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*How to Prepare for and Successfully Complete  
an NRC Inspection:  
A Review for Nuclear Pharmacists*

*by:*

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**HOW TO PREPARE FOR AND SUCCESSFULLY COMPLETE  
AN NRC INSPECTION:  
A REVIEW FOR NUCLEAR PHARMACISTS**

**STATEMENT OF OBJECTIVES**

The primary goals of this correspondence course are to a) describe and list for the reader the NRC Nuclear Pharmacy inspection process and b) identify and explain the requirements against which the NRC will inspect. This information will provide the reader with the necessary elements to successfully prepare for, and learn from, an NRC inspection.

*Upon successful completion of this course the reader should be able to:*

1. Know the fees charged by the NRC for inspections.
2. Know the importance of the condition of the physical plant to the overall inspection process.
3. Train employees to work naturally while being inspected.
4. Maintain and organize the records most commonly inspected by the NRC.
5. Understand why it is useful and necessary to periodically review radiation safety records.
6. Describe the recent changes in NRC regulations which a) allow limited compounding, and b) have done away with recordkeeping requirements.
7. Describe the differences in types of training required for radiation workers.
8. Maintain and organize the records most commonly associated with receiving and shipping radioactive materials (RAM).
9. Maintain and organize personnel dosimetry records.
10. Understand and appreciate the difficulties associated with being an NRC inspector, and the limitations management places on these individuals.
11. Know which office within the NRC to contact if you believe an inspector has not acted in a manner consistent with his/her duties.
12. State the usual frequency at which nuclear pharmacies are inspected by the NRC.
13. Coach your employees to maximize the success (and learning potential) of an NRC inspection by cooperating with the inspector.
14. Be knowledgeable of the major subject headings (areas of emphasis) in the NRC inspector's field guidance and notes.
15. Understand the rationale that the NRC uses in inspecting each subject heading (area of emphasis).
16. Understand the various inspection techniques at the inspector's disposal, (e.g., record review, interviewing, direct observation, and independent measurement).
17. Know the various forms of NRC information dissemination.
18. Avoid the most common violations found during NRC inspections.
19. Know the value of providing the inspector with additional or mitigating information at the time of the inspection.
20. Appreciate the fact that the NRC inspector is probably the best source of information on the radiation safety regulatory requirements for Nuclear Pharmacy Practice.

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# HOW TO PREPARE FOR AND SUCCESSFULLY COMPLETE AN NRC INSPECTION: A REVIEW FOR NUCLEAR PHARMACISTS

by

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*Editor's Note: The text of this CE lesson was based on current (1993) regulations. However, some of the regulations referred to in this lesson will soon undergo change. Specifically, the new 10 CFR 20 will take effect in January 1994 and the proposed, so-called "Radiopharmacy Rule" (published for comment in 58 FR 33396, June 17, 1993) will likely be implemented sometime in 1994. Therefore, the reader should be mindful of impending regulatory changes (and any future changes) as they impact upon the recommendations made in this publication.*

## INTRODUCTION

There are several types of US Nuclear Regulatory Commission (NRC) inspections. Categories of inspection listed on the NRC inspection field notes include announced or unannounced, routine or special, initial or reinspection. The most common type of inspections are routine and unannounced, usually done at two year intervals depending on the type of license. Special inspections generally are done in addition to routine inspections, and often immediately follow an incident or misadministration. Initial inspections are sometimes a pre-licensing site visit or a post-licensing pre-start up inspection. The fee charged by the NRC to the licensee for the inspection process ranges from \$1500.00 for a routine inspection to \$2000.00 for a non-routine inspection. The principles of inspection preparation are the same for all types of NRC inspections.

The best advice for inspection preparation and the best formula for violation-free inspections is to a) know the NRC regulations and your license conditions, b) keep neat, complete, and easily accessible records, and c) adhere to the concept of ALARA (as low as is reasonably achievable; 10 CFR 35.20) at all times. The best time to prepare for an inspection is as far in advance of the inspector's arrival as possible.

## PRE-INSPECTION RECOMMENDATIONS

### Physical Plant

Start by carefully looking over the building or physical plant within which your nuclear pharmacy operates. Is the building neat, clean, and of sound construction? Is your business name and address clearly announced? Are the entrances and exits clearly marked, solidly constructed and secure? Inside the building, in what condition are the floors, walls, and ceilings? Is the site a safe workplace, free of electrical, mechanical, chemical and environmental hazards? Is it properly ventilated, heated, cooled, and lighted? Is there adequate workspace and storage space? Are the work areas delineated by radiation levels? Are you aware of the occupancy rates in the areas surrounding your nuclear pharmacy? Is there adequate and secure parking space for the delivery vehicles? Can the delivery employees load and unload their vehicles with a minimum of exposure, while maintaining the security of RAM packages?

Inspectors, like anyone else, are positively or negatively impacted by appearances. A well-marked business is easier to find, and a clean, spacious, neat, well-lighted, and properly ventilated facility is more pleasant to inspect. Inspectors are often very busy and have many inspections of various licensees to perform. Inspectors may, in the course of a week, inspect a wide variety of licensees in one particular area of their territory for which they are responsible (e.g., a typical week's work may consist of inspecting three or four hospitals, a nuclear pharmacy, and several commercial sealed source users such as pipeline radiographers, moisture/density gauge users, and gas chromatograph users). Inspectors, most likely, are traveling while in your city and often have a tight schedule to follow, so making the inspection proceed quickly through the use of better organization benefits everyone.

### Personnel

There are basic regulatory and license requirements for personnel and these requirements will be discussed later in this lesson. The basic, universal, good business practices of employing individuals who know the rules and regulations of the business, who know their job responsibilities and the lines of authority, and who are polite and courteous apply to nuclear pharmacy as well. Your nuclear pharmacy should be secure, so that the NRC inspector (or anyone else) cannot enter any restricted area without being screened by your personnel. When the inspector arrives, an introduction will be made, identification provided and a request to see someone listed on the license, usually the Radiation Safety Officer (RSO). This first line of contact will often shape the inspector's first impression of the

pharmacy. This person (usually a secretary or receptionist) should be polite and cheerful, but firm in stating the nuclear pharmacy's policy on non-staff entering into the restricted area without an escort. If your policy is to ask the inspector to wait while the RSO is paged, then do so; if the RSO is unavailable, then immediately find someone else (an authorized user, AU) to escort the inspector. The inspector should not be prevented from entering the facility while waiting for the requested person. It is important for the inspector to see that access to restricted areas is controlled. Once the inspector has contacted the RSO or AU and inspection has begun, quietly notify all the employees that an inspection is in progress and ask them to cooperate fully with the inspector. Show the inspector to a suitable work area and ask if he/she would first like to tour the facility, observe workers, or review records. If record review is first, assign one person to bring the inspector the necessary records, or allow the inspector to browse through the records once their location has been identified.

It is advisable to have practice (simulated) inspections and, in fact, a large number of commercial nuclear pharmacies have corporate inspections. During these practice inspections the staff will learn to operate in a relaxed, efficient manner while being observed. This is a good time to refine radioactive material (RAM) handling skills to maintain exposure ALARA. Though conversation and humor in the workplace certainly can be a morale booster, it should be discouraged during an inspection. The staff should be trained to do everything right all the time and to continue to do the daily routine during an inspection. The inspector will quickly notice procedures and practices that appear put on, forced, or done solely for his/her benefit.

## **TECHNICAL, PROFESSIONAL, AND RECORD-KEEPING REQUIREMENTS**

The recordkeeping requirements for your nuclear pharmacy will be dependent on the regulations and your RAM license. Before beginning an in-house record review, first examine your RAM license and supporting communication to insure that there are no additional recordkeeping commitments that may have been overlooked. Since these requirements vary, only the most common ones will be discussed in this lesson.

The RAM license, and any amendments, letters, communications, and procedures described in the license should be kept together and easily retrievable. Previous inspection reports, and any other NRC or Agreement State Information Notices (IN), Bulletins, Regulatory Guides (Reg Guides), or directives should also be kept with the RAM license.

In-house or corporate inspection findings should be

catalogued in a separate binder, but in the same location as the RAM license. It is important to document any negative findings, along with the corrective action taken. Also, document any additional training which resulted from self-identified violations and the subsequent corrective action.

A generally efficient method for recordkeeping is to have preprinted on the form all the necessary information that is not variable. For instance, the forms should have the name of the nuclear pharmacy, the RAM license number, and the name of the record being kept or type of information contained therein. Additionally, if appropriate, it should include the name of the instrument being tested or being used to conduct the test, model number, serial number, trigger level, and procedure if trigger level is achieved. Some survey forms will have scale drawings and factors for converting cpm to dpm; thus the areas surveyed or wipe-tested along with the findings can be seen and reviewed "at a glance."

### **Dose Calibrator**

The linearity, accuracy, and geometry tests must be done after installation or repair, and prior to any patient dosage measurements. Testing frequency varies for each of the four tests depending on licence conditions (see individual test descriptions below). The daily constancy test must be done prior to patient dosage administration as well. Keep these records for a minimum of three years (or whatever your State or RAM license requires). It is interesting to note that for the linearity, accuracy, and geometry tests, the RSO need only to *sign* the document which shows test results. Although approval is implied in 10 CFR 35.21 as a duty of the RSO, there is no regulatory requirement for the RSO to approve these tests.

The dose calibrator is probably the single biggest generator of important records for an NRC inspector. Documentation which indicates that the dose calibrator is functioning properly is critical to insuring that patient doses are correct. Generally speaking, dose calibrators are very reliable, needing little, if any, maintenance or repair. Because of this reliability and accuracy, there is a tendency to place daily dose calibrator quality control in a low priority position, and forget or neglect this very important daily duty.

