as they pertain to the use of byproduct materials in diagnosis and/or radiopharmaceutical therapy. The regulations also include changes in sealed source therapy and ^{60}Co teletherapy which was not the intent of this article. It is imperative that each licensee and user obtain a copy of the new Part 35 and correlate it with statements and conditions of your present NRC license. It would also be helpful to obtain a copy of the NRC Regulatory Guide 10.8 (A Guide For The Preparation Of Applications For Medical Use Programs, Rev. 2, August, 1987). The Guide suggests procedures that will help you in maintaining compliance with these regulations. There are situations where the Guide goes beyond the requirements of 10 CFR Part 35. It is important to realize that 10 CFR Part 35 is a *regulation;* Regulatory Guide 10.8 is a *guide* and, therefore, simply a suggestion. Should the licensee, however, decide to incorporate any or all of the procedures of Regulatory Guide 10.8 into his license application, they now become a procedure that must be implemented by the licensee. That implementation is subject to inspection and enforcement by the NRC.

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