U.S. NUCLEAR REGULATORY COMMISSION

NRDOCS

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

NRC FOIA REQUEST NUMBER(S)
FOIA — 93-177

RESPONSE TYPE
XX FINAL | | PARTIAL

DATE
JUN 29 1993

DOCKET NUMBER(S) *(If applicable)*

REQUESTER
Marcy L. Colkitt

PART I.--AGENCY RECORDS RELEASED OR NOT LOCATED *(See checked boxes)*

	No agency records subject to the request have been located.
	No additional agency records subject to the request have been located.
	Requested records are available through another public distribution program. See Comments section.
	Agency records subject to the request that are identified in Appendix(es) _____ are already available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
XX	Agency records subject to the request that are identified in Appendix(es) A are being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
	The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
	Agency records subject to the request that are identified in Appendix(es) _____ may be inspected and copied at the NRC Local Public Document Room identified in the Comments section.
	Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
	Agency records subject to the request are enclosed.
	Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.
XX	Fees
XX	You will be billed by the NRC for fees totaling $ 30.20 .
	You will receive a refund from the NRC in the amount of $ _____ .
	In view of NRC's response to this request, no further action is being taken on appeal letter dated _____ . No. _____

PART II. A--INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

	Certain information in the requested records is being withheld from public disclosure pursuant to the exemptions described in and for the reasons stated in Part II, B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 2120 L Street, N.W., Washington, DC in a folder under this FOIA number.

COMMENTS

The fees for processing your request are as follows:

15 minutes clerical search:	$ 3.60
133 pages duplication:	26.60
	30.20

SIGNATURE, DIRECTOR, DIVISION OF FREEDOM OF INFORMATION AND PUBLICATIONS SERVICES

James L. Blaha

Re: FOIA-93-177

APPENDIX A
DOCUMENTS BEING PLACED IN THE PDR

NUMBER	DATE	DESCRIPTION
1.	2/19/91	NRC Inspection Manual - Licensed Materials Programs. (133 pages)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NRC INSPECTION MANUAL

INSPECTION PROCEDURE 87100

LICENSED MATERIALS PROGRAMS

PROGRAM APPLICABILITY: 2800

87100-01 INSPECTION OBJECTIVES

01.01 To determine if licensed programs are being conducted in accordance with NRC requirements.

01.02 To determine if licensed activities are being conducted in a manner that will ensure the health and safety of workers and the general public. R

87100-02 INSPECTION REQUIREMENTS

Review of the licensed activities should be commensurate with the scope of the licensee's program. To the extent possible, a determination regarding compliance with an NRC requirement should be based on direct observation of a work activity, interviews with workers, a demonstration by a worker of how he/she performs a task that is regulated by NRC, or an independent measurement of radiation conditions at the facility (rather than exclusive reliance on a review of records). Specific inspection requirements follow:

02.01 Program Administration. Review the following elements in sufficient depth to verify that organization and administrative systems have been established to ensure safe conduct of the licensed activity.

a. Organization

Reference: Applicable license conditions.

The organizational structures will be found in license applications and may involve one or more individuals. Examine any changes in the organization with respect to changes that have occurred in personnel, functions, responsibilities and authorities since the previous inspection. If individuals are named in the license application, an amendment must be provided whenever changes in personnel are made (except for some broad and radiography licenses, where only responsibilities are defined). If there have been no changes in the organization since the previous inspection, there is no need to pursue that element in any depth, except to ask the licensee if there have been changes and to make inquiries of personnel to confirm (to the inspector's satisfaction) that no changes have taken place.

b. QA Program and Licensee Audits

References:

Medical QA program to mitigate therapeutic misadministrations (only if the program being inspected has QA requirements in the license). Applicable license conditions. R R R R

The quality assurance program will be in the form of procedures specified in the license and covering a variety of activities and methodologies. Generally, the procedures will specify limitations, "do's," and "don'ts," and how to perform one or more tasks. In any event, the licensee is bound to the procedures. The inspector should verify (preferably by direct observation) the implementation of a selection of procedural activities to the extent that the inspector is satisfied that procedures are being followed.

The inspector also should verify that internal audits are performed, as required. The results of audits of activities will be found in records of audits. Examine those records with particular attention to deficiencies found by the auditors and note corrective actions taken as a result of deficiencies found. If no corrective actions were indicated whenever deficiencies were found, ask the licensee's representatives what actions were taken and determine why they were not noted in the records.