### **Daily Constancy**

The daily constancy test is a measure of the reproducibility of assay of a constant activity over a long period of time. The constant activity measured must be assayed at all the commonly used radionuclide settings. The non-variable information that can be preprinted on recordkeeping forms for the dose calibrator constancy test includes the pharmacy name and RAM license

number; the test name; the make, model, and serial number of the dose calibrator; the sealed radionuclide source as well as the manufacturer/supplier, model number, serial number, and theoretical activity of the source; the allowable range of activity within which test results should fall; the potentiometer radionuclide settings; the trigger level; and the person to contact if the trigger level is achieved. The variables to be recorded include the date of test; initials of person doing the test; and the measured activity. The NRC regulations allow an error of up to 10%. Although some have adopted even more restrictive conditions, most licensees set their trigger level at 5% to 7%. Additionally, this test should be done before first use of the dose calibrator on each day that it will be used to measure radiopharmaceutical doses for administration to patients. Should your dose calibrator not demonstrate constancy it must be repaired or replaced, and subsequently retested before use. A commonly observed error is failure to do this test on weekends and holidays. There should also be space for notes should a trigger level be reached or approached, or should the tester wish to record something related to dose calibrator constancy checks. (See 10 CFR 35.50 and Reference 1 and 2.)

### Linearity Test

Linearity means that the dose calibrator is able to measure radioactivity linearity over the range of activity for which it is normally used. The linearity test requires quarterly testing, or testing after repair, over the range of patient doses from the highest dosage (don't forget therapy doses) a patient might receive down to 10 microcuries. The non-variable information that can be preprinted on recordkeeping forms for the dose calibrator linearity test (**decay method**) include the pharmacy name and RAM license number; the test name; make, model, and serial number of the dose calibrator; the test radionuclide; the initial measured activity; the potentiometer radionuclide setting; the calculated activity for the period of time that the linearity test will be performed; the range of deviation from linearity allowed; the trigger level; and the person to contact if the trigger level is achieved. The non-variable information that can be pre-printed on recordkeeping forms for the dose calibrator linearity test (**shield method**) include the pharmacy name and RAM license number; the test name; make, model, and serial number of the dose calibrator; the name of the shield test plus model number and serial number (if applicable); the test radionuclide name and initial measured activity; the trigger level; and the person to contact if the trigger level is achieved. Additional documentation required for the shielded method are the measurements and calculations that determined the "equivalent decay time" for each thickness of sleeve (shield). This determination

need only be done once; the numbers should be constant from then on, and the only number used for that instrument. The variables to be recorded are the date of test; initials of person doing the test; and the measured activity for each point in time, or for each sleeve. The RSO must sign the linearity test records. NRC regulations allow an error of up to 10%, but most licensees set their trigger level at 5% to 7%. Should your dose calibrator not be linear throughout the entire range of dosage measurements, a mathematical correction factor must be used to compensate; otherwise, repair or replace and then retest the dose calibrator before use. The most common mistakes observed are a) failure to carry the test out to 10 microcuries or below, b) when non-linear, failure to determine and use correction factors, and c) failure to test quarterly, or after repair. (See 10 CFR 35.50 and Reference 1 and 2.)

### Accuracy Test

Accuracy means that for a given standard reference source, the assay is equal to, or within preset limits of, the assay of the source manufacturer. The accuracy test is done annually or after repair using, at a minimum, two different sources of different activities and principal photon energies. The non-variable information that can be preprinted on recordkeeping forms for the dose calibrator accuracy test include the pharmacy name and RAM license number; the test name; make, model and serial number of the dose calibrator; the sealed radionuclide source name, model number, serial number, and theoretical activity; the potentiometer radionuclide settings used to measure the sources; the allowable range of activity within which test results should fall; the trigger level; and the person to contact if the trigger level is achieved. The variables to be recorded include the date of test; initials of person doing the test; the measured activity for each source; and the percent deviation of measured activity from theoretical activity. The RSO must sign the accuracy test records. NRC regulations allow an error of up to 10%, while most licensees set their trigger level at 5% to 7% (although some have adopted even more restrictive conditions). Should your dose calibrator not be accurate it must be repaired or replaced, and subsequently retested before use. (See 10 CFR 35.50 and Reference 1 and 2.)

### Geometry Test

The geometry test is performed to document that dose assays are independent of geometric variation for the range of volumes used in both syringes and vials. This test is done before first use, and after repair. The non-variable information that can be preprinted on recordkeeping forms for the dose calibrator geometry test include the pharmacy name and RAM license number; the test name; make, model, and serial number

of the dose calibrator; the test radionuclide; the initial measured activity; the potentiometer radionuclide setting; the range of deviation allowed for geometry; the trigger level; and the person to contact if the trigger level is achieved. The variables to be recorded include the date of test; initials of person doing the test; and the measured activity for each volume change for both syringes and vials. The RSO must sign the geometry test records. Again, the NRC regulations allow an error of up to 10%, but most licensees set their trigger level at 2% (this lower number is found in the NRC licensing guidance and subsequently has found its way into most licenses). Should your dose calibrator not have geometric variation independence throughout the entire range of dosage measurement configurations, a mathematical correction factor must be used to compensate; otherwise repair or replace and then retest the dose calibrator before use. ***A word of caution: As radiopharmaceutical therapy with monoclonal antibodies (or any other non-conventional dosage forms) becomes more popular, the volumes dispensed have a much higher likelihood of exceeding the volumes traditionally used or dispensed; thus, they may not have been tested for geometric independence.*** (See 10 CFR 35.50 and Reference 1 and 2.)

### Survey Instruments

The recordkeeping requirements for survey instruments will vary depending on whether the instrument calibration is done in-house, or contracted out. In either case the instrument must a) be calibrated in dose rate (mR/hour) from 0 to 1000 mR/hour, b) provide measurements within 20% of the calculated exposure rate, and c) be calibrated before first use, after repair and yearly. In-house calibration requires a complete record of each survey meter calibration, while contracting out for calibration services only requires that a licensee maintain a "certificate" of calibration from the service. For in-house calibration, the required records include a description of the calibration procedure; the date of calibration; a description of the source and the certified exposure rates; the rates indicated by the instrument; any correction factors deduced from calibration; and the signature of the person doing the calibration. Keep these calibration records for three years or whatever your RAM license conditions or State requires. Beware, however, that not all calibration services calibrate survey instruments to NRC specifications. The two most common failings are using electronic calibration and/or only using one source. Be sure to place a sticker or tag on the survey instrument denoting its calibration specifications, date of calibration, date next calibration is due, and name (signature) of person doing the calibration. Although no recordkeeping is required for this, the survey instrument must be

checked for proper operation daily before use with a dedicated check source. Most nuclear pharmacies will have several survey instruments. Typically, at least one will be an ion chamber designed to measure dose rates primarily, and have a low efficiency at finding contamination. Another will be a classic end window or pancake probe "geiger" counter for finding low level contamination. Some "geiger" counters are calibrated for measuring dose rate, although most are not, and a common mistake is to use the contamination survey instrument to look for contamination, and then record dose rates into the daily survey log using the readings from this meter. It is best to first look for, locate, and remove contamination, then return with the dose rate meter for recording the radiation levels on the daily survey. (See 10 CFR 35.51 and Reference 3 and 4.)

### Dosage Assay

In general, commercial nuclear pharmacies are required to measure the dosage of radiopharmaceuticals prior to dispensing. This is not a regulatory requirement, but almost always is a license condition. The licensing guidance is sufficiently vague so that the details of the recordkeeping cannot be determined without examining the issue on a license by license basis. Nuclear pharmacies based in nuclear medicine departments are required to assay patient radiopharmaceutical doses as described in 10 CFR 35.53. Part 35.53 requires the following records be kept for three years: the name of the radiopharmaceutical (including the radionuclide plus the generic or trade name or abbreviation); lot number (prescription number); expiration date (time); patient's name and identification number, if appropriate; prescribed dosage; measured dosage and date (time) of measurement, or a notation that the dosage is less than 10 uCi; and initials of person measuring the dose. It would appear logical to attach these records to the radiopharmaceutical preparation record from which the assayed dose was drawn. Where possible, it would be advisable for all nuclear pharmacies to keep such records of dosages dispensed. There are situations where an individual patient's name will not be known, and then it is sufficient to dispense to the AU who ordered the radiopharmaceutical (depending on State board of pharmacy regulations). (See 10 CFR 35.53 and Reference 5 and 6.)

### Radiopharmaceutical Preparations

For commercial nuclear pharmacies there does not appear to be any regulatory requirement or licensing guidance that mandates radiopharmaceutical preparation records. To some extent, however, the recordkeeping is required through an indirect means. 10 CFR 30.34 (g) requires a <sup>99m</sup>Mo assay, and sets limits for <sup>99m</sup>Mo per mCi of <sup>99m</sup>Tc. In addition, in 10 CFR 30.51, there is a

requirement to maintain records of receipt, transfer and disposal of byproduct material, i.e., a "perpetual inventory" requirement. Since these regulations require that inventory be maintained and tracked, and that  $^{99}\text{Mo}$  levels in each patient dose be measured and recorded, radiopharmaceutical preparation records may be a critical component in helping to fulfill these regulatory requirements. These records must be retained for three years. There is specific guidance on radiopharmaceutical preparation recordkeeping for nuclear pharmacies based in nuclear medicine departments. (See Reference 6.)

