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STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

July 20, 2001

Mr. Dennis Sollenberger
Office of State and Tribal Programs
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Sollenberger:

As discussed in our telephone conversation on July 9, 2001, I am sending a copy of our "Inspection and Enforcement Policy and Procedures" manual. This manual and our expectations of our radioactive material license inspectors have been discussed with them numerous times since our IMPEP review last August. Our I&E Manager met with our Field Office Managers in December 2000 to discuss the findings made by the IMPEP reviewer and the apparent misunderstandings between the reviewer and our inspectors. The need for better documentation and clearer statements of our non-compliance findings in our reports and letters was also discussed at this meeting. The Division contracted with the NRC Training Center and in February 2001 almost our entire inspection staff attended the "Inspecting for Performance" course. Several inspectors attended the "Inspection Procedures course in March 2001. Field office mangers have conducted meetings with their staff and reinforced our policies and procedures.

Several staff members are currently in intensive on-the-job training in the materials inspection program. During a recent (July 9-10) meeting between the I&E Manager and the Field Office Managers, minor revisions to our manual were made to better reflect our current policies. Some of our staff have reviewed NRC inspection reports from the various Regions to compare our documentation of observations during inspections to those of the NRC's inspectors. We have found these reports to be very useful as training tools for our staff. We believe that our inspectors have been and are performing

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inspections utilizing an appropriate mix of performance-based **and** compliance-based techniques. We look forward to the upcoming inspection accompaniments and the opportunity to discuss the reviewer's findings with him/her during the review.

As you requested, enclosed you will also find a list of license inspections due during the months of July/August/September by region (Memphis, Nashville, Chattanooga, and Knoxville) and a list of qualified individuals to perform those inspections. Please contact the respective Field Office Managers to schedule the accompaniments. Please note that the week of August 27th is not available due to an emergency response exercise at Watts Bar Nuclear Power Plant. If you have any questions, you may call me at (615) 532-0426.

Sincerely,

Debra Shults
Deputy Director
Division of Radiological Health
L&C Annex, 3rd Floor
401 Church Street
Nashville, TN 27243

Radioactive Material License Inspectors

Memphis EAC
Suite E-645, Perimeter Park
2510 Mt. Moriah Road
Memphis, TN 38115-1502

1. Allen Grewe, Manager
(901) 368-7966

2. Grigsby Stevens

Nashville EAC
711 R. S. Gass Blvd.
Nashville, TN 37243

1. Anthony Hogan, Manager
(615 687-7017

Chattanooga EAC
540 McCallie Avenue, Suite 550
Chattanooga, TN 37402

1. John Politte, Manager
(423) 634-5777

2. Steve Seeger

Knoxville EAC
2700 Middlebrook Pike, Suite 220
Knoxville, TN 37921

1. Billy Freeman, Manager
(865) 594-5518

2. Mark Andrews
3. Shawn Drake
4. John Thompson
5. Roger Macklin
6. Chuck Johnson

Memphis Inspections Due July/August/September			
License Number	**Name & City**	**Category**	**NRC Category**
1. R-57033	Care South Clinic, PC Jackson, TN	3.c. Med. Diagnostic Or Therapy	02200
2. R-79195	Diagnostic Imaging Memphis, TN	3.c. Med. Diagnostic or Therapy	02200
3. R-57028	Digestive Disease Clinic Jackson, TN	3.c. Med. Diagnostic or Therapy	02200
4. R-79171	Duratek Memphis Group Memphis, TN	11.a. Brokerage 10.a. Storage for transfer 10.b. Decontamination Services 13. Case by case	99998
5. R-40002	Henry Co. Medical Center Paris, TN	3.c. Med. Diagnostic or Therapy 4.a. Medical Treatment	02120
6. R-57032	The Jackson Clinic Jackson, TN	3.c. Med. Diagnostic or Therapy	02200
7. R-79249	Mediphysics Memphis, TN	6.c. Dist. Radio pharmaceutical	02500
8. R-79270	Memphis Cancer Center Memphis, TN	3.c. Med. Diagnosis or Therapy	02200
9. R-92003	Methodist Hospital Martin, TN	3.c. Med. Diagnosis or Therapy	02200
10. R-24002	Methodist Healthcare Somerville, TN	3.c. Med. Diagnosis or Therapy	02120
11. R-57011	Methodist Healthcare Jackson, TN	3.c. Med. Diagnosis or Therapy	02120
12. R-79027	Methodist Hospital Memphis, TN	4.a. Medical Treatment 3.e. Calibration for Hire 3.f. Leak Tests for Hire	02230 02121 02210
13. R-23002	Methodist Hospital Dyersburg, TN	3.c. Med. Diagnosis or Therapy 3.h. Invitro>300 microcuries	02120 02410
14. R-27011	Milan General Hospital Milan, TN	3.c. Med. Diagnosis or Therapy	02120
15. R-57027	Radiation Oncology Jackson, TN	4.a. Medical Treatment	02230
16. R-57025	Syncor International Jackson, TN	6.c. Dist. Radio pharmaceutical	02500
17. R-79210	Tri State Testing Memphis, TN	6.d. Radiography	03320
Nashville Inspections Due July/August/September			
License Number	**Name & City**	**Category**	**NRC Category**
1. R-19180	American Red Cross Nashville, TN	4.b. Irradiator, Self-Contained	03510