Audits of field radiography sites are especially important. If at all practicable, accompany a licensee's auditor to a field site (this may require special scheduling). Other kinds of internal audits for different categories of licensees may involve such determinations as the use of syringe shields (hospitals), whether technetium generators are properly shielded (hospitals), and whether established ALARA programs are being implemented (all licensees). These are only a few examples; the inspector should examine the licensee's commitments in the license to determine the kinds and extent of audits required.

As one part of assist inspections, the inspector should determine that the licensee's internal inspection program is actually being carried out in that facility. For example, the date of the last internal inspection findings and those corrective actions taken should be determined. The above information should be included in the inspection summary report sent to the home region and, if negative, so stated. R

c. Medical Licensees

Radiation safety quality assurance procedures for radioactive drug and device research programs may be found in the US Food and Drug Administration (FDA) accepted investigational new drug (IND) or investigational device exemption (IDE) application. These procedures should be audited by the RSO and/or the Radiation Safety Committee (RSC). R R R R R R

For nuclear medicine and teletherapy, secondary checks of dose calculations should be done to provide assurance that the final treatment plan will provide the dose prescribed on the patient's chart, if required in the license.

d. Training

References:

10 CFR 19.12, Instructions to workers.
10 CFR 34.31, 35.900-972, 39.61, Training.
Applicable license conditions.

Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. The inspector should verify that proper training and initial instructions are being accomplished as specified in the license or regulations. Discuss with licensee's representatives how and by whom the training is conducted and the content of the training (generally found in the license application).

Verify, pursuant to 10 CFR 19.12, that the initial instructions have been given to workers who enter restricted areas. Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements.

Of the training program elements in the license application, training given to authorized users is of primary importance. One or more users of radioactive materials should be interviewed to determine that they have received the required training, both in the basic instructions and that specified in the license application. For medical licensees, this includes specific training needed to perform infrequent medical procedures and prepare and use radioactive material in medical research studies. For the radiographers, the initial training should cover 40 hours of classroom instruction in those topics in Appendix A of 10 CFR Part 34. The 40 hour classroom training may vary by ± 20% as long as all topics in Appendix A are covered.

To become a radiographer, a radiographer's assistant must have completed 520 hours of on-the-job training as a minimum. The training must include the topics in 10 CFR Part 34, Appendix A, and the operating and emergency procedures.

Randomly examine records of training of personnel and attendant tests or examinations (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities. For radiographers, a written test consisting of approximately 50 practical questions should be taken dealing with the topics in Appendix A of Part 34. A field examination also should be given to determine that the individual is competent to perform all assigned operations.

The competence of an individual who has been a radiographer for another licensee should be determined. As a minimum, that individual must be instructed in the operating and emergency procedures and the use of equipment. The individual also must take the written and field examinations.

Whenever possible, observe a radiographic operation, including the conduct of surveys, to detemine the adequacy of a radiographer's training.

e. Operating and Emergency Procedures, Safety Component Defects

Reference:

10 CFR 34.32, 10 CFR 39.63 Operating and emergency procedures. R
Applicable license conditions.

Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures for radiography programs to more generalized procedures for lower inspection priority licenses. The procedures will be approved by the NRC and reviewed and updated by the licensee. Any revision requires an amendment to the license except for broad licenses.

Examine the emergency procedures to determine that the procedures are as approved by NRC. Discuss with the licensee's representatives, or observe (for the higher priority licensees), the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material. Also verify that operational procedures are being followed by observation of personnel performing tasks at selected work stations and comparison of their activities with operational procedure requirements.

For the larger licensees there may be agreements with other agencies to respond to emergencies. Such agreements may be in writing and include state regulatory commissions (or equivalent) and hospitals. Generally, there will be no agreements in writing with fire departments. Discuss with licensee's representatives what has been done to ensure that agencies (for which agreements are in effect) understand their roles in emergency responses. Also, inquire if fire departments are knowledgeable of fires involving large quantities of radioactive materials and high radiation levels and whether they are equipped to fight such fires.