$^{99}\text{Mo}$  breakthrough test records must also be retained for three years. The non-variable information that can be preprinted on recordkeeping forms for the  $^{99}\text{Mo}$  assay include the pharmacy name and RAM license number, and the test name. The variables to be recorded include the date of test; initials of person doing the test; the measured activity of  $^{99}\text{Mo}$  in uCi; the measured activity of  $^{99\text{m}}\text{Tc}$  in mCi; the ratio of uCi of  $^{99}\text{Mo}$  to mCi of  $^{99\text{m}}\text{Tc}$ ; if more than one dose calibrator is used, the dose calibrator identity; the date and time of measurement; and initials of person making the measurement. The upper limit ratio of uCi of  $^{99}\text{Mo}$  to mCi of  $^{99\text{m}}\text{Tc}$  that can be administered to a patient is 0.15. Through licensing guidance (and thus license conditions) most nuclear pharmacies have a limit of 0.07 (ratio of uCi  $^{99}\text{Mo}$  to mCi of  $^{99\text{m}}\text{Tc}$ ) at the time of kit preparation. This is to insure that the radiopharmaceutical can be used until its usual expiration time (six hours). This approach is somewhat simplistic and does not work for  $^{99\text{m}}\text{Tc}$  Sodium Pertechnetate (expiration time = 12 hours), or any radiopharmaceutical with a "shelf" life in excess of six hours. A reasonable recommendation would be to establish an in-house policy that would limit acceptable  $^{99}\text{Mo}$  breakthrough levels to a quantity which insures that the  $^{99}\text{Mo}$  to  $^{99\text{m}}\text{Tc}$  ratio never exceeds 0.15 for any radiopharmaceutical dose dispensed. It then follows that the upper limit of  $^{99}\text{Mo}$  to  $^{99\text{m}}\text{Tc}$  ratio would be based on the expiration time of the radiopharmaceutical with the longest shelf life. If you have developed a  $^{99}\text{Mo}$  trigger level, post it near the dose calibrator, and have it preprinted onto the dosage assay forms. (See 10 CFR 30.34(g), 35.204 and Reference 5 and 6.)

The  $^{99}\text{Mo}$  breakthrough test requires a special lead-shield container (pig) that is designed to be used with the dose calibrator. If you choose to use a lead pig of your own design for the breakthrough test, you must have the documentation to show that it is functionally equal to the one provided by the dose calibration manufacturer.

### Sealed Sources

The record keeping requirements for sealed sources apply mainly to calibration sources used for the quality control of the dose calibrator. Some nuclear pharmacies

do distribute sealed sources for other nuclear medicine purposes; those sealed sources that remain on the nuclear pharmacy license must have appropriate records maintained on them. New sealed sources must be smear wiped to test for leakage, or have a certificate from the supplier a) stating that the source was leak tested within the last six months and b) the results of that test. After initial tests, sealed sources must be tested every six months (or more often in some license conditions) to insure detected leakage is less than 0.005 uCi. The records must be kept for five years and must contain the make, model and serial number of each sealed source; the radionuclide name and activity (in uCi); the type of test (describe wipe test); test date; and signature of RSO. (See 10 CFR 35.59 and Reference 5 and 7.)

In addition, nearly every license has inventory conditions that call for a physical inventory every six months to account for sources received and possessed. The records, kept for two years (some licenses require three, or five years), must contain the kind and quantity of byproduct material contained in the sealed source; name of the source manufacturer; model numbers and location of sources; and the date of inventory. Interestingly enough, there does not appear to be any requirement that this inventory be signed by the RSO or by the person maintaining the inventory.

### Daily Surveys and Weekly Wipe Tests

The records of daily dose rate surveys and the weekly contamination smear wipe tests are kept for three years. The daily survey must be done with an instrument sensitive to 0.1mR/hour, and the weekly smear wipes counted in an instrument capable of accurately counting below 2000 dpm/wipe sample. Although wipe sample is undefined in the regulations, licensing guidance suggests a limit of 220 dpm/wipe, where sample covers 100cm<sup>2</sup>. The areas that must be surveyed include any areas where RAM was used routinely. Areas where very small quantities are used can be surveyed monthly, and waste storage areas can be surveyed weekly. Your RAM license may have slightly different requirements for areas and frequency of survey. Both daily and weekly surveys must have trigger levels established; the RSO must be notified if the trigger level is reached. The non-variable information that can be preprinted on recordkeeping forms for the daily dose rate survey and weekly smear wipe test include the pharmacy name and RAM license number; the test name; make, model, and serial number of survey instrument; a list of sites to be surveyed/wiped and/or a drawing of the areas; the trigger level; and the person to contact if the trigger level is achieved. The variables to be recorded include the date of test; initials of person conducting the test; and the measured dose rate or counts/wipe for each area. There should also be space for notes should a trigger level be reached or

approached, or should the tester wish to record something related to these surveys. In addition, there should be documentation on the counting efficiency of the instrument used to count the smear wipes. This is necessary as the data must be recorded in dpm units, and thus the results must be converted from cpm to dpm.

Using forms for recordkeeping that have the areas to be surveyed/wiped drawn on them facilitate visualization of areas potentially contaminated, and help spot trends, or sloppy work habits. (See 10 CFR 20.401, 35.70 and Reference 8 and 9.)

### **Decay in Storage (DIS) for Disposal of RAM**

Records for RAM held in storage until decayed to background (and then disposed of as ordinary trash) are required to be retained for three years. The non-variable information that can be preprinted on recordkeeping forms for the DIS method of RAM disposal include the pharmacy name and RAM license number; the record name; make, model, and serial number of the survey instrument used to measure the dose rate of the waste. The variables to be recorded include the waste radionuclide; the date the waste was entered into storage; the date of waste disposal; the name of person responsible for the disposal; the measured dose rate of each item to be disposed of; the area in which the survey was done; and the background reading in the survey area at the time of the survey. There are some additional constraints on DIS; the material to be disposed of must a) have a physical half life of less than 65 days (thus longer-lived waste must be disposed of by another means), b) be held in storage for a minimum of 10 half lives, and c) found to have a reading (with no shielding interposed) that cannot be distinguished from background with the survey instrument on its most sensitive setting. The most common violations reported by NRC inspectors relate to a) not waiting the full 10 half lives before surveying and disposal b) not surveying in a low or normal background area, thus not detecting low level contamination or residual activity and c) not fully defacing the radiation symbols and product labels. The radiation symbols and labels must be defaced prior to disposal as ordinary trash. (See 10 CFR 20.401, 35.92 and Reference 10.)

### **Inventory and Possession Limits of RAM**

Although there does not appear to be any specific regulation requiring that an inventory of RAM be kept, it is required indirectly. Each license will have specific "maximum amount(s) that the licensee may possess at any one time." In order not to violate license conditions (which vary, depending on the scope of the program), a perpetual, or running inventory must be kept. This is generally a duty assigned to the RSO, but in nuclear pharmacies is done by the computer (electronically).

This electronic inventory must match a physical inventory. It may be necessary to demonstrate to the inspector how your inventory control system works, and to document that electronic and physical inventories match. The major source of violations in this area is related to radioiodine inventory. This usually occurs when several Na<sup>131</sup>I therapies are ordered, prepared, and dispensed on a single day. On these occasions, it is sometimes noted that possession limits of <sup>131</sup>Iodine need to be raised. (See 10 CFR parts 20, 30, 35 and Reference 4 and 6.)

### **Compounding (Pharmacy- or Physician-Directed Departures)**

From August 23, 1990 to October 2, 1992, all radioactive drugs prepared in ways not listed in the package insert pursuant to a written directive (prescription) required certain records be kept. When first published in the Federal Register (55 FR 34513) this requirement was called the "Immediately Effective Interim Final Rule." It was put in place in response to a petition (PRM 35-9) from the American College of Nuclear Physicians and the Society of Nuclear Medicine to address certain restrictions in the regulations that might hinder the practice of medicine and pharmacy. This Interim Final Rule gave physicians and pharmacists the flexibility to compound (deviate from the manufacturer's instructions when preparing radiopharmaceuticals) provided certain records were kept. On October 2, 1992, the NRC ended the recordkeeping portion of the Interim Final Rule (57 FR 45568). The Interim Final Rule was scheduled to terminate on August 23, 1993; however, the NRC has extended the Interim Final Rule (without the recordkeeping requirements) until December 30, 1994 (58 FR 26938). This extension is necessary, so that the planned revision of 10 CFR part 35, also known as the Radiopharmacy Rule, can be made final. This proposed rule will allow a qualified nuclear pharmacist (Authorized Nuclear Pharmacist [ANP]) to prepare, or an AU physician to use, any byproduct material for any medical use. This, in essence, will make the practice of nuclear pharmacy the same as the traditional practice of pharmacy with respect to compounding.

When preparing for an inspection, keep in mind that certain records were required to be retained during the initial phase of the Interim Final Rule (8/23/90 through 10/2/92). Specifically, the required information includes a written directive giving a specific departure for a patient (or patients) or radiopharmaceutical, the nature of the departure, a description of the departure, and the reason(s) why the departure from the package insert is medically necessary. These records must be kept in an auditable form for a period of five years. (See 10 CFR 30.34(i)(1), 35.200(c)(1), 55 FR 34513, 57 FR 45568, and 58 FR 26938.)

## **Radiogases and Radioaerosols**

No specific records are required with regard to radiogases and radioaerosols, and most license conditions call for limiting possession to unit doses. A related set of records and documents are those required by 10 CFR part 20 regarding radioactive air concentrations. These records and calculations must be maintained for the entire period the RAM license is active and include the measurement and calculations used to determine the time necessary to reduce room air concentration to levels prescribed by 20.103 and/or 20.106 and any additional license conditions. These clearance times and emergency procedures must be posted in the appropriate areas. Common violations noted are a failure to post the area, or to recalculate clearance times after remodeling. (See 10 CFR 20.103, 20.106, and Reference 11.)

## **ALARA**

The licensee shall have a written radiation protection program which incorporates the philosophy of ALARA. Although this program is submitted as part of the license, it is expected, whenever there are significant changes in the operation, that the ALARA program will be updated as well. These program changes should be documented. Usually the changes that occur here are part of the duties of the RSO to routinely evaluate the radiation safety of the nuclear pharmacy and to update procedures as they are refined or changed. Sometimes previous violations, and their corrective action, result in changes in the ALARA program. (See 10 CFR 20.1(c), 35.2, Regulatory Guides 8.10 or 8.18, NUREG-0267, and Reference 12.)

## **Training and Supervision**

The regulations require two types of training and supervision of the workers by an AU. The initial training is somewhat generic and is directed at instructing the workers on the regulations and license conditions that apply to them, and to instruct them in basics, such as, which areas are restricted, who to contact in an emergency, and what rights they have as radiation workers. The licensee is responsible for this basic training. The second type of training is more job/profession specific and is related to the tasks for which the worker is responsible. This also includes all in-house policies and procedures. The supervisor (AU) is responsible for this second type of training, and for the actions of the supervised individuals. The records of training must be kept for the length of the license and include the name of the person conducting the training, the attendees, date of training, and the topics covered. (See 10 CFR 19.12, 35, NUREG 1134, and Reference 2 and 13.)