2. R-60019	Environmental Site Assessments Columbia, TN	3.i. < 3 gauges Temp. Jobsites	03121
3. R-16020	General Physics Corp. Arnold AFB, TN	6.d. Radiography	03320
4. R-19219	JANX Nashville, TN	6.d. Radiography	03320
5. R-81001	Nelson Engineering Service Dover, TN	5.f. 3+ Gauges, Temp. Jobsites	03121
6. R-19014	Professional Services Industries Nashville, TN	6.d. Radiography	03320
7. R-19190	Saint Thomas Radio pharmacy Nashville, TN	6.c. Dist. Radio pharmaceuticals	02500
8. R-19197	Skyline Medical Center Nashville, TN	4.a. Medical Treatment	02121
9. R-16011	Sverdrup Technology Arnold AFB, TN.	6.d. Radiography	03320
10. R-19149	Syncor International Nashville, TN	6.c. Dist. Radio pharmaceuticals	02500
11. R-19017	Tenn. Dept. of Transportation Nashville, TN	6.h. Gauges	03121
12. R-95009	World Testing Mt. Juliet, TN	6.d. Radiography	03320 03310

Chattanooga Inspections Due July/August/September

License Number	Name & City	Category	NRC Category
1. R-06002	Bradley Memorial Hospital Cleveland, TN	3.c. Med. Diagnostic or Therapy	02120
2. R-89003	Columbia River Park Hospital McMinnville, TN	3.c. Med. Diagnostic or Therapy	02120
3. R-33137	Diagnostic Center Chattanooga, TN	3.c. Med. Diagnostic or Therapy	02200
4. R-33138	Exam, Inc. Chattanooga, TN	6.d. Radiography	03320
5. R-25003	Fentress County Hosp. Jamestown, TN	3.c. Med. Diagnostic or Therapy	02120
6. R-54007	Mobile Tech Services Athens, TN	6.c. Dist. Radio pharmaceuticals	02220
7. R-33036	Parkridge Medical Center Chattanooga, TN	3.c. Med. Diagnostic or Therapy 4.a. Medical Treatment	02120
8. R-26005	Superior Diagnostics Winchester, TN	6.h. Use at Satellite Facility	02200

9.	R-33130	Testing & Technology Chattanooga, TN	6.d. Radiography	03320
10.	R-33139	Volunteer NDT Corp Chattanooga, TN	6.d. Radiography	03320
11.	R-18009	Well Surveys Crossville, TN	6.f. Well Logging	03111
12.	R-N4005	PET Scans of America Corp. Chattanooga	6.c. Dist. Radio pharmaceuticals	02500
Knoxville Inspections Due July/August/September				
License Number		**Name & City**	**Category**	**NRC Category**
1.	R-73021	Bionomics, Inc. Kingston, TN	13. Case by Case	03234
2.	R-90033	Clinical Pharmacy Services Gray, TN	6.c. Dist Radio Pharmaceutical	02400
3.	R-73014	DSSI, INC. Kingston, TN	11.a. Brokerage	03233
4.	R-73018	Duratek Radwaste Processing Oak Ridge, TN	11.a. Brokerage	03900
5.	R-47152	IT Corp Knoxville, TN	11.a. Brokerage	03900
6.	R-01083	Methodist Medical Center Oak Ridge, TN	4.a. Medical Treatment	02230
7.	R-13004	Naseem, Shoaib A., M. D. Tazewell, TN		
8.	R-01068	Nuclear Equipment Services Center Oak Ridge, TN	10.b. Decontamination Services	0321
9.	S-86001	Nuclear Fuel Services Erwin, TN	11.e. Processor	11300
10.	R-47176	Roy Osborne Knoxville, TN	3.e. Calibration for Hire 3.f. Leak Tests for Hire	02120 02210
11.	R-86011	Studsvick Processing Erwin, TN	11.e. Processor	03234
12.	R-01085	Surface Technology Systems Oak Ridge, TN	13. Case by Case	03219

STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
Division of Radiological Health
3rd Floor, L&C Annex
401 Church Street
Nashville, TN 37432-1532

Division of Radiological Health's

INSPECTION AND ENFORCEMENT POLICY AND PROCEDURES

AREA OFFICES

July, 2001

INSPECTION AND ENFORCEMENT POLICY AND PROCEDURES

AREA OFFICES

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INSPECTION AND ENFORCEMENT POLICY AND PROCEDURES AREA OFFICES

1000.01 General Description

The Division of Radiological Health currently maintains four (4) Inspection and Enforcement (I&E) area offices (Memphis, Nashville, Knoxville and Chattanooga). The area offices and their personnel are primarily responsible for the inspection of x-ray registrants and radioactive material licensees. Additional duties involve responding to radiation incidents and participating in exercises with other Division personnel for responding to an incident at a nuclear powered reactor.

The area offices were geographically located in this manner for the following reasons: (1) they contain large cities and/or are in close proximity to a large number of nuclear facilities, (2) these cities more easily provide the necessary services to maintain the Division's Program, and (3) the natural geographic disposition of the State of Tennessee necessitates a number of area offices.

01.01 Central Office

The area offices report and their main contact to the central office is the I&E Health Physics Program Manager in Nashville, TN. However, interaction between other sections and members of the Division is encouraged to further the main goal of the Division in protecting the citizens of Tennessee from the harmful effects of radiation.