The inspector may, at his option, visit one or more agencies or departments to determine their understandings of their roles in responding to emergencies. R

f. Reports and Notifications

References:

10 CFR 19.13 Notifications and reports to individuals.
10 CFR 20.402 Reports of theft or loss of licensed material.
10 CFR 20.403 Notifications of incidents.
10 CFR 20.405 Reports of overexposures and excessive levels and concentrations.
10 CFR 20.407 Personnel monitoring reports.
10 CFR 20.408 Reports of personnel monitoring on termination of employment or work.
10 CFR 31.5 Certain measuring, gauging, or controlling devices.
10 CFR 32.12 Records and material transfer reports.
10 CFR 32.16 Certain items containing byproduct material reports of transfer: Records and reports of transfer
10 CFR 32.20 Records and material transfer reports.
10 CFR 32.25 Conditions of licenses issued under §32.22: Quality control, labeling, and reports of transfer.
10 CFR 32.29 Conditions of licenses issued under §32.26: Quality control, labeling, and reports of transfer.
10 CFR 32.52 Material transfer reports and records.
10 CFR 34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.
10 CFR 35.21(a) and (b)(2)(xi) Internal audits or inspections and records of the audits. R R
10 CFR 35.33(a) Reports of therapy misadministrations. R
10 CFR 35.33(c) Reports of diagnostic misadministrations. R
10 CFR 35.645 Reports of teletherapy survey, checks, tests, and measurements. R R
10 CFR 150.20 Recognition of Agreement State licenses.
Applicable license conditions.

1. 10 CFR 19.13 requires that licensees provide individuals with reports of external and internal exposures on an annual basis only if the individual requests the reports.

   The inspector need not inquire of licensees that they have provided reports unless a worker files a complaint that he was not provided a report when he requested it. For those employees who worked under contract temporarily and for permanent employees who have left the company, the licensee must provide the report within 30 days. An exception is that when licensees file a report to the NRC, they must also provide reports (of excessive exposures) to the workers involved. The regional offices that receive the reports should examine them for accuracy and completeness.

Prompt followup of reports of excessive exposures under certain conditions may be necessary; for example, reports filed under 10 CFR 20.403(a) and (b) may require prompt followup to determine if adequate medical care is being provided. Other essential items (including medical care) that are missing from the reports (initially reported by telephone, telegraph, etc.) may be obtained by telephone or by dispatch of an inspector to the site to determine the causes of overexposure and adequacy of corrective actions.

In the case of high exposures to personnel, if the exposure is believed to be valid, an inspector must be dispatched to the site to conduct an inspection to support possible escalated enforcement action. This also applies to reports filed only under 10 CFR 20.405 if exposures are greater than 3 rems but less than 5 rems, depending on the circumstances. An inspector need not be dispatched to a site promptly if, for example, the report submitted under 10 CFR 20.405 shows 3.01 rems. In these cases, an inspection should be scheduled as soon as practicable. However, this decision is best left to the judgment of the region, depending on the circumstances set forth in the reports and by telephone communications.

During routine inspections, inspectors need only inquire if 10 CFR 20.407 reports have been submitted without going into further depth, unless the Office of Nuclear Regulatory Research has requested a followup because no report was submitted. The same applies under 10 CFR 20.408 for terminated employees. Those reports should only be examined at random so that the inspector is satisfied that the reports are being generated.

2. 10 CFR 20.402 requires licensees to report losses or theft of licensed material when it appears to the licensee that a substantial hazard may result to persons in unrestricted areas. R R R

   Because of the legalities and details involved for inspection and followup purposes, two interpretive guides were developed. The guides should be used for followup on losses or thefts of radioactive material. The guides are entitled "10 CFR 20.402: 'Lost or Stolen (Missing) Radioactive Materials at Licensee's Facilities'" and "20.402: Transportation, 'Lost or Stolen Radioactive Sources Involved in Transportation.'" These guides may be found in the "10 CFR" section of the Inspection Manual.

3. The remaining reports listed in 02.01f deal with leak tests above limits (10 CFR 31.5, 34.25); materials transfer reports for manufacture or transfer of certain items (10 CFR 32.12, 32.16, 32.20, 32.25, 32.29, 32.52); reports of medical therapeutic and diagnostic misadministrations (10 CFR 35.33(a) and (c)); and Form 241, reports of activities conducted in Agreement States (10 CFR 150.20). R R

4. Inspections should be done for therapy misadministrations that result in serious illness or death, etc. Depending on the content of the reports, where significant cause appears to exist for followup, the followup shall be done promptly to gather additional details about the cause of the event and the circumstances under which the event occurred. Reports that indicate moderate health and safety problems may be followed up during the next inspection unless there appears to be sufficient cause for possible escalated enforcement actions. Judgment should be exercised on a case-by-case basis.

g. Records

References:

10 CFR 20.401	Records of surveys, radiation monitoring, and disposal.	
10 CFR 30.41	Transfer of byproduct material.	
10 CFR 30.51	Records.	
10 CFR 34.24	Radiation survey instruments.	
10 CFR 34.25	Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.	
10 CFR 34.26	Quarterly inventory.	
10 CFR 34.27	Utilization logs.	
10 CFR 34.28	Inspection and maintenance of radiographic exposure devices, storage containers and source changers.	
10 CFR 34.31	Training.	
10 CFR 34.33	Personnel monitoring.	
10 CFR 34.43	Radiation surveys.	
10 CFR 35.632	Full calibration measurements.	R
10 CFR 35.634	Periodic spot checks.	R
10 CFR 35.630	Dosimetry equipment.	R
10 CFR 35.961	Training for teletherapy physicist.	R
10 CFR 35.33	Records and reports of misadministrations.	R
10 CFR 35.59(e)	Leak testing sealed sources.	R
10 CFR 40.61	Records.	
Applicable license conditions.		

During the course of an inspection, most items examined will have attendant records to support each portion of the licensed activity. Some records should be only randomly examined; i.e., spot-checked to the satisfaction of the inspector that the records are being maintained and complete. Other records that are more closely related to health and safety (such as personnel exposure records) should all be examined.

However, examinations of records should not be construed as the primary part of the inspection program. Rather, observations of areas where personnel work, equipment, usage, etc., will give the inspector a better idea of what is going on than records review and may also support what the records reveal. During examinations of records, look for trends, such as trends in air sampling. Records such as surveys, waste disposal, effluent release, receipt and transfer of radioactive materials, training, utilization logs, and

air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete.

Records that should be examined in their entirety include personnel monitoring; leak testing of sealed sources; instrument calibrations; radiography quarterly inventory of devices and sources; inspection and maintenance of radiographic exposure devices; source changers used; storage devices used; receipt and transfer records; final radiation surveys of radiographic exposure devices upon completion of usage; pocket dosimeter results and calibrations; and for teletherapy units, full calibration, spot-check measurements and records of calibration of dose calibrators and checks of dose calibrators. Other records to be examined may be found in license conditions such as ALARA records, records of safety committee minutes, etc.

The extent to which records are to be examined, either randomly or in their entirety, will depend on the category of the licensee as well as the history of noncompliance of the licensee inspected. In each case, judgment will need to be exercised so that the inspector is satisfied that the licensed program is being operated safely to protect the health and safety of the workers and general public.

As a general rule, records should be examined for the preceding three-year period or back to the last inspection, whichever is less. Older records preceding the three-year period should be inspected if warranted by circumstances such as a history of non-compliance or high radiation exposures.

02.02 Authorized Materials, Uses, and Users

Determine from reviewing records, observing the use of radioactive material, and discussing the activities with licensee personnel, that the type, quantity, and use of material at the licensee's facility are authorized by the license. Specific records and areas to be reviewed are as follows:

a. Receipts, Transfers, and Package-handling Procedures:

References:

10 CFR 20.205 Procedures for picking up, receiving, and opening packages.
10 CFR 30.41 Transfer of byproduct material.
10 CFR 40.51 Transfer of source or byproduct material.
Applicable license conditions.

Depending on the size of the licensed program, the procedures (a few or many) will be found in the license application. The procedures should be carefully reviewed before an inspection is conducted. The reason for such a review is to determine completeness, repeated procedures that may be contradictory, and procedures that should be in the application but are missing.

The procedures for picking up, receiving, and opening packages should include how and when packages will be picked up, radiation surveys and wipe tests of packages upon receipt, and procedures for opening packages, such as where in the facility packages are received, surveyed, and opened. The procedures also should include what actions are to be taken if packages are contaminated in excess of specified limits and radiation levels are higher than limits (the latter would depend on the package index, i.e., the dose rate at 3 feet for each category). If packages have arrived during the course of an inspection, observe the person performing the surveys as an indication of training.

The inspector should randomly examine records of surveys of packages received and also determine if inventories for each licensed nuclide is within the license limits. In this regard, records of inventories following receipt and transfer should always show that the materials on hand at any one time are within the license limit. The records examined should be compared with the physical inventories of materials possessed.

By discussions with the licensee, inquire if the procedures have been changed or added to (requiring license amendment except for broad scope licenses and, in general, medical licensees that can change minor procedures by regulation). Randomly examine procedures used by the licensee to determine if they are in accordance with those in the license application (if the licensee's procedures are supplementary to those in the license application, or if the changes in certain procedures were minor.) R R R R

b. Authorized Users

References:

10 CFR 33.17 Conditions of specific licenses of broad scope.
10 CFR 34.25 Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.
Applicable license conditions.