## **Misadministrations**

Employees of centralized nuclear pharmacies do not administer radioactive drugs to patients; rather, they dispense radiopharmaceuticals to AU physicians who practice with RAM licenses issued under 10 CFR part 35. Therefore, nuclear pharmacies cannot be solely responsible for a misadministration, and cannot be the reporting licensee. However, occasionally a dispensing error by a nuclear pharmacist is the reason a misadministration occurs. Nuclear pharmacies so involved in a misadministration should carefully document the event and any corrective actions(s) taken, should the misadministration trigger an inspection.

The triggering factors for a misadministration were changed fairly dramatically when the Quality Management Rule became final in January of 1992 (10 CFR 35.2, and 35.32). The good news is that the trigger level for diagnostic radiopharmaceutical (other than radioiodine) misadministrations increased from 5 rem to 50 rem dose equivalent for any individual organ. This will eliminate nearly all diagnostic misadministrations (except radioiodine). With the political fallout from the recent print media articles in the Cleveland Plain Dealer (December 13, 14, 15, 16, 17, 1992), and the lethal brachytherapy misadministration in Indiana, PA (November 16, 1992) the NRC, under close scrutiny by the U.S. Congress, has taken a much more aggressive and serious stance on misadministrations. Regulatory Guide 8.33 is an excellent tool for learning the "ins and outs" of the Quality Management Rule.

## **RAM Receiving Records**

Generally the conditions and records required for receiving RAM are linked to RAM package opening procedures, and are license conditions. The regulations require recordkeeping in a general sense (again, linked to inventory and possession limits), monitoring of the packages received to assure compliance with shipping exposure rate limits, and testing for leakage. The receiving area must be located so as to keep radiation levels in unrestricted areas at or below levels in 10 CFR 20.105(b)(1 and 2). The regulations simply state that records of receipt of RAM must be kept for three years past transfer or disposal of the material. 10 CFR 20.205 requires smear wiping of packages (NRC notification is required if levels are in excess of 0.01uCi or 22,000dpm/100cm<sup>2</sup>) and surveying them to confirm that the dose rate is less than 200 mR/hour at the surface or less than 10 mR/hour at three feet (NRC notification is required if levels exceed these limits). These tests must be done within three hours if received during working hours, and within 18 hours if received after work hours, and records must be kept on these procedures. 10 CFR 20.401(b) and (c) require records of the results of the surveying be kept in the same units as the surveys, and

be kept for two years. However, should contamination or dose rate violation be detected the licensee is required to notify the shipper and the NRC. The implication is that documentation of the finding of a violation is necessary. Noting on the invoice that the package was surveyed and that it was in compliance with the applicable regulations (along with the name of surveyor and the date the survey was due) is sufficient to document compliance with the regulations. Package opening is a license condition procedure, and is an extension of the receiving procedure. Package opening procedures may lead to discovery of other shipping violations, and this is discussed in the section on Shipping. [See 10 CFR 20.205, 20.401(b) and (c), 30.51, 35.23 and Reference 12 and 14-16.]

### Shipping Records and Requirements

Shipping papers shall include a description of the hazardous material being shipped. [See 49 CFR 172.101 and 172.200(a).] All RAM used in nuclear pharmacies are considered hazardous material. The description must be legible and printed, may not contain any codes or abbreviations, and must contain an emergency response phone number (49 CFR 172.600). In addition, other requirements include the proper shipping name (technical and chemical group names may be entered in parentheses directly after proper shipping name), the hazard class (may be contained in the proper shipping name), the identification number, the total quantity by weight or volume (including units of measure), the packaging type and destination marks and, if a limited quantity, this must be so stated. Moreover, for RAM, there are other special regulations [see 49 CFR 172.203(d)]. The shipping paper requirements for RAM include: the name of each radionuclide (abbreviations are acceptable but must come from the table in 49 CFR 172.435), a description of the physical and chemical forms, the activity in each package, the category of shipping label, and the transport index (TI). (The TI is a dimensionless number found by rounding up the highest dose rate (in mR/hour) at 1 meter from the package [173.403(bb)(1)].)

Package markings shall include the words "Type A" at least 1/2" in height and plainly marked on the outside of the package (see 172.310). The package must also be marked with a Radioactive label, properly completed, based on the requirements in 49 CFR 172.403.

For RAM used in nuclear medicine a dose rate (highest reading) at package surface of less than 0.5 mR/hour would require a "white I" Department of Transportation (DOT) label (49 CFR 172.436); a dose rate of greater than 0.5 mR/hour but less than 50 mR/hour with TI of 1.0 or less require the use of a "yellow II" label (CFR 172.438); and a dose rate greater than 50 mR/hour with a TI greater than 1.0 require the

use of a "yellow III" (49 CFR 172.440), [see 49 CFR 172.403(b)]. These Radioactive labels must be on two sides of the package (opposite each other), [see 172.406(e)(3)]. The radioactive labels must also contain, in legible writing of a durable nature, the name of the radionuclide (from 49 CFR 172.435), the activity, and the TI. Additional design requirements for Type A packages are described in 49 CFR 173.412. The most important feature, for nuclear pharmacies is the security seal. The security seal shall not be readily breakable and, if intact, it provides evidence that the RAM has not been previously opened. In the case of exclusive use vehicle shipping, the cargo area may be sealed in lieu of the individual package. Absorbent packing in shipping containers is required when shipping liquids, and must be capable of absorbing twice the volume of liquid contained in the package [49 CFR 172.412(n)(2)].

Package surveys for shipping packages have specific limits. The normal limit is 200mR/hour on the surface (highest reading) and a TI not exceeding 10.0. A package in excess of these readings can be transported in an "exclusive use shipment only" vehicle. This vehicle must be marked. Additional requirements include the following: the dose rate of the package surface must be between 200 and 1000 mR/hour; the package must be secured to remain motionless while being transported; there must be no loading or unloadings between beginning and ending of shipment; the dose rate on the outer surface (any place) of the transportation vehicle must not exceed 200 mR/hour; the dose rate at 2 meters from the outer surface (any place) of the transportation vehicle must not exceed 10 mR/hour; and the dose rate in any normally occupied space (e.g., drivers seat) must not exceed 2 mR/hour. This 2 mR/hour limit does not apply to private carriers if the driver (or other exposed personnel) are under control of shipper (employees who are operating under a RAM license) and wear dosimetry devices (49 CFR 173.441).

Shipping boxes and containers (e.g., ammunition cans, specially designed attaché cases) shall be designed so that each package can be easily handled and properly secured for transportation. Packages from 22 to 110 pounds shall be designed to be manually handled, with a minimum safety factor of three built into the design, so that if a failure does occur, it does not impose an unsafe stress on the structure of the package, or impair the ability of the package to meet all the other requirements for shipping containers. The outer surface must be easily decontaminated, and designed so as to not collect water. Any feature(s) added to this container at the time of transportation must not reduce the safety of the package (49 CFR 173.411).

Most nuclear pharmacies will use type A packaging, which must meet DOT 7A specifications (49 CFR 178.350). You must have on file the documentation of

certification for any Type A packaging you use, for a period of one year past latest shipment (49 CFR 173.415).

### **Delivery vehicle**

The RAM license will require written procedures for delivery of RAM which address requirements of 49 CFR parts 170 through 189, and describe procedures used to provide security of the RAM (prevention of loss of control to a non-RAM license holder). Each vehicle should have documentation describing a) contents of the vehicle in general, b) persons (with phone numbers) to notify in case of emergency (traffic accident), c) general radiation safety directions for drivers or personnel responding in an emergency. These documents should be reviewed and updated when necessary with each change documented.

### **Customers**

Nuclear pharmacy licensees are required to have on file copies of current RAM licenses for all recipients of RAM shipped. The RAM can only be transferred to another RAM license holder. The recipient must have a current RAM license from the NRC or an agreement state, and the nuclear pharmacy must have the documentation to support the validation of the recipient's RAM license (10 CFR 30.41). Records for transfers of RAM must be kept for three years past transfer as required in 10 CFR Part 30.51.

### **Dosimetry**

The nuclear pharmacy's personnel monitoring program must require "film" and/or "TLD" badging for all employees who enter restricted areas. Some personnel may only be required to have whole body badging, while most RAM handlers will be required to wear extremity badges as well. Exposure records must be monitored and compared to ALARA program trigger levels, and this review must be documented. Any abnormality in the exposure record must be investigated, and the investigation documented. Common abnormalities are "lost" film badges, or badges which are unreadable (washed in the laundry). In both cases, a "reconstruction" of work done during that time period should be used to estimate the exposure. This also must be documented, and entered into the permanent record of that individual (10 CFR 20.201).

The film badge contractor who processes and assigns a dose to each film badge must be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) (10 CFR 20.202). If the dosimetry report provided by the contractor does not state "NVLAP accredited" then such a statement should be obtained from the contractor and file it with the dosimetry records.

Also, dosimetry from prior employment must be

obtained and maintained for each employee. This can be a signed statement from an employee new to radiation work, or an NRC-4 form from a veteran radiation worker. In addition, for a previous radiation worker all of his/her previous exposures must be summed to insure that his/her future exposures are not limited by previous exposures in excess of the limits (10 CFR 20.101).

### **GENERAL PHILOSOPHY**

Without a doubt, the best mechanism to have a successful NRC inspection is to have well trained, ALARA-conscious, competent RAM handlers; to follow all the rules, regulations, license conditions; and keep well organized, retrievable, and complete records. It is also very important to practice radiation safety every day, just as you would if the NRC inspector was watching. This means filling out forms, performing the surveys, and filing the records daily. Routinely review the files to insure proper placement, completeness, and clear organization. The manager or RSO should observe employees and make radiation safety (ALARA) a number one priority.

Although an inspection by any regulatory agency can be an uncomfortable and tense situation, it need not always be that way. Try being upbeat and interested in the inspector/inspection process. Act like the inspection is a college midterm exam in a course for which you were well prepared. Try to make "aceing" the inspection your goal.

