

# How to Prepare for a Regulatory Inspection \*

K. David Steidley

*Veterans Administration Hospital, East Orange, New Jersey*

**Guidelines for the proper preparations prior to a regulatory inspection are presented. A periodic series of mock inspections with a standardized format is advocated. A review of needed documentation and health physics considerations is given.**

Many nuclear medicine technologists must act as radiation safety officers for their own activities. This is a difficult task and many may feel an uncomfortable sense of apprehension when faced with the prospect of an inspection by either the Nuclear Regulatory Commission (formerly the Atomic Energy Commission) or a state regulatory agency for radiologic health. The intent of this communication is to provide some guidelines for achieving a satisfactory level of compliance with the many existing rules and regulations. Since, in most instances, inspection visits are unannounced, the time to plan for a successful inspection is now.

Preparation for an inspection involves work in three main areas: (A) securing, studying, and systematically filing various documents, (B) generating certain records, and (C) mastering basic health physics procedures. A mock inspection should be undertaken after these tasks are completed.

## Necessary Documents

The most important federal document governing the regulation of by-product materials is Title 10 of the Code of Federal Regulations (CFR). A copy can be obtained from the United States Government Printing Office.† Those sections that are most pertinent to a nuclear medicine facility are Part 19 (“Notices, Instructions, and Reports to Workers: Inspections”), Part 20 (“Standards for Protection Against Radiation”), and Part 35 (“Human Use of Byproduct Material”). The possession of copies of Parts 19 and 20 is mandatory for any nuclear medicine facility. Materials contained in 10-CFR can be continuously updated by subscribing to the *Federal Register*‡ or by use of a commercial service. Despite the fact that the language of these regulations is sometimes difficult to read, the exact answers to many questions are contained there. What degree of radiation constitutes a radiation area and therefore requires

posting? What amount of radioactive material constitutes the necessity for a “Caution—Radioactive Material” sign? Answers to questions of this nature can be found in this document. It should be noted here for the benefit of those working in agreement states that similar state documents exist.

Another important document is the USAEC Regulatory Guide 8.10.§ This particular guide may well prove to be a benchmark in the regulation of radiation exposure. While specific compliance with any regulatory guide is not required, they do give methods acceptable for implementing specific parts of the regulations.

Among the various documents that one must have available is the original copy of the license(s). Most licenses have as their last condition a sentence reading like this: “Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material in accordance with statements, representations, and procedures contained in the application dated May 1, 1969, and letters dated May 1, 1969, and June 1, 1969.” This means that the original application as well as certain subsequent communications are as binding as any other condition of the license and these various letters must be on hand. These should be reviewed to ensure compliance with each and every item. In many instances original applications have stated that a certain procedure (e.g., a wipe test) will be done at an unrealistically high frequency, and one is then bound to do this. If for a particular operation the stated frequency is found to be unnecessarily high, then a letter must be written requesting a change in this condition. The original condition is still binding until approval for

---

For reprints contact: K. David Steidley, Radiology Service (114A), VA Hospital, East Orange, N.J. 07019.

\*Presented as a workshop on April 25, 1975, at the Fourth Annual Spring Symposium sponsored by the Society of Nuclear Medicine Technologist Section, Greater New York Chapter.

†Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; \$3.90.

‡Available from Superintendent of Documents for \$45.00 per year (published daily).

§For a free copy, write to: U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Attention, Director of Regulatory Standards.



UNITED STATES OF AMERICA ATOMIC ENERGY COMMISSION  
Washington, D.C. 20545

# NOTICE TO EMPLOYEES

## STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20); NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19)

In Part 20 of its Rules and Regulations, the Atomic Energy Commission has established standards for your protection against radiation hazards from radioactive material under license issued by the Atomic Energy Commission. In Part 19 of its Rules and Regulations, the Atomic Energy Commission has established certain provisions for the options of workers engaged in AEC-licensed activities.

### YOUR EMPLOYER'S RESPONSIBILITY

- Your employer is required to—
1. Apply these AEC regulations and the conditions of his AEC license to all work under the license.
  2. Post or otherwise make available to you a copy of the AEC regulations, licenses, and operating procedures which apply to work you are engaged in, and explain their provisions to you.
  3. Post Notices of Violation involving radiological working conditions, proposed imposition of civil penalties and orders.

### YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the AEC regulations, and the operating procedures which apply to the work you are engaged in. You should observe their provisions for your own protection and protection of your co-workers.

### WHAT IS COVERED BY THESE AEC REGULATIONS

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding AEC inspections; and
7. Related matters.

### REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The AEC regulations require that your employer give you a written report if you receive an exposure in excess

of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in Sections 20.101, 20.103, and 20.104 of the Part 20 regulations. These Sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.

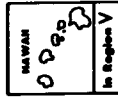
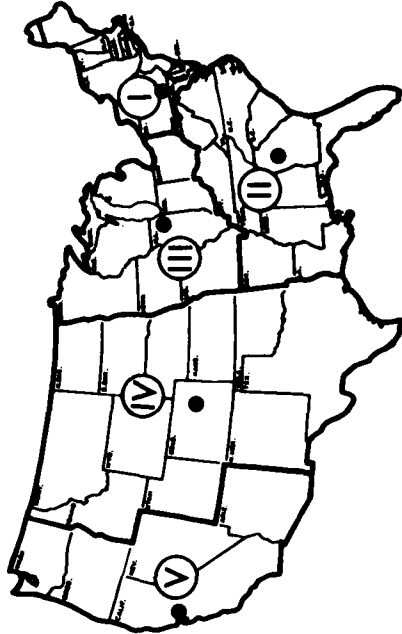
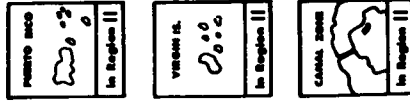
2. If you work where personnel monitoring is required pursuant to Section 20.202:
  - (a) your employer must give you a written report of your radiation exposures upon the termination of your employment, if you request it, and
  - (b) your employer must advise you annually of your exposure to radiation, if you request it.

### INSPECTIONS

All activities under the license are subject to inspection by representatives of the AEC. In addition, any worker or representative of workers who believes that there is a violation of the Atomic Energy Act of 1954, the regulations issued thereunder, or the terms of the employer's license with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the appropriate United States Atomic Energy Commission Regulatory Operations Office (shown on map at right). The request must set forth the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, AEC inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

### POSTING REQUIREMENT

Copies of this notice must be posted in a sufficient number of places in every establishment where activities licensed by the AEC are conducted, to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.



### UNITED STATES ATOMIC ENERGY COMMISSION REGULATORY OPERATIONS OFFICES

REGION	ADDRESS	TELEPHONE	
		DAYTIME	NIGHTS AND HOLIDAYS
I	Region I, Directorate of Regulatory Operations, USAEC 631 Park Avenue King of Prussia, Pennsylvania 19406	215-387-1150	215-387-1150
II	Region II, Directorate of Regulatory Operations, USAEC Suite 818, 230 Peachtree St., NW, Atlanta, Georgia 30303	404-526-4503	404-526-4503
III	Region III, Directorate of Regulatory Operations, USAEC 759 Roosevelt Road Glen Ellyn, Illinois 60137	312-858-2660	312-739-7711
IV	Region IV, Directorate of Regulatory Operations, USAEC 10952 West Colfax Avenue Denver, Colorado 80215	303-837-4211	303-237-5095
V	Region V, Directorate of Regulatory Operations, USAEC P.O. Box 1515 Berkeley, California 94704	415-486-3141	415-273-4237

FIG. 1. Form AEC-3, which must be posted in nuclear medicine area.

change has been granted. If these letters have been lost or misplaced, as some hospitals have done, a copy can be obtained by writing the appropriate regulatory agency.

Another set of documents that must be maintained on file concerns the radioisotope committee. A current membership list must be available, and the regulatory agency must have a similarly updated list. A copy of the committee responsibilities as well as the minutes of each meeting must also be on file.

Documents that must be posted are Form AEC-3 (Fig. 1) (or the state equivalent) and the notices as specified in Title 10, Part 19. Table 1 shows the form that we use in our institution. Since an inspection can take place at any time, all documents and records should be filed in such a manner that another person would be able to handle the inspection in the absence of the radiation safety officer.

### Necessary Records

Accurate, up-to-date records of personnel radiation monitoring and radioisotope inventory are mandatory and should be readily available for an inspection, along with a copy of the radiation safety manual.