01.02 Personnel Structure

Each area office is headed by a Health Physics Field Office Manager. These individuals are assisted in maintaining the area office duties by an assistant manager or supervisor. Each area office is, also, staffed with Health Physicists with a wide range of experience and educational background. The number of Health Physicists designated to each area is based upon the number of x-ray registrants and radioactive material licensees in each region.

01.03 Maintenance of Files and Support Staff

Each area office maintains a duplicate copy of the x-ray files, radioactive materials files, and proprietary information associated with the registrants and licensees they inspect in their region.

01.04 Equipment

Survey equipment, air sampling equipment, and kits composed of the necessary supplies to conduct health physics and environmental surveys are stored in a designated area and/or room in each area office. Each area office is, also, equipped with a dark room and the necessary supplies needed to develop x-ray film.

01.05 Transportation

A Motor Pool is available to the personnel of each area office, and its use in routine Division business is encouraged. In addition, an emergency vehicle pre-equipped with the necessary survey instruments and kits has been designated for emergency response and must be within close proximity of each area office at all times.

01.06 Laboratory Services

Laboratory services are provided to each area office by the Tennessee Bureau of Laboratory Services. The samples, swipes, smears, and etc. are collected and logged by the Health Physicist and sent to the Tennessee Bureau of Laboratory Services either directly, or via the Liaison of the Technical Services Program of the Division of Radiological Health.

01.07 Employment Policies

Pertinent policies and procedures addressing the employment of each individual of the Division of Radiological Health are addressed in the Tennessee Department of Environment and Conservation Employee Handbook.

01.08 Documentation and Records Confidentiality

Each report and/or letter generated as a result of an inspection and/or investigation shall be approved by its generator and shall receive at least one level of review and approval from a person supervising the originator of the letter and/or report. Approval shall be denoted by a dated mark-off of the individual's initials. The review and approval process for reports and/or letters generated as a result of an inspection and/or investigation is as follows:

(1) All reports and/or letters originating within an area office, including the Nashville area office, shall be reviewed and approved by the Health Physics Field Office Manager (or Health Physics Field Office Supervisor, where appropriate) of the area office.

(2) All reports and/or letters originated by a Health Physics Field Office Manager shall be routed to Central Office (the I&E Manager) for the required single level of review and approval.

(3) Certain radioactive material licenses may be designated by the Director's Office for review and approval at that level. Reports and/or letters regarding such designated licenses and/or registrations shall receive review and approval by both the Health Physics Field Office Manager/Supervisor and the I&E Manager. Radioactive material licenses currently designated for this type of review are as follows:

- radioactive material licenses assigned a six month inspection frequency
- radioactive material licenses requiring financial assurance
- radioactive waste license(s)-for-delivery (shippers' license)

Notwithstanding the above, the originator or a reviewer of a letter and/or a report is authorized and encouraged to route reports and/or letters, when appropriate, to any personnel in the Central Office, including the Director's Office (normally the Deputy Director), for review and/or approval. This is discretionary and is in addition to the required single level of review. This decision should be based on the individual's judgment regarding the need or desirability of obtaining input or approval on matters such as, but not limited to, enforcement or licensing policy, interpretation of requirements, proper citation language and/or construction, and documentation of findings. Health Physicists in early stages of training should receive consideration toward the provision of a second level of review.

It has been determined by the Division regarding the provisions of "State Regulations for Protection Against Radiation" 1200-2-5-.135(5) and the rule referenced therein, 1200-2-4-.10 (specifically 1200-2-4-.10(4)), and 1200-2-5-.143, that the policy of the Division would be to protect the privacy of any individual who,

(1) as a patient, is referred to in a document written regarding licensed or registered activities. Patient identification (name or social security number) shall not normally be used in records by Division staff. Records or reports obtained from, or submitted by or on behalf of, licensees or registrants which contain patient identification shall normally be edited so as to delete the patient's identification before inclusion in any Division file. If in some particular case it is determined that retention of a patient's identification is important, this shall be accomplished using the Division's proprietary file system as set up to implement 1200-2-4- .10.

(2) as a radiation worker, is monitored by an individual monitoring device (film badge, TLD, lapel sampler, etc.), or by bioassay. It will normally be the policy of the Division to not include an individual's identification in records created by Division staff, except in particular cases where we may use the proprietary file as noted above. A significant point is that, if we copy or acquire licensee or registrant records which contain a monitored individual's identification for the purpose of inclusion in a Division record, the identification of the individual shall normally be deleted. If, however, a licensee or registrant submits unsolicited (but perhaps required) information (such as an event report, overexposure report, etc.), which contains a monitored individual's identification, we will not delete or declare proprietary such identification as the licensee or registrant has included, since they themselves had ample opportunity, in accordance with 1200-2-4-.10, to protect the individual's identity.

The intent is that, in preparing Division records, Division staff will follow the recommendation included in the cited rules, especially for patient records, even though the Division is not obligated to do so. Except for patient records, Division staff will not edit unsolicited information submitted by licensees and registrants. Reports which Division staff prepare, including information which the Division requests from licensees or registrants for inclusion, will not identify monitored individuals unless treated as proprietary information.