Consider the inspector as a friend who will audit your program and clearly indicate areas that are not acceptable. Inform the inspector of your wish to have a perfect operation. Ask the inspector about areas in the regulations/recordkeeping that are unclear. Ask specifically if there are any areas in your practice that could be tweaked/finetuned and if he/she has seen another facility that perhaps does a certain function better or safer. If so, ask the inspector for the name of that facility so you can contact the RSO or manager for advice.

Specifically, you should ask the inspector during the exit interview what he/she thinks of the pharmacy operation. How does it compare to the many others that the inspector has seen? Does the inspector have any specific or general recommendations to improve the pharmacy?

***An observation: Inspectors often work long hours, alone, and usually have to travel for periods of a week more. Inspection work can be lonely and, often because of the nature of their job, the inspectors are treated as if they had a communicable disease. Yet, in reality, the inspector is probably a fellow "radiation" worker, often with some form of patient care experience, and your absolute best source of information about the***

*regulations, the recordkeeping requirements, licensing actions, regulatory guidance, and any upcoming changes in the regulations. Try to make the inspection a positive experience for both the inspector and the inspectee.*

Should the inspector find some flaws in your program that will likely become violations, resist the temptation to become defensive and argumentative. First of all, the inspector has guidance and directives from management that do not allow much flexibility with respect to violations. The inspector's job rating is linked to inspections, and how they are handled. Secondly, should a violation be overlooked by one inspector and found by another, especially if the overlooked violation is linked to a spill, source loss, or misadministration, it may have a negative impact on the career of the inspector who did not document the violation. Lastly, finding violations means a great deal more paperwork and a large time commitment for the inspector, thus decreasing his/her ability to fulfill the overall inspection requirements of the involved NRC regional inspection program.

Take a positive approach when the inspector finds a violation. Ask to be shown the details, how this violation can be remedied for the next inspection, and if the inspector requires any additional information on the violation. Now is a good time to provide the inspector with any additional information you may have, or extenuating circumstances that surround the violation.

Sometimes extenuating circumstances and additional information can mitigate the finding of a violation. A classic example of this was a hospital that had a Radiation Safety Committee (RSC) violation, i.e., the members were not promptly receiving copies of the minutes, and the committee was not, itself, retaining a copy of the minutes. During a subsequent inspection the same violation was found, thus becoming a "repeat" violation, and the hospital was facing escalated enforcement action. During the exit interview management was informed of the repeat violation and very skillfully informed the inspector of the "unusual" circumstances. Previously, the hospital had an employee who had released privileged information to the press and as a result, the hospital had established very tight controls on documents. In fact, all the members had read and initialed the RSC minutes, but then the only copy was filed in a controlled access file in the hospital administrator's office. Thus the "intent" of the regulation was met. The inspector then added the additional information to the report, and regional NRC management decided that this was not a violation. The rationale was that each member did get a copy of the minutes to review and sign, and the minutes of the meeting were available for review, but had to be requested from the hospital administrator. This

additional information, plus the statement (and history) of the hospital's policy were sufficient to mitigate away a repeat violation.

This brings us to, perhaps, the most misunderstood aspect of inspectors. Inspectors, generally, are not encouraged to make discretionary judgements. They are encouraged to write up all apparent violations, and then let regional NRC management and the licensee work out mitigation. This gives regional management the decision making responsibility, because they have a broader view of the violation with respect to the mission of the NRC to protecting the public health and safety.

A common complaint is that some inspectors find violations where previous inspectors found none. This happens routinely and is, in fact, to be expected. Each inspector has his/her own style, and areas of concern. Moreover, for many reasons (lack of time, or a diversion of allocated time to investigate a perceived safety problem), a given inspector may not thoroughly inspect every aspect of the operation. It is unreasonable to expect each and every inspector to be exactly the same. My personal experiences with fellow pharmacists is that each of us compounds and handles paperwork differently, some more carefully and completely than others. Therefore, give the inspector the same professional latitude you would a fellow nuclear pharmacist.

If a violation is found by the inspector which was missed on a previous inspection, calmly state that since the area of concern was not cited on a previous inspection, you were unaware it was a problem. Then ask how to address the underlying problem. Listen, ask questions and make the required changes to be in compliance.

So, in summary, do encourage the inspector to ask questions, then provide the specific information and any other information that may bear on the topic. Don't pressure the inspector to mitigate in the field; rather, provide the facts and let the decision be made elsewhere. Remember the inspector is coming into your facility without any "inside" knowledge specific to your operation, so what appears clear and logical to you may, in fact, not be so to the inspector. Take the advice of the inspector and make the necessary changes.

Encourage the inspector to take field notes of the inspection and share those observations with you. Use this interaction to get constructive criticism that will help you maintain regulatory compliance.

Many complaints have been voiced about inspectors ranging from incompetent, uninformed, attitude problems, to unprofessional conduct. The NRC has, within itself, an independent investigative branch, the Inspector General (IG). It is the duty of the IG, among others, to investigate all allegations made against any NRC employee. The IG answers directly to the

Commissioners, and is highly respected by all NRC employees. If you feel that an inspector has acted improperly, you may describe, in writing, the offending act(s), and notify the IG, or call the Office of the Inspector General at 1-800-233-3497.

## **INSPECTION FREQUENCY**

Although there are some exceptions, centralized nuclear pharmacies are usually inspected every other year, community hospitals every third year (heightened interest in medical use of byproduct material has pushed this to every other year), and licenses of broad scope are inspected yearly. Variations from the schedules given above may be based on past inspection history or a recent misadministration.

Generally each inspection will be only for the period of time from the last inspection to the present. The exception would be if a violation is discovered, the inspector may proceed back through the records to determine the duration of time the noted problem has been occurring. Clearly note, on the records, the date of the last inspection. This will lessen the burden of the inspector in finding the starting date for records review for the present.

## **THE INSPECTION**

### **Introductory Comments**

Occasionally, the inspector will observe the operation of the nuclear pharmacy from a distance, prior to announcing himself. The NRC is encouraging inspectors to do more direct observation of radiation workers and less record review. In a business that is done indoors, observation at a distance is limited to viewing loading and unloading of delivery vehicles. Therefore, it is advisable to properly train the drivers on topics such as basic radiation protection and security. Also, make sure delivery vehicles are properly placarded and have met all DOT requirements for manifests, invoices, and emergency notification instructions. Recently, security of the packages in delivery vehicles and in nuclear pharmacies within nuclear medicine departments has been a topic of increased inspection vigilance. It would seem advisable to reinforce the concept of locking doors in areas where RAM is held when those areas are not attended by a radiation worker.

Following these initial observations, the inspector will walk into the nuclear pharmacy and announces his/her intentions. This is not a good time to panic or try to catch-up on those records you have been meaning to update or file. Instead, the inspector should be introduced to the pharmacy manager and/or RSO and given a business card from each of these individuals; in return, a business card should be requested from the

inspector.

Should the inspector arrive at a critically busy time, briefly explain this to the inspector and ask if he would like to take this time to either observe work in progress or start reviewing records. Give the inspector an estimate of the duration of time for this "busy" period. If the inspector wishes to observe, show him/her the basic layout of the facility and suggest a few places where an observation can be made without impeding the flow of traffic. If records review is the inspector's first choice, then ask an employee who is "nonessential" to this critical time to show the inspector to an area suitable for records review. Then instruct the employee to bring any records the inspector might want.

Once the critical period is over, introduce each of the employees to the inspector, inform them what the inspector is there to do, and ask them to attend the exit conference. If the employees have any questions the inspector might be able to answer, they should be encouraged to ask them as time permits. Ask the inspector to accompany you on an orientation tour so that the physical plant may be briefly examined. Then await instructions on what part of the inspection process will be next.

Each inspector will have different preferences for the order of inspection. All areas on the inspector's field notes will eventually be covered. The major inspection subject headings are:

1. Organization
2. Scope of Program
3. Inspection History
4. Internal Audits or Inspections
5. Training, Refresher Training, and Worker Instruction
6. Facilities and Equipment
7. Radiological Protection Procedures
8. Radioactive Materials
9. Receipt and Transfer of RAM
10. Area Surveys
11. Personnel Radiation Protection - External
12. Personnel Radiation Protection - Internal
13. Radioactive Waste Disposal
14. Notification and Reports and Misadministrations
15. Radiation Safety Officer
16. Transportation
17. Independent Measurements
18. Bulletins and Information Notices
19. Special Procedures

The following information describes what the inspector is likely to ask or observe with regard to each of the 19 areas of emphasis (subject headings). The inspector will have reviewed, before arrival, your RAM license and all correspondence, previous inspection reports, previous violations and corrective action, if any.

## **Organization**

The inspector will question workers about the duties of various employees, their functional roles, and their job titles, in order to insure that the organizational structure in the RAM license is displayed/represented accurately in the nuclear pharmacy. Two major areas of interest will be to determine if a) the AUs are listed on the RAM license and if they are qualified, and b) the RSO is performing his/her duties and if he/she has sufficient authority to enforce the ALARA program and corresponding radiation safety endeavors. Also, the inspector may want to see organizational charts, chains of command, lines of authority, and job descriptions.

## **Scope of Program**

This is a helpful indicator to gauge the amount and types of activities in which the licensee engages. Since inspection frequency is approximately every two years, an operation can grow and change significantly in that period of time. As a result the inspector will want to know the number of a) current employees, b) doses dispensed at the present time per day and a year ago (or at last inspection), c) generators received per week, d) delivery vehicles presently in use, and e) drawing stations. He/she will also desire to know any changes in internal procedures or policies which occurred since the last inspection. For example, has there been a change in RAM waste disposal procedures?

## **Inspection History**

Inspection history will contain the findings and observations of previous inspectors. Any areas of concern to previous inspectors will be given top priority in the present inspection. The first thing which will be looked at and verified is the corrective action taken on previous violations. Second, any areas or functions thought to be weak by a previous inspector will be revisited by the present inspector. This might be a good time to explain previous violations or program weaknesses found and the corrective actions taken (along with the documentation of the corrective action). The inspector will want to determine if there are any uncorrected violations. Some corrective actions will involve equipment purchases which can be observed. Others will involve changes in procedures and practices which can be verified through observation and interviewing.