Authorized users will normally be named in the license application, or, if the license is a broad license, will be appointed as authorized users by the radiation safety committee or isotopes committee.

The inspector should determine during an inspection that named authorized users are doing the work authorized rather than someone else not named in the license. This will depend on the wording in the license with phrases such as "used by or under the supervision of" except for radiography licensees in which supervision for users is defined in 10 CFR Part 34. Guidance on the phrase "used by or under the supervision of" may be found in the "10 CFR" Section of the IE Manual under 10 CFR Part 30 issued on 10/1/79 entitled "License Condition'...used by or under the supervision of....'" For some specific or broad licenses (Types A, B, and C), the phrase for users is "under the direct supervision of" which implies the authorized user should be present at the facility for easy contact or to observe the individual(s) working under the authorized user.

However, another phrase not often seen in licenses is "under the direct supervision and physical presence of" which means the authorized user must directly supervise and be present at the work station. Another phrase used for physicians doing patient therapy states "may only be used by."

The inspector must use more than the usual amount of judgment during inspections to interpret the role of the authorized users, considering the many license condition phrases used above. First, a determination of qualifications should be made. Second, for the broad licenses, the radiation safety committee appoints the authorized users based on qualifications.

For a determination of required training, see "Training" under 02.01d of this procedure. In general, authorized users must be specifically licensed by the Commission or otherwise listed in the license application and in a license condition for specific tasks that only the individual(s) named can perform. This includes leak testing of sealed sources, replacement of sealed sources, modification and opening for purposes of repairing or replacing sealed sources in teletherapy units and for radiography programs, changing sources from source changers or containers. Such authorized users may not be those of the licensee but of a separate firm specifically authorized by the Commission.

c. Authorized Uses

References:

10 CFR 33.13	Requirements for the issuance of a Type A specific license of broad scope.	
10 CFR 33.14	Requirements for the issuance of a Type B specific license of broad scope.	
10 CFR 35.100	Medical uses of byproduct material for uptake and dilution studies.	R R
10 CFR 35.200	Use of radiopharmaceuticals, generator, and reagent kits for imaging and localization studies.	R R
10 CFR 35.300	Use of radiopharmaceuticals for therapy.	R
10 CFR 35.400	Use of sources for brachytherapy.	R
10 CFR 35.500	Use of sealed sources for diagnosis.	R
10 CFR 35.600	Use of a sealed source in a teletherapy unit.	R
Applicable license conditions.		

Authorized uses of radioactive materials, excluding broad license applications, will be found in the licenses and license applications. Specific licenses will list the isotopes, physical or chemical forms, and the maximum quantities. The inspector should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that quantities and forms are as authorized. For medical licenses of broad scope (Type A, B, C) the maximum quantities are listed (or narrated for Type A) in 10 CFR 33.100. For broad licenses, any chemical or physical form is authorized.

The inspector must determine that nuclides are used as authorized, particularly for human use, that could otherwise become a misadministration if not used as authorized. For medical facilities or institutions, examine patient log books to determine that radioactive materials are used in proper chemical form on patients. For well - logging inspections, the inspector should request a demonstration of use of handling tools by one or more individuals doing well - logging operations. If actual operations are not observed, ask for a demonstration. R R R R

d. Material Control

References:

10 CFR 20.207 Storage and control of licensed materials in unrestricted areas.
10 CFR 34.22 Locking of radiographic exposure devices, storage containers, and source changers.
10 CFR 34.23 Storage precautions.

Applicable license conditions.

The inspector should examine storage areas in unrestricted and restricted areas. Such storage areas should be locked and have limited and controlled access. In general, there will be procedures for access controls. Additional controls should include logging out radioactive material from storage areas and logging it in after use. This is especially important for medical institutions because of the use of small implant seeds for therapy. In the past, many seeds have been lost because of the failure of controls. The inspector also should determine that radioactive storage devices and source changers are locked when in storage and that storage areas also are locked when not in use.

During the conduct of a nuclear medicine inspection, ask the medical technician to perform a constancy check on the dose calibrator to determine adequate training.

e. Area Radiation and Contamination Control

References:

10 CFR 19.11 Posting of notices to workers.
10 CFR 20.105 Permissible levels of radiation in unrestricted areas.
10 CFR 20.201 Surveys.
10 CFR 20.203 Caution signs, labels, signals, and controls.
10 CFR 20.204 Caution signs, labels, signals, and controls: exceptions.

Applicable license conditions.