Personnel monitoring records must extend back in time to the start of the nuclear medicine program. Monitoring records should include the name and social security number of each person. If there are some badge records with only identification numbers, immediately write in the name of each person who wore each badge for the appropriate period of time. Next, contact the badge service to make the conversion to names and social security numbers. If any unusually high exposures have been recorded, a memorandum explaining the circumstance of that exposure should be affixed to the badge record. Even in the case of overexposure due to malicious mischief, an explanation as to why the results are high must be available.

Radioisotope inventory records are extraordinarily important. The arrival of each shipment of radioisotopes must be logged regardless of where the radioactive material comes from or for what use. The use of material must be recorded by entering (A) to which patient the material was given, (B) what amount of the material decayed, (C) what amount was disposed of via the sanitary sewer system, a commercial radiologic disposal service, or was given to another hospital, etc. All these amounts should then add up to the total that was initially brought into the hospital so that a complete bookkeeping system of credits and debits is established.

Each nuclear medicine program must have a radiation safety manual. This can be simple or complex depending on the departmental needs and desires. Make sure that each employee using radionuclides is familiar with the safety manual so that he or she can answer questions on radiation safety procedures to the extent that they pertain to their job.

### Some Selected Health Physics Considerations

The true keystone to satisfactory compliance is a thorough and energetic health physics program. Most violations are probably the direct result of the ignorance of the licensee. One can consult any number of excellent textbooks on nuclear medicine, medical physics, or health physics containing suitable sections on basic health physics principles that can bridge any gaps in your comprehension. Chapter 14 of the textbook, *Basic Medical Radiation Physics (1)*, has a number of charts and tables that are helpful for preinspection purposes.

The question often arises as to how often should surveys be done. Once a day, once a week, or once a month? The answer, of course, depends on the particular operation. The survey needs to be done often enough to establish what the dose rates and the degrees of contamination are or what they might be at *any time*. The dose rates will tend to be the same in an operation that changes very little from day to day. However, removable contamination can change rather quickly for any given day especially with the use of  $^{99m}\text{Tc}$ .

For any sealed source one owns, the license will spell out the terms and conditions that should be employed to perform leak tests. A leak test is usually unnecessary for quantities below 100  $\mu\text{Ci}$  (e.g., a small calibration rod) if they contain beta and/or gamma emitters and 10  $\mu\text{Ci}$  if they are alpha emitters. If an operation also includes the use of  $^{137}\text{Cs}$  needles or tubes for brachytherapy, it would be well to secure NCRP Report No. 40, "Protection Against Radiation From Brachytherapy Sources."\* Since leak tests are usually performed every 6 months, it might be helpful to make a list of the due dates in advance for any calendar year.

Calibration of various surveillance instrumentation is necessary periodically. The frequency and methodology of these calibrations may have been specified in the original application and if so must be adhered to. In general, such instruments should be calibrated at a frequency appropriate to the accuracy that is expected from the instrument and to the general drift of the instrument with time. Therefore, there is no hard and fast rule as to what constitutes a frequent-enough calibration. However, it can be noted that the various national laboratories generally use a frequency of once a quarter for the various kinds of hand-held G-M counters and ionization chambers (such as the Cutie Pie). Just as a reminder, the G-M counter is, of course, quite suitable for detecting contamination on surfaces (given that the general radiation background is not too high) but it is not suitable for making accurate measurements of the radiation field because of its strong energy dependence in the range of the most common clinical radionuclide,  $^{99m}\text{Tc}$ . For such exposure measurements

\*Available from NCRP Publications, P. O. Box 30175, Washington, D.C. 20014.

**TABLE 1. Notice to Employees**

Various documents governing the use of radioactive materials are available for your perusal in the Radiation Safety Office located in the Radiotherapy Department. The following are on file:

1. Part 19 of Title 10, The Code of Federal Regulations.
2. Part 20 of Title 10, The Code of Federal Regulations.
3. Our Nuclear Regulatory Commission licenses.
4. Various documents incorporated into our license by reference and amendments thereto.
5. Operating procedures applicable to our licensed activities with radioactive material.

(DO NOT ALTER, DEFACE OR REMOVE THIS DOCUMENT WITHOUT PRIOR APPROVAL OF THE RADIATION SAFETY OFFICER. POSTED AS REQUIRED BY 10-CFR-19.11.)

an ionization-type instrument such as the Cutie Pie can be used. It is also advisable to discard any batteries that are in an instrument at the end of each quarter and consider them dead unless proven otherwise. This eliminates any possibility of damage caused by the mechanical rupture of a battery. Furthermore, most instruments lose a good deal of their stability and accuracy once their batteries no longer generate their rated voltage.