## **Internal Audits and Inspections**

The inspector will want to know if internal audits (inspections) are done, the frequency with which they are done, the person who performs the audit, and if records of these audits are retained. An important concern or principle which the NRC purports is self-identification of, and correction of, violations by the

licensee. Some consider these actions to be consistent with continuous quality improvement (CQI), a process that, when applied to radiation safety, has been very successfully employed in nuclear power facilities. It is a policy being adopted by many major medical providers to improve patient care. If such a program exists in the nuclear pharmacy (internal inspections and/or CQI), whether it consists of a "hired gun" or an in-house program, make certain that the inspector is aware of it. Give the inspector some examples of how it has worked to improve the pharmacy. Some licenses have independent audits as a license condition and, if so, the inspector will want to review those records as well.

## **Training, Refresher Training, and Worker Instruction**

As required in 10 CFR 19.12, worker training (instruction) is commensurate with potential radiological health protection problems in the restricted areas that the worker frequents. This training consists of information on basic radiation protection, principal license conditions, and NRC regulations. The worker is given the training necessary to protect himself/herself from unnecessary exposure and to comply with the license conditions and regulations. Strictly speaking, there are no recordkeeping requirements for this training, but from a practical standpoint, documenting worker instruction makes good sense. This can be accomplished by having the instructed worker sign and date a note which outlines the subjects on which they were instructed and which contains the name of the instructor.

Employee training is quite variable and is usually found as a license condition. If the pharmacy has a license-mandated training program, then be prepared to show the inspector documentation of its implementation. Generally, this will be initial training for new employees and refresher training for existing employees. Training, if not license-mandated, is the responsibility of the supervising AU or the RSO, depending on the type of training. Records of initial and refresher training must include date of training, subject matter, instructor and instructee. Some types of training are related to job duty and the supervising AU is usually responsible for this type of training. Some training covers general radiation safety or is refresher in nature, and it is the duty of the RSO to provide this type of training. Required training which includes generic radiation protection and regulatory requirements is outlined in 10 CFR 19.12. As long as the topics listed in 10 CFR 19.12 are covered, job-specific training can fulfill both requirements. The inspector will review these training documents to verify compliance.

Refresher training is done yearly, or as often as a license condition requires. The topics may vary but, at a minimum, should contain a review of the basics of

radiation protection and NRC regulations. Document this training by keeping records of topics, attendees, instructor, and dates taught.

The inspector may interview certain workers to ascertain their knowledge of the regulations that impact their duties as a test of the training program. It is likely the inspector will ask staff about 10 CFR 19.12 training and the RAM license, the shippers and drivers about DOT requirements, female workers (with obvious child bearing potential) about Regulatory Guide 8.13 (Instruction Concerning Prenatal Radiation Exposure), and nuclear pharmacists and technologists about <sup>99</sup>Mo breakthrough testing and limits.

### **Facilities and Equipment**

This part of the inspection is often done simultaneously with another part of the inspection, while the inspector is observing or taking independent measurements. The size, the state of maintenance (lighting, paint and floor condition), layout, and equipment will be noted and evaluated. The RAM license will have described the facility, and the inspector, at a minimum, will insure that the license conditions are fulfilled. Some of the questions the inspector will consider during the facility inspection are the following: Is the facility designed with ALARA in mind? Is it a safe workplace for the workers? Is the employee lounge clearly separate from the work areas? Is the RAM refrigerator clearly marked "No Food or Drink?" Are there any obvious OSHA or EPA violations? Is the RAM area secured from unauthorized entry? Are the RAMs secured from theft? Is the physical plant clean, well ventilated (heated and/or cooled), and conducive to preparing and dispensing radioactive drugs? Are there signs of an adequate ALARA program? Is there adequate shielding and posting? If decay in storage is used for radioactive waste disposal, is the storage area well shielded, separated from work areas, and secure?

**Posting and Labeling.** Is the NRC-3 "Notice to Workers" posted in each work area? Is the RAM license posted in a worker-accessible area along with the applicable parts of 10 CFR 19, 20, and 21?

Are the restricted areas clearly delineated? Are they marked as a radiation area or posted with a RAM sign? Is the pharmacy permit (license) current and displayed? (A current pharmacy permit is a licensing condition.) Are the emergency procedures clearly posted?

**Equipment.** The inspector will look to confirm that equipment listed on the license is present and operating properly. At a minimum, this includes a dose calibrator, survey instruments (both a "geiger" type and an ionization chamber type), and syringe and vial shields.

It may also include biological safety cabinets, fume hoods, multichannel analyzers, HPLC, autoclaves, and a host of other items. The role that these additional items play in radiation safety will determine their importance to the inspection process.

It may be helpful to affix labels to the dose calibrator noting that the instrument is linear, accurate, geometrically independent, and constant, and indicating the retest due date for each test. The calibration label for the survey instruments should also note when the next calibration is due. For any instrument not operating properly and requiring a mathematical correction, a clear, prominent, label should be affixed noting that a correction factor is required. Any instrument not currently in use (e.g., in storage or awaiting repair) should be so noted with a label in order to prevent inadvertent use.

Equipment must be quality control (QC) checked post repair (battery changes are not considered repair). Survey meters need to be recalibrated post repair and prior to use, then recalibrated yearly thereafter (or sooner if license conditions so require). Dose calibrator constancy checks should be performed at the beginning of each day. Dose calibrators require a complete QC check post repair and prior to use. This means accuracy, geometry, linearity, and constancy testing before first use and post repair. Neither the regulations in 10 CFR 35.50 nor the guidelines in Reference 1 require retesting post relocation, but Reference 2 does require this procedure. Check your license on this point, and ask the inspector what constitutes a relocation. Is it a move within a room, a move within the same facility, or a move to an entirely new facility?

The inspector will look for vials and containers to be properly labeled with the radiation symbol, radionuclide compound name, date/time of assay, radioactivity concentration, and volume. Some licenses will have color-coding conditions which will also be confirmed.

### **Radiological Protection Procedures**

To determine the adequacy of the radiological protection program, the inspector will initially observe the equipment and instrumentation and then procedures and practices (document review and direct observation). Is the use of RAM in accordance with the license? This can be determined by observation and interviewing workers. Do the workers understand the general rules for safe use of RAM? Were the workers given part 10 CFR 19.12 training? Is there an "emergency plan," and do the workers understand it? The inspector will observe workers to determine if proper lab attire is worn, if gloves are used (and frequently changed while handling RAM), and if hand monitoring is performed post RAM use. Are the workers using vial and syringe shields? Are hands, feet, containers, and syringe shields

routinely monitored for contamination? Are the work areas covered with absorbent material which is changed routinely or after positive survey findings? Are areas outside the facility (or non-radiation areas within the facility) surveyed?

**Surveys.** The wipe tests which are done to determine if removable contamination is present (usually done weekly) must be counted using suitable instrumentation. Is the counting instrument sensitive enough to detect contamination below the trigger level? What is the counting efficiency of the instrument? A determination of counting efficiency is necessary to display smear wipe data in disintegrations per minute (dpm). Data collected in counts per minute (cpm) must be converted into dpm. Is the staff trained to make area smear wipes covering a minimum of 100 cm<sup>2</sup>? When contamination is found, is it documented and corrective action taken? Was the RSO notified? Are follow up smears taken to confirm that the contamination is either below trigger level or non-removable?

### **Radioactive Materials**

The inspector will survey the scope of use of RAM by the licensee, and compare it to the RAM license. Is there any inventory control mechanism/procedure to assure that the quantity of RAM possessed is below license limits? Is the licensee knowledgeable of the license possession limits? Are there written directives for deviations from the package insert for the period of time records were required? Has a <sup>99</sup>Mo breakthrough test been done for each generator elution, and the appropriate records retained? Have the sealed sources been inventoried and wipe tested? Are gaseous and volatile RAMs stored in a chemical fume hood or glove box?

**Radiopharmaceutical Preparation.** Most nuclear pharmacies have license conditions that require radiopharmaceutical preparation in accordance with the package insert instructions. Even those nuclear pharmacies which have obtained license amendments for future unspecified departures have procedure manual requirements, record keeping requirements, and/or QC requirements. Thus, the inspector may want to review radiopharmaceutical preparation records to determine if "deviations" from the package insert instructions have occurred without a written directive from the prescriber.

**Radiopharmaceutical Quality Control.** Some nuclear pharmacies have QC license conditions. Generally a good place to keep these records is with the records for RAM. Usually records will be retained that describe each elution of the generator and disposition of each mCi of the eluate. The <sup>99</sup>Mo breakthrough records are typically kept along with elution records. If your license

also requires aluminum ion testing or radiochemical purity testing, then records of this procedure should also be kept in this same location. For each radiopharmaceutical prepared, similar records need to be on file. The inspector will confirm compliance with license requirements by reviewing records.

### **Receipt and Transfer of Radioactive Material**

The inspector will examine by observation, interview, and records review, the procedures for package receipt and opening. Is this done with the concept of ALARA (radiation safety) and security in mind? Are these procedures compatible with the license conditions and 10 CFR part 20? Are the packages surveyed and wipe tested as required? Are the records in order? Is the procedure for after-hours receipt of packages current and adequate?

**Transfer (Shipping) of RAM.** Preparation of RAM for transportation is obviously a large part of the work in a nuclear pharmacy. Has each outgoing package been surveyed and wipe tested? Is the shipping area sufficiently large and does it have a low background for proper TI determination? Are the shipping papers filled out properly? Are DOT labels and security seals affixed? Are all liquids shipped with absorbent material? Are the delivery cases secure and do they contain the required information? Are DOT 7A shipping containers used, and used as tested? Is the DOT 7A certification on file? Do the drivers have a manual containing the required material? If containers are being returned in accordance with the DOT definition of "empty," are the original DOT labels covered (with a label that reads "empty") or defaced (to be unreadable)?