1000.02 STATE REGULATIONS FOR PROTECTION AGAINST RADIATION

The guiding tools for the area offices and their personnel in performing their duties are "State Regulations for Protection Against Radiation" and Tennessee Code Annotated. These regulations and laws set forth the requirements of individuals, groups, and corporations which possess and use x-ray equipment and radioactive material.

1000.03 ENFORCEMENT

Enforcement activities usually begin with a routine inspection conducted by the Health Physicist. Other circumstances that could initiate enforcement activities are allegation(s) and/or complaint(s)

made by an employee at a facility or a member of the public that caused an investigation or non-routine inspection to be performed. Any items noted during the inspection and/or investigation by the Health Physicist which do not meet the requirements set forth in "State Regulations for Protection Against Radiation" and/or the specific radioactive material license are communicated to the registrant and/or licensee in a Notice of Noncompliance letter. Each citation made in the Notice of Noncompliance letter must be supported and substantiated by the Health Physicist's notations, data, and calculations recorded in the inspection forms or report.

1000.04 X-RAY INSPECTION SPECIFICS

X-ray inspections are performed at intervals set forth in "State Regulations for Protection Against Radiation" and Tennessee Code Annotated. These intervals are based on a hazard assessment of the types of operations. X-ray machines and equipment are inspected as follows:

Class	Includes	Inspection Frequency
1	Dental Diagnosis	4 years
2	Medical Diagnosis (includes veterinary & chiropractic)	2 years
3	Diagnostic Radiologists Orthopedic Surgeons & Hospitals	1 year
4	Medical Therapy Veterinary Therapy (< 9 MeV)	1 year
5	Industrial Education (closed beam, shielded room, cabinet)	2 years
6	Industrial (open beam analytical)	1 year
7	Accelerators	1 year

04.01 Mammography

As a result of the Mammography Quality Standards Act of 1992, after October 1, 1994, mammography can only be performed by facilities that have been accredited by a designee of the Secretary of the Department of Health and Human Services. This act subjects all mammography (diagnostic and screening) to mandatory quality assurance provisions. The accreditation process specifies the following:

(1) equipment used be dedicated to mammography;

(2) personnel performing mammography be licensed or certified;

(3) physicians interpreting mammograms be certified;

(4) and mammographic and film processing equipment be inspected by a medical physicist annually.

The area offices have dedicated a Health Physicist to be trained and certified to perform inspections upon mammography facilities in accordance with the standards and guidelines set forth by the Department of Health and Human Services in conjunction with the Mammography Quality Standards Act of 1992 in their respective regions. The inspection of these mammography facilities will be on an annual basis.

1000.05 X-RAY INSPECTION PROCEDURES

Inspection of facilities with x-ray equipment is assigned and approved by the Health Physics Field Office Manager and/or the Health Physics Supervisor of x-ray inspections. The basis for choosing a facility for inspection is inspection due date and facility location. This information is obtained from the Central Office in a computer printout form and sent to each area office.

The Health Physicist needs to be organized and prepared for an inspection before leaving the office. After receiving approval of the facilities chosen to be inspected, the files should be reviewed to key him/her to any areas that may need special attention. Packages of film, forms, and all necessary equipment should be organized for the trip. For maximum efficiency, the most direct route to all facilities should be mapped and facilities should be batched in order to inspect all due facilities in the same area at one time. Each Health Physicist is supplied with a library of maps of each county under the jurisdiction of each area office. Flexibility is necessary due to offices being closed, congested or any variety of reason which may keep the Health Physicist from following the prearranged inspection plan.

Upon arrival at a facility, the Health Physicist should cordially introduce himself and/or herself by explaining the purpose of the visit and requesting to speak to the person in charge of the x-ray equipment. The Health Physicist performing the inspection should take special precautions in ensuring this contact person is the responsible party. Diplomacy is the key to avoiding confrontational situations with a registrant. The Health Physicist should remember each inspection may involve a variety of mitigating circumstances.

Using the Division Inspection Form and/or the form supplied to Registered Inspectors for inspection of x-ray equipment in the State of Tennessee, the Health Physicist should be able to efficiently cover all the necessary information needed to determine compliance. Special attention should be given to documenting the person interviewed during the inspection.

05.01 Close-out Meetings

A "close-out meeting" between the Health Physicist(s) performing the inspection of x-ray equipment and the person responsible for the x-ray equipment should occur at the end of each inspection. The purpose of this meeting is to review items of noncompliance that may be itemized in the Notice of Noncompliance, as well as areas where improvements could be made, and areas of exemplary performance. Facility managers or administrators should always be included in these meetings unless they decline the invitation.

1000.06 CONDUCTING X-RAY INSPECTIONS

All x-ray inspections are based on the "State Regulations for Protection Against Radiation." Protecting the health and safety of people by securing the compliance of the facility and the x-ray units with these regulations is the purpose and goal of the inspection.

All x-ray facilities are reviewed in the following areas:

1. Proper registration of units
2. Personnel monitoring
3. Posting of appropriate documents
4. Proper film development (when relevant to patient or personnel exposure)
5. Protective equipment

Other types of x-ray machines and types of x-ray facilities are reviewed in the following specific areas:

06.01 X-ray Machines in Dental Facilities

X-ray units generally found in dental facilities, listed in the order of prevalence, are:

1. Dental units - intraoral
2. Panoramic units
3. Cephalometric units
4. Temporal Mandbular Joint units (TMJ units)

Dental units are tested for compliance in these areas:

1. Beam size
2. Filtration of soft x-rays
3. Timer and exposure reproducibility, exposure termination, and exposure interruption
4. Proper markings and warnings
5. Scatter and shielding

Exposures are checked against average levels for recommendation.