There are two additional items that one might consider in order to prepare for an inspection.

**Dose calibrator.** If one uses a high energy source to periodically check instrumentation accuracy, it is also advantageous to check the accuracy at lower energy levels. The <sup>99m</sup>Tc calibration can be checked by matching it with an affordable quantity (e.g., 5 mCi) of <sup>57</sup>Co. Documentation of the results of such accuracy checks must be maintained.

**Therapeutic radionuclides.** There are a number of special activities and documentation procedures that one must adhere to when using therapeutic quantities. Further information may be obtained by referring to NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

**Mock Inspections**

For the technologist supervising both a clinical program and his own radiation safety program, it is most important to develop a fresh objective outlook when he operates in the latter role. A regular series of mock inspections with a standardized format can help achieve this objective. The system of mock inspections can be further strengthened by the use of a "buddy system." Given the right geographic and personal relationship with another hospital, it is most helpful if one can exchange mock inspections with another technologist.

Now would be a good time to perform a mock inspection aided by the form shown in Table 2 (or use this form as a starting point to make your own). Examine all

**TABLE 2. Nuclear Medicine Inspection and Survey Report**

Date of inspection: \_\_\_\_\_ Inspector: \_\_\_\_\_

**Documents**

- Form AEC-3 posted  Yes  No  N/A
- Notice to workers posted  Yes  No  N/A
- Emergency procedures posted  Yes  No  N/A
- Warning signs posted  Yes  No  N/A
  - Caution—radioactive material  Yes  No  N/A
  - Caution—radiation area  Yes  No  N/A
  - Caution—high radiation area  Yes  No  N/A
- Copy of 10-CFR, Parts 19 and 20 available  Yes  No  N/A
- Isotope receipt records adequate  Yes  No  N/A
- Isotope use records adequate  Yes  No  N/A
- Isotope disposal records adequate  Yes  No  N/A
- Radiation safety manual available  Yes  No  N/A
- Documents as listed available
  1. \_\_\_\_\_  Yes  No  N/A
  2. \_\_\_\_\_  Yes  No  N/A
  3. \_\_\_\_\_  Yes  No  N/A
  4. \_\_\_\_\_  Yes  No  N/A
  5. \_\_\_\_\_  Yes  No  N/A

**Health physics considerations**

- Only authorized isotopes on hand  Yes  No  N/A
- Quantities of isotopes on hand within authorized possession limits  Yes  No  N/A
- Isotope technique handling adequate  Yes  No  N/A
- Waste disposal procedures adequate  Yes  No  N/A
- Sealed sources leak tested at proper intervals  Yes  No  N/A
- Isotope storage facilities adequate  Yes  No  N/A
  - Location: \_\_\_\_\_  Yes  No  N/A
  - Shielding: \_\_\_\_\_  Yes  No  N/A
- Functional survey meter (s) available  Yes  No  N/A
  - Calibration date(s): \_\_\_\_\_

**Surveys**

- Records of past surveys adequate  Yes  No  N/A
- Radiation field instrument used: \_\_\_\_\_

Location of reading (see sketch for location)			Meter reading (cpm or mR/hr)
1.	6.	11.	_____
2.	7.	12.	_____
3.	8.	13.	_____
4.	9.	14.	_____
5.	10.	15.	_____

Radiation counter used for removable contamination: \_\_\_\_\_

Location of wipe test (see sketch for location)			Net cpm
A	F	K	_____
B	G	L	_____
C	H	M	_____
D	I	N	_____
E	J	O	_____

Comments and recommendations \_\_\_\_\_

areas of activity with as much impartiality and objectivity as possible. Try to correct any deficiency found within 30 days. Mock inspections should be repeated about four times a year.

If you have made yourself thoroughly familiar with the regulations, have a good basic understanding of health physics, and have conducted quarterly mock in-

spections, you should have no problem passing any regulatory inspection. You will be looking at it in the same way the inspectors will, with you having the advantage of more familiarity with your operation.

## References

1. Stanton L: *Basic Medical Radiation Physics*. New York, Appleton-Century-Crofts, 1969