***A word of caution: Drivers are often a weak link in a chain of radiation safety. They should be carefully instructed in radiation safety principles and practices pertaining to shipping and delivering. Initial training should be followed up with refresher training as needed. The drivers will likely be observed (often at a distance, and unannounced) and interviewed.***

**Delivery Vehicles.** The inspector may examine the delivery cars for compliance with DOT shipping regulations by checking on items such as bracing capabilities for packages containing RAM, emergency notifications, signs and procedures, placarding, emergency equipment, security (working locks), operational seat belts, and driver procedures for reporting accidents or contamination.

### **Area Surveys**

Survey records will be reviewed by the inspector to determine if surveys are done, and to determine which areas are routinely surveyed. On occasion, the inspector

will observe surveys in progress and try to determine if the surveyor is using the instrument appropriately. Was a (turn on) battery check and a check source test performed?

Are the areas surveyed reflective of work areas? Are the surveys done at times most likely to detect contamination? Is the survey instrument appropriate for its intended use? The inspector will confirm that ambient exposure rate surveys are done daily [10 CFR 35.70(a)(b)(c)], that contamination surveys are done weekly [35.70(e)(f)], and that the counting instrument for the smear wipes is operational, calibrated, and appropriate for its intended use. The inspector will examine trigger levels for each survey. Are the exposure rate surveys recorded in mR/hour? Are the contamination survey data recorded in dpm?

Often the inspector will compare daily dose calibrator constancy checks and daily surveys to determine if work with RAM was done (or doses dispensed). The inspector will look for a mismatch, a day, usually a weekend or holiday, when doses were prepared and assayed without dose calibrator quality control and/or a survey being done. A large number of violations are found, especially on weekends and holidays, doing this kind of comparison. It is important to remember that, if you work with RAM, even on a weekend or holiday, you must survey. If you prepare a patient dose, you must also do dose calibrator quality control (constancy check) prior to dose assay.

### **Personnel Radiation Protection - External**

The inspector will observe workers and confirm that dosimetry devices are being worn by all required workers. Also, the inspector will review the dosimetry reports for completeness and for dose reported. The inspector will confirm that dosimetry is done by a NVLAP-certified lab, that the reports are reviewed by all appropriate personnel, and that any exposures reaching a trigger level were investigated. He will review these investigations, corrective action taken, and follow up to insure ALARA is maintained.

Any unreported exposures will require an investigation, and a "reconstruction" of the activities of that employee to estimate an exposure for the missing period of time. This should include an interview with the employee. Estimated exposure must then be permanently entered into the dosimetry record, and the estimation process documented by the licensee.

Were there any overexposures? Were they reported to the NRC (10 CFR 20.403), and a written report made (10 CFR 20.405)? Are personnel dosimetry records kept (on proper NRC forms)? Were they retained for the required time?

### **Personnel Radiation Protection - Internal**

Internal dosimetry assessment and recordkeeping is more complicated depending on license conditions. Generally, there are two acceptable routes to take: urine counting, and thyroid counting. Whichever method is included as a license condition, the inspector will confirm its use, and assure that the method is sensitive to below the minimum detectable level as given in the RAM license. Procedures for bioassay equipment should include adequate QC to insure accuracy. In areas where volatilization of radioiodine is possible, are breathing zone and room air monitors used? Is the air monitor tested to insure sensitivity to the levels stated in the license?

For protection against exposure to radioactive gases, safety procedures and room clearance times for the gases should be posted in appropriate work areas. Recorded information should include hood flow rates, negative room pressure determinations, and ventilation rates (room air exchanges). The inspector will review records to confirm that this information is on file and may observe if minimum hood door closing is followed. An easy way to encourage compliance is to affix a label on each hood which lists measured flow rate, the date the next measurement is due, and the values for the minimum door opening required to maintain the minimum acceptable flow rate.

### **Radioactive Waste Disposal**

Assuming that most waste disposal in nuclear pharmacies will be handled by DIS, the inspector will review the current waste disposal program and compare it to the license conditions and the regulatory requirements. The inspector will look for segregation of waste by liquid versus solid, and by half life. Also, the inspector will look at records of radioactive waste disposal. Is the radioiodine waste stored in sealed containers or in the hood? Is activated charcoal used to trap volatile radioiodine? Are radioiodine-containing syringes stored in the hood as well? Is radioactive waste stored for 10 half lives, and then surveyed in a low background area? Was all shielding removed from generators prior to surveying? Were all the radioactive labels obliterated prior to disposal in ordinary trash?

### **Notification, Reports and Misadministrations**

The inspector will review the records to insure that the workers are informed of their exposure records (routine - 10 CFR 19.13; overexposures - 10 CFR 20.405), and that any thefts or losses (10 CFR 20.402) have been reported to the NRC. Any incidents or spills that exceed the routine contamination resulting from day-to-day work must be reported [10 CFR 20.403 and Information Notice (IN) 91-86]. Although, in theory, a nuclear pharmacy would not be directly responsible for

a misadministration, mistakes in nuclear pharmacies do occur (although rarely), and these mistakes often result in a misadministration (or sometimes multiple misadministrations stemming from a single nuclear pharmacy mistake). Since the medical licensee may mention in its misadministration report that the dose which was misadministered was obtained from a centralized nuclear pharmacy, that nuclear pharmacy should have a written report of the incident and the corrective action taken on file. Discussion among NRC staffers has raised the question of whether nuclear pharmacies should have reporting requirements for nuclear pharmacy-generated misadministrations since each incident can affect several patients. The sum of the doses to the affected patients could easily trigger the new, higher (single patient) misadministration trigger levels.

### **Radiation Safety Officer**

The performance of duties by, and management support of, the RSO are, in the eyes of the NRC, critical to the success of any radiation safety program. The inspector will want to interview the RSO to determine if he/she takes an active role in the ALARA program, and in the day-to-day radiation safety of the nuclear pharmacy. The inspector will be particularly interested in any regulatory or internal radiation safety audits and documentation; content and records of training provided by the RSO; the RSO's knowledge of the license and regulations; and evidence of support for the RSO from management.

### **Transportation**

The inspector will check for compliance with the requirements in 10 CFR parts 61, 71, and 49 CFR parts 171 through 189. A license to dispose of radioactive waste is required in 10 CFR part 61, so the licensee will have waste disposal as a license condition. Additionally, the nuclear pharmacy may be disposing of returned spent radiopharmaceuticals, and assuming responsibility for their shipping requirements. 10 CFR Part 71 describes requirements for transportation of licensed material, which includes the DOT requirements of 49 CFR parts 171 through 189 (labeling, placarding, marking, packaging, monitoring, recordkeeping, and accident reporting).

### **Independent Measurements**

The inspector may measure dose rates at various sites within your facility and compare them with measurements made with in-house meters. This is done to confirm reported dose rates and proper operation of survey instruments. Also, some inspectors will look for contamination in areas supposedly free of contamination, such as, ordinary waste cans, or door knobs in

unrestricted areas. Another often-used procedure is to survey ordinary trash containers (dumpsters) to check for improper disposal of RAM.

### **Bulletins and Information Notices**

Besides licensing correspondence, the NRC sends out Bulletins and Information Notices (IN), publishes notices in the Federal Register (FR), and has a newsletter (NMSS Licensee Newsletter). The inspector will look to see if these have been received and complied with, where appropriate. The NRC has published 16 INs on nuclear medicine subjects from 1981 to present.

INs of the past 13 years are:

### ***Nuclear Medicine Subjects***

IN 81-32	Transfer and/or Disposal of Spent Generators
IN 84-27	Recent Serious Violations of NRC Requirements by Medical Licensees
IN 85-61	Misadministrations to Patients Undergoing Thyroid Scans
IN 88-53	Licensee Violations of NRC Regulations Which Led to Medical Diagnostic Misadministrations
IN 89-12	Dose Calibrator Quality Control
IN 89-85	EPA's Interim Final Rule on Medical Waste Tracking and Management
IN 90-58	Improper Handling of Ophthalmic Strontium-90 Beta Radiation Applicators
IN 90-59	Errors in the Use of Radioactive Iodine-131
IN 90-71	Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs
IN 91-03	Management of Wastes Contaminated with Radioactive Materials ("Red Bag" Waste and Ordinary Trash)
IN 91-71	Training and Supervision of Individuals Supervised by an Authorized User
IN 91-86	New Reporting Requirements for Contamination Events at Medical Facilities (10 CFR 30.50)
IN 93-04	Investigating and Reporting of Misadministrations by the Radiation Safety Officer
IN 93-07	Classification of Transportation Emergencies
IN 93-10	Dose Calibrator Quality Control
IN 93-14	Clarification of 10 CFR 40.22, Small Quantities of Source Material
IN 93-36	Notifications, Reports, and Records of Misadministrations

Other INs that may be of interest to nuclear pharmacists are:

### *Management Control*

- IN 88-10 Materials Licensees: Lack of Management Controls over Licensed Programs
- IN 88-100 Memorandum of Understanding Between NRC and OSHA Relating to NRC Licensed Facilities
- IN 89-25 Unauthorized Transfer of Ownership or Control of Licensed Activities
- IN 89-35 Loss and Theft of Unsecured Licensed Material
- IN 90-01 Importance of Proper Response to Self-Identified Violations by Licensees
- IN 90-14 Accidental Disposal of Radioactive Materials
- IN 92-37 Implementation of the Deliberate Misconduct Rule Radiation Protection
- IN 88-15 Availability of US FDA Approved KI for Use in Emergencies Involving Radioactive Iodine
- IN 90-44 Dose-Rate Instruments Underresponding to the True Radiation Fields

### *Transportation*

- IN 80-32 Clarification of Certain Requirements for Exclusive Use Shipments of Radioactive Materials
- IN 87-31 Blocking, Bracing, and Securing of Radioactive Materials Packages in Transportation
- IN 91-35 Labeling Requirements for Transporting Multi-Hazard Radioactive Materials

Other NRC publications that may be of interest to nuclear pharmacies, beside the ones previously referenced in this course are:

### *NRC Regulatory Guides*

- 7.3 Procedures for Picking Up and Receiving Packages of Radioactive Material
- 8.7 Instructions for Recording and Reporting Occupational Radiation Exposure Data
- 8.10 Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Reasonably Achievable
- 8.15 Acceptable Programs for Respiratory Protection
- 8.18 Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be as Low as Reasonably Achievable

- 8.20 Applications of Bioassay for 1-125 and 1-131
- 8.23 Radiation Safety Surveys at Medical Institutions

### *NUREGS*

- 1400 Air Sampling in the Workplace
- 1446 Standards for Protection Against Radiation 10 CFR Part 20, A Comparison of the Existing and Revised Rules
- 1460 Guide to NRC Reporting and Recording Requirements

There are numerous other NRC documents that may be of use to nuclear pharmacy but are beyond the scope of this course to list. They are Bulletins, Policy and Guidance Directives, and notices in the FR.