Cephalometric units, in addition to the above, must meet regulations concerning limited beam size to film size used.

06.02 X-ray Machines in Medical Facilities

Medical radiographic units (including chiropractic units) are tested for the following:

1. X-ray field size coordinating with film size, field size indicator markings, x-ray field center and crosshair match, alignment of x-ray field and light field centers, and x-ray field center alignment with bucky field center
2. Source to image distance indication and accuracy
3. Exposure reproducibility
4. Timer reproducibility
5. Proper filtration - Beam Quality
6. Proper use of variable collimator
7. Visibility of patient
8. Exposure interrupt and timer termination of exposure

Units tests on fluoroscopic:

1. Table top output
2. Timer
3. Field size
4. Minimum source to skin distance
5. X-ray quality - filtration

Veterinary units are tested against the above except for:

1. Timer and exposure reproducibility
2. patient (animal) visibility

In addition, these facilities are required to keep an animal holding log, and to provide personnel monitoring for holders, if employees are ever used to hold animals during x-ray exposures.

1000.07 RADIOACTIVE MATERIALS INSPECTIONS SPECIFICS

Radioactive material licensees are assigned to one of a number of categories based on the type of material, its use, and its potential health and safety risk to the public. Categories of licensees having similar potential hazard levels are assigned to one of seven inspection priority groups, each of which has an inspection frequency associated with it. The frequency and scope of inspections are commensurate with the quantities of materials used or processed, the inherent potential hazards, and previous inspection findings. To ensure compatibility with the regulatory program of the United States Nuclear Regulatory Commission (NRC), each category of license is given an inspection priority which results in inspections being performed at least as frequently as a similar category under the NRC would receive. Radioactive material licenses are inspected as follows:

Categories	Priorities	Inspection Frequencies
NUCLEAR LAUNDRY	1A	6 months
DISPOSAL/PROCESSING FACILITIES	1A	6 months
INCINERATORS	1A	6 months
WASTE HANDLER - PREPACK	1A	6 months
WASTE HANDLER - REPACK	1A	6 months
DISPOSAL FACILITY (BURIAL)	1A	6 months
RARE EARTH EXTRACTION & PROCESSING	1A	6 months
SOURCE MATERIAL > 150 KILOGRAMS	1	1 year
MEDICAL INSTITUTION BROAD	1	1 year
MEDIUM DOSE RATE AFTERLOADER	1	1 year
HIGH DOSE RATE REMOTE AFTERLOADER	1	1 year
PULSED DOSE RATE AFTERLOADER	1	1 year
NUCLEAR PHARMACY	1	1 year
RADIOGRAPHY (FIELD)	1	1 year
RADIOGRAPHY (FIXED)	1	1 year
MANUFACTURING & DISTRIBUTION (BROAD)	1	1 year
ACADEMIC RESEARCH-TEACHING BROAD	2	2 years
MOBILE NUCLEAR MEDICINE VANS	2	2 years
RESEARCH AND DEVELOPMENT	2	2 years
SEALED SOURCE FABRICATION	2	2 years
TELETHERAPY	3	3 years
WELL LOGGING (SEALED SOURCES)	3	3 years
WELL LOGGING (SEALED SOURCES/TRACERS)	3	3 years
DISTRIBUTION OF RADIOPHARMACEUTICALS	3	3 years
HUMAN/ANIMAL MEDICAL RESEARCH	3	3 years
MANUFACTURING & DISTRIBUTION	3	3 years
ANALYTICAL TESTING	3	3 years
FIELD FLOODING STUDIES	3	3 years

3. Personnel monitoring, including the use of external radiation dosimeters, bioassays including in vivo counting of employees, personnel and station air samplers, is sufficient to evaluate internal and external exposure to personnel.

4. The radiation safety committee adequately performs its functions.

5. Management audits of all operations and of administrative controls are performed as required, and identified deficiencies are corrected.

08.03 General Policy Concerning Inspections

It is the licensee's responsibility to conduct a radioactive materials program or to operate a facility safely in compliance with all regulatory requirements. Inspections by the Health Physicist are performed on a sampling basis, and do not duplicate or substitute for licensee management audits or controls. While the Health Physicist may raise questions, make suggestions, and at times make

08.04 General Scope of Inspection

The minimum required scope for inspections of materials program is provided in the sections for inspection requirements for specific facilities or programs. Inspections are conducted on an unannounced basis, except as approved by Division management in cases where past experience has demonstrated it to be difficult to locate key licensee personnel. A post-inspection review is conducted with the Health Physics Field Office Manager and the Health Physicist(s) who performed the inspection to review the findings.

08.05 Priority of Effort

The major inspection efforts are to ascertain if the licensee is operating the facility or using the radioactive material safely and in compliance with "State Regulations for Protection Against Radiation." The inspection effort expended against various portions of these regulatory requirements should be commensurate with their relative importance to safety.

08.06 Identification of Regulatory Requirements

The attached guidelines and checklists indicating inspection items to be examined for each type of program or facility utilizing radioactive materials should be used in conjunction with "State Regulations for Protection Against Radiation" and specific conditions of the radioactive materials license. The depths and lengths of each inspection should be commensurate with the potential hazard of the licensed operation, the previous inspection and enforcement record of the licensee, and the particular health and safety problems and/or violations discovered during the inspection.

08.07 General Inspection Items

The basic elements that comprise an inspection are outlined in the attached guidelines and checklists and should be used in conjunction with "State Regulations for Protection Against Radiation" and license conditions. If all aspects of a program are inspected at one time, each planned series of inspections or each inspection by a Health Physicist should be sufficient to ascertain if all licensed activities are conducted with adequate attention to safety and are in compliance with "State Regulations for Protection Against Radiation."

During the course of each inspection, the Health Physicist should review for any changes in the health and safety organization which comprises the radiation safety program, corrective actions on previously identified enforcement matters, and/or incidents involving radioactive material since the last inspection.

The Health Physicist should review the licensee's radiation safety program for control and evaluation of personnel exposures, control and evaluation of the discharge of effluents, operating and emergency procedures, employee training, and packaging and transportation activities. Selective records of the licensee's radiation program should, also, be reviewed.

08.08 Review of Changes in Process Facilities and Equipment

Significant changes in the facilities, equipment, and/or procedures described in the licensee's application and/or subsequent amendments should be examined by the Health Physicist to determine compliance with "State Regulations for Protection Against Radiation" and/or the radioactive materials license. If any significant changes are found, the Health Physicist should determine if the licensee has performed an adequate evaluation of these changes, documented these changes, and submitted the required reports and amendment requests(s) to the Division. These changes in the licensee's program should, also, have been authorized by the Division before being implemented.

08.09 Sampling Plan

Licensee's records involving repetitive action should be audited by the Health Physicist performing the inspection using a sampling plan to provide reasonable confidence that these records and activities are satisfactory. Records are generally reviewed for the time period since the last inspection and review was made.

08.10 ALARA (As Low As Reasonable Achievable)

"State Regulations for Protection Against Radiation" 1200-2-5-.40 states that persons engaged in NRC licensed activities shall, to the extent practicable, maintain occupational doses and doses to members of the public ALARA.

08.11 Documentation

The results of each inspection should be documented in accordance with current agency procedures and practices as previously mentioned in section entitled "Documentation and Records Confidentiality."

08.12 Close-out Meetings

A "close-out meeting" between the Health Physicist(s) performing the inspection of the radioactive material license and the person responsible for the radioactive materials program should occur at the end of each inspection. The purpose of this meeting is to review items of noncompliance that may be itemized in the Notice of Noncompliance, as well as areas where improvements could be made, and areas of exemplary performance. Facility managers or administrators should always be included in these meetings unless they decline the invitation. The "close-out meeting" is an integral part of all inspections, but assumes a greater importance in radioactive materials inspections.

08.13 Enforcement

During the course of the inspection of the licensee by the Health Physicist and the subsequent review of the inspection by Division management, the licensee is determined to be in Compliance or in Noncompliance.

If the licensee is determined to be in compliance with "State Regulations for Protection Against Radiation" and the licensee's radioactive materials license, then the Health Physicist composes letter to the licensee stating the Division's findings. This letter and the inspection report of the licensee are forwarded to the Health Physics Field Office Manager and the I&E Program Manger for their final reviews before being sent to the licensee.

If the licensee is in violation of "State Regulations for Protection Against Radiation" and/or the licensee's radioactive materials license, a Notice of Noncompliance letter is assembled by the Health Physicist conducting the inspection, and is sent along with the inspection report to the Health Physics Field Office Manager for approval and/or disapproval. After all the necessary changes have been completed and approved, the Notice of Noncompliance is forwarded to the Health Physics Field Office Manager and/or the I&E Program Manger for review. After the review of the Notice of Noncompliance, it is forwarded to the licensee. The licensee has fifteen (15) days to respond to the Notice of Noncompliance. If this does not occur, further enforcement action and investigation may be pursued by the Division.

1000.09 CATEGORIES AND INSPECTION FREQUENCIES

09.01 Purpose

The frequency of inspections of licensees is established with a priority system, the frequency and scope of inspections being commensurate with the quantities of materials used or processed, the inherent potential hazard, and the nature of the previous inspection findings. To provide an administrative basis for management of the program, all categories of use of radioactive materials licensed by the Division have been grouped into priorities as set forth previously. As will be seen below, the priority automatically determines scheduling of initial inspections and periodic routine inspections.

The primary purpose of the Priority System is to define the minimum frequency of inspection of licensed radioactive materials operations, and to insure this frequency of inspection is compatible with the United States Nuclear Regulatory Commission. A secondary purpose is to provide an administrative basis for the inspection program, and guidance for the effective use of staff. The system requires that a licensed radioactive materials program with a specific potential hazard should be inspected at a definite frequency.

The Division management reserves the prerogative to impose a higher inspection frequency on any licensee when conditions warrant it.

09.02 Administrative

A category(ies) and priority are assigned to each radioactive materials license after the initial inspection. Such designations are to be reviewed and updated when a radioactive materials license is renewed, amended, and/or inspected.