NUREGS and Regulatory Guides can be purchased from:

US Government Printing Office  
Supervisor of Documents  
P.O. Box 37082  
Washington, DC 20013-7082  
(202) 512-2249

IN and Bulletins can be obtained from:

Linda Stevenson, P-370  
USNRC  
Washington, DC 20555  
(301) 492-9531

### **Special Procedures**

Some licenses may have certain radiopharmaceuticals or certain radiolabeled agents that require some special precautions and procedures. If possible, the inspector will want to observe these procedures. If this is not possible, the inspector may review the procedures and equipment used. The inspector is also likely to request an interview with the workers most familiar with these special procedures. An example of this might be compounding of 1-131 capsules from bulk radioiodine. Another example is cell labeling. This procedure often results in biohazardous/mixed radioactive waste issues, and it requires special precautions to help insure that radiolabeled blood is properly labeled, thus facilitating reinjection of the product into the correct patient.

### **Exit Interview**

The exit interview signals the end of the inspection. At this time, the inspector will usually insist on briefing management of his/her findings. He/she will take this opportunity to stress the importance of a) supporting radiation safety initiatives and policies of the pharmacy,

and b) fulfilling the regulatory and license requirements of the NRC. Any programmatic weaknesses or violations will be mentioned at this time, and any actions to follow will also be described. If a violation is found, the inspector will mention that a Notice of Violation (NOV) will be delivered by mail following the inspection, and it will require a written response. More serious violations may require an enforcement conference or civil penalties, depending on the severity level of the violation. Generally, an exit interview is an appropriate time for the inspector to mention strong and weak points in the inspection. This exit interview time is also ideal for the licensee to ask questions of the inspector.

## SUMMARY

Although what may have seemed a long, tedious, and convoluted process, this CE lesson has reviewed the recordkeeping requirements of the NRC for nuclear pharmacies. Also reviewed were the items which are most likely to be assessed with regard to each of the major subject headings listed on the NRC inspector's field notes. This review, when used as a guide for self evaluation, prior to an NRC inspection, will be a template for a successful inspection. The most common violations found in nuclear pharmacies have been discussed to provide the nuclear pharmacist with areas that might need additional vigilance. A strategy for inspector relations, derived from interviews with inspectors that will insure minimum anxiety during the inspection process has been proposed. Remember that there is no substitute for thorough preparation, complete records, and safe work habits.

## REFERENCES

1. Appendix E, "Procedures for Calibration of Dose Calibrators" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
2. Appendix C, "Model Procedure for Calibrating Dose Calibrator" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
3. Appendix D, "Procedures for Calibration of Survey Instruments" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
4. Appendix B, "Model Procedure for Calibrating Survey Instruments" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
5. Appendix H, "General Rules for Safe Use of Radioactive Material" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
6. Appendix M, "Records of Byproduct Material Use" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
7. Exhibit B (Numbers 13 and 14) of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
8. Appendix J, "Area Survey Procedures" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
9. Appendix N, "Model Procedure for Area Survey" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
10. Appendix R, "Model Procedure for Waste Disposal" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
11. Appendix O, "Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
12. Appendix G, "Model Program for Maintaining Occupational Radiation Exposure at Medical Institution ALARA" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
13. Appendix A, "Training and Experience for Authorized Users and Day-to-Day Radiation Safety Officer" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" and Appendix A, "Model Training Program" of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."
14. Appendix F, "Procedures for Ordering and Receiving Radioactive Material" of Task FC 410-4, "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses."
15. Appendix K, "Model Guidance for Ordering and Receiving Radioactive Material" of Regulatory Guide 10.8, "Guide for the preparation of Applications for Medical Use Programs."
16. Appendix L, "Model Procedure for Safely Opening Packages Containing Radioactive Material" of Regulatory Guide 10.8, "Guide for the preparation of Applications for Medical Use Programs."

## QUESTIONS

1. The fee charged by the NRC for a routine inspection is:
  - A. \$150.00
  - B. \$1000.00
  - C. \$1500.00
  - D. \$2000.00
2. NRC inspectors, in the course of a week, may inspect all of the following except:
  - A. pipe radiographers
  - B. coal moisture density gauge users
  - C. nuclear power plants
  - D. nuclear pharmacies
3. The recordkeeping requirements which the NRC will inspect stem from all of the following except:
  - A. 10 CFR parts 20, 30, 32 (NRC)
  - B. RAM License conditions and amendments
  - C. 49 CFR parts 170 - 189 (DOT)
  - D. 21 CFR parts 0 - 1200 (FDA)
4. Which dose calibrator quality control test must be done quarterly?
  - A. constancy
  - B. geometry
  - C. accuracy
  - D. linearity
5. Survey instruments must be calibrated before first use and
  - A. quarterly and post repair
  - B. yearly and post repair
  - C. every three years and post repair
  - D. post repair and/or battery replacement
6. The limiting ratio of  $\mu\text{Ci } ^{99}\text{Mo}$  to  $\text{mCi } ^{99\text{m}}\text{Tc}$  that may be administered to a patient is:
  - A. 0.015
  - B. 0.15
  - C. 1.5
  - D. 5.0
7. Sealed sources require a wipe test and a physical inventory every:
  - A. quarter
  - B. six months
  - C. year
  - D. three years
8. Daily dose rate surveys and weekly wipe test records must be kept in units of \_\_\_\_\_ and \_\_\_\_\_, respectively.
  - A. MR/hour and dpm
  - B. mR/hour and cpm
  - C. mR/hour and dpm
  - D. MR/hour and cpm
9. For decay in storage, the half life of the radionuclides must be less than \_\_\_\_\_, and the RAM stored for \_\_\_\_\_ half lives.
  - A. 65 hours and 10
  - B. 65 days and 100
  - C. 65 hours and 100
  - D. 65 days and 10
10. Which radionuclide is most likely to cause possession limit violations?
  - A.  $^{99\text{m}}\text{Tc}$
  - B.  $^{99}\text{Mo}$
  - C.  $^{131}\text{I}$
  - D.  $^{201}\text{Tl}$
11. Compounding, on a limited basis, pursuant to a written directive, is allowed by which rule?
  - A. Quality Management Rule
  - B. The Radiopharmacy Rule
  - C. The Immediately Effective Interim Final Rule
  - D. The Nuclear Pharmacy Guideline (1984 Lavender Report)
12. With respect to radiation safety, the acronym ALARA means:
  - A. As Low As Reality Allows
  - B. At Lowest Assay Reason Allows
  - C. As Low as is Reasonably Achievable
  - D. A Little or Almost no Radiation is Allowed
13. In January 1992, the definition of misadministration changed, and the trigger level increased to \_\_\_\_\_ REM for dose equivalent for any individual organ.
  - A. 5
  - B. 15
  - C. 25
  - D. 50

14. RAM packages received during normal working hours must be formally received according to license procedures within:
- three hours
  - six hours
  - twelve hours
  - eighteen hours
15. The absorbent material used in packing liquid RAM shipments must be able to absorb \_\_\_\_\_ the volume being shipped.
- 1/2
  - 2 times
  - 3 times
  - 5 times
16. The highest dose rate at the surface of a package, and the highest TI allowed for shipping other than exclusive use shipments are:
- 2000mR/hour and 10.0
  - 200mR/hour and 1.0
  - 20mR/hour and 0.1
  - 200mR/hour and 10.0
17. You must have valid documentation of which of the following before shipping RAM?
- the medical license of the recipient
  - the HCFA registration of the receiving hospital
  - the RAM license of the recipient
  - the JCAHO certification for the recipient
18. If an NRC inspector finds a violation, you should:
- argue loudly and try to change his mind then threaten to call the NRC's Inspector General.
  - calmly explain the circumstances surrounding the violation and present any additional information that might be useful.
  - state, "The last inspector didn't cite us for that!"
  - say, "We have always done it that way. What's wrong with that?"
19. Which NRC office should you contact if you have a significant problem involving behavior or conduct of an NRC employee?
- Office of State Programs
  - Office of Nuclear Materials Safety and Safeguards
  - Office of the General Counsel
  - Office of Inspector General
20. Nuclear pharmacies are usually inspected every:
- year
  - two years
  - three years
  - five years
21. During an inspection, the inspector will be especially interested in \_\_\_\_\_ records because they may be helpful in identifying past and present program weaknesses.
- area surveys and dosimetry
  - training and equipment
  - inspection history and internal audit
  - radioactive waste disposal and shipping
22. Which topic has been of considerable concern to NRC inspectors within recent years?
- state of the art equipment
  - compounding
  - security of RAM
  - qualification of nuclear pharmacists
23. Dosimetry services ("film" badge readers) must be certified by:
- MYLAR
  - KEVLAR
  - NVLAP
  - LORAN
24. For the Decay in Storage method of radioactive waste disposal, after 10 half lives you must:
- survey the waste and find it indistinguishable from background before placing in ordinary trash
  - obliterate any radiation signs/symbols before placing in ordinary trash
  - crush in a trash compactor
  - answers A and B
25. The inspector is most likely your best source of information on:
- professional consultants
  - regulatory requirements
  - NRC policies
  - answers B and C