If a radioactive materials license encompasses more than one category, the category associated with the shortest interval between inspections determines the priority. Initial inspections and periodic routine inspections may be conducted earlier than required by this instruction, at the discretion of the Division management, if it appears to be warranted.

09.03 Priorities for Scheduling Inspections

For all licensed radioactive materials programs, the number and types of problems observed during the inspection(s) by the Health Physicist(s) will be one of the basis for scheduling special inspections. The established priorities of initial inspections and routine periodic inspections are as follows:

Priority 1A Initial inspection within three (3) months after license is issued and operations under the license have begun. Thereafter, routine periodic inspections are at six (6) month intervals.

Priority 1 To be inspected within six (6) months after initial license is issued and operations under the license have begun. Thereafter, routine periodic inspections will be at intervals not to exceed one (1) year.

Priority 2 To be inspected within six (6) months after initial license is issued and operations under the license have begun. Thereafter, routine periodic inspections will be at intervals not to exceed two (2) years.

Priority 3 To be inspected within six (6) months after initial license is issued and operations under the license have begun. Thereafter, routine periodic inspections will be at intervals not to exceed three (3) years.

Priority 5 To be inspected within six (6) months after initial license is issued and operations under the license have begun. Thereafter, routine periodic inspections will be at intervals not to exceed five (5) years.

Priority 7 To be inspected within one (1) year and thereafter normally only for resolution of problems.

Whenever the Division deems it necessary, radioactive material licensee may be reinspected within the normal routine periodic inspections to review the details of reported incidents, or to follow-up on violations or safety matters identified during a previous inspection or investigation.

09.04 Reciprocity Inspections

It is the goal set forth by the Division to inspect at least ten (10) percent of the licensees who are authorized to perform licensable activities under reciprocal recognition of a radioactive materials license issued by the United States Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

APPENDIX A

CHECKLISTS

INDUSTRIAL RADIOGRAPHY

(in field)

A. VEHICLE (Transporting and storing)

1. Posting
2. Radiation Level
3. Proper Container
4. Shipping Papers

B. CAMERA

1. Security
2. Source Information
3. Manufacturer
4. Model Number
5. Serial Number
6. Levels

C. RECORDS

1. Dosimeter Records
2. Source Security Records
3. Site Survey Records
4. Number of Exposures and Duration of Each
5. Latest Leak Test and Survey Instrument Calibration Records

D. SURVEY INSTRUMENT(S)

1. Manufacturer
2. Model Number
3. Serial Number
4. Proper Range
5. Working Correctly?

E. MUST HAVE AND USE

1. Radiation Area Signs
2. High Radiation Area Signs
3. Barrier Tape (if required by company's operating procedures)
4. Regulations
5. License
6. Emergency Procedures
7. Operating Procedures
8. Film Badge
9. Dosimeter

F. PROCEDURES (observations)

CO-60 TELETHERAPY

1. **Leak Test Records**
2. **Film Badge Records**
3. **Interlock Check records (every 6 months)**
4. **Installation Data and Survey**
5. **Signs and Labels**
   1. Area
   2. Head
   3. Form RHS 8-3
6. **Emergency Procedures**
7. **"ON-OFF" at Head**
8. **Interlock Check**
9. **Radiation Levels**
10. **Workload**
11. **Survey Instruments**
12. **License**
13. **Regulations**
14. **Users**
    1. Doctors
    2. Technicians
15. **Is Any one Ever in Room Other Than Patient**
16. **Mechanical or Electrical Stops**
17. **5 Year Maintenance**
18. **Continuous Monitor With Battery Back-up**
19. **Miscellaneous License Conditions**

INDUSTRIAL RADIOGRAPHY

1. **Records of Receipt**
2. **Leak Tests Records**
3. **Disposal Records**
4. **Inventory**
5. **Film Badge and Dosimeter Records**
6. **Survey Instruments (adequacy, calibration records)**
7. **In-shop Facilities**
8. **Annual Dosimeter Checks**
9. **Security Records - (survey)**
10. **Work Records (Utilization Log - kept at address on licensee)**
    a. Location
    b. Source Description
    c. Radiographer (records)
    d. Survey Records
    e. Number of Exposures and Duration of Each
11. **Internal (Management) Inspection**
12. **Posting and Protection at Site**
13. **Collimation**
14. **Camera Description**
15. **Inspection and Maintenance (daily, quarterly)**
16. **Transportation**
17. **Storage Facilities**
18. **Form RHS 8-3**
19. **License**
20. **Regulations**
21. **Users and Titles**
22. **Operating and Emergency Procedures**
23. **Training**
24. **Replacement of Sources**
25. **Shipping and Receiving Procedures**
26. **Miscellaneous License Conditions**

CHROMATOGRAPHS & DEW POINT ANALYZERS

1. **Records of Receipt**
2. **Records of Disposal**
3. **Leak Test Records (H-3 excluded)**
4. **Inspect Unit**
   a. Radiation Levels
   b. Signs
   c. Labels
   d. Serial and Model Numbers
   e. Temperature Control Device
   f. Users
   g. Venting
5. **Cleaning Procedures**
6. **Form RHS 8-5**
7. **License**
8. **Regulations**
9. **Miscellaneous**

INDUSTRIAL GAUGES

1. **Records of Receipt and Installation**
   a. Installation Leak Test
   b. Installation Survey

2. **Leak Test Records**

3. **Personnel Dosimetry**

4. **Installation and Maintenance Personnel (If devices moved, who?)**

5. **Users - Trained and Authorized**

6. **Check Location Against License**

7. **Inspect Gauges**
   a. Signs
   b. Labels
   c. Radiation Levels
   d. Closest Approach
      1. Routine
      2. Non-routine
   e. Control Location
   f. Serial and Model Numbers (Check against license)

8. **Form RHS 8-3**

9. **License**

10. **Regulations**

11. **Miscellaneous License Conditions**

PORTABLE GAUGES

1. **Manufacturer, Model Number, Serial Number**
   a. Radiation Levels
   b. Labels
   c. Maintenance

2. **Personnel**
   a. Trained
   b. Authorized
   c. Monitored (If authorized)

3. **Storage Facilities (Office and Field Locations)**
   a. Security
   b. Radiation Levels
   c. Posting

4. **Transportation**
   a. Security
   b. Containers
   c. Labels (and placards, if required)
   d. Shipping Papers

5. **Records of Receipt, Transfer, and Disposal**

6. **Leak Tests and Records**

7. **Operating and Emergency Procedures**

8. **RHS 8-3**

9. **License**

10. **Regulations**

11. **Miscellaneous License Conditions**

WELL - LOGGING
(In Field - Sealed Sources)

1. **Vehicle (Transporting and Storing)**

   a. Placard

   b. Radiation Levels

2. **Equipment**

   a. Security

   b. Source Information
   - Isotope - Manufacturer
   - Amount - Model and Serial Number

   c. Labeling (Source, Source Holder, and/or Tool - Danger/Radioactive)

   d. Labeling (Transport Container - Danger/Radioactive - Notify Civil Authorities)

   e. Survey Instrument(s)
   - Manufacturer - Calibration Date
   - Model and Serial Number - Batteries (operable?)

   f. Remote Handling Equipment

   g. Personnel Monitoring

3. **Documents and Records**

   a. License

   b. Operating and Emergency Procedures

   c. Applicable Regulations

   d. Record of the Latest Survey Instrument Calibration

   e. Record of the Latest Leak Test

   f. Use Log

   g. Site Survey/Records

   h. Storage Survey Records

4. **Procedures (observations)**

NUCLEAR MEDICINE AND BRACHYTHERAPY

1. **Use and Possession**

   a. Compare Isotopes Used With Authorized Possession
   b. Determine Amount of Possession
   c. Compare Physician Users With Authorized Users
   d. Adequate Security Present

2. **Training of Personnel**

   a. Check Training of Technologists
   b. See if Training/Information Provided to Auxiliary Personnel

3. **Operating Procedures and Associated Records**

   a. Molybdenum Tests Performed
   b. Doses Checked in Dose Calibrator
   c. Dose Calibrator Quality Assurance Tests Performed
   d. Leak Tests and Inventory of Sealed Sources
   e. Proper Surveys Performed
   f. Receipt and Disposal Procedures
   g. Required Thyroid Bioassays
   h. Radioactive Gas/Aerosol Procedures Followed

4. **Protective Equipment and Associated Records**

   a. Personnel Monitoring Provided
   b. Adequate Shielding
   c. Syringe Shields Used
   d. Gloves and Protective Clothing Worn
   e. Portable Survey Meter

5. **Posting**

   a. Documents Posted/Available
   b. Area and Containers Properly Posted

6. **Isotope Therapy and Brachytherapy**

   a. Private Room
   b. Instructions Posted/Provided
   c. Surveys Made
   d. Determination of Hospital Release
   e. Proper Posting

7. **Independent Measurements (Radiation, Contamination Levels)**

8. **Administrative**

   a. Determine if Medical Isotopes Committee is Present and Functional
   b. Review Medical Isotopes Committee Minutes
   c. Summarize Inspection With Administration and/or Designate

BROAD LICENSES

1. **Use and Possession**

   a. Compare Isotopes Used/Possessed With Authorized Possession
   b. Determine Amount of Possession
   c. Check if Users Have Been Properly Approved
   d. Determine Locations of Use/Possession

2. **Training of Personnel**

   a. Adequate Training Program Present
   b. Training Level of Radiation Safety Office Sufficient

3. **Operating Procedures and Associated Records**

   a. Procurement and Receipt System
   b. Transfer and Waste Disposal
   c. Leak Tests of Sealed Sources
   d. Survey Program
   e. Personnel Monitoring and Bioassay
   f. Effluents to Unrestricted Areas

4. **Protective Equipment and Associated Records**

   a. Portable Monitoring Equipment
   b. Low Level Counting System
   c. Adequate Shielding
   d. Proper Ventilation Systems
   e. Protective Clothing

5. **Posting**

   a. Documents Posted/Available
   b. Areas and Containers Properly Posted

6. **Committee**

   a. Examine Organization and Function
   b. See if Procedures for Human Use and Research Are Present
   c. Document Minutes of Meetings

7. **Inspector Visits/Surveys**

   a. Visit and Observe Work in Representative Labs, Medical Areas, and RSO
   b. Record Independent Measurements of Radiation and/or Contamination Levels
   c. Review Records
   d. Interview Employees
   e. Analyze Security
   f. Summarize Inspection With Management and/or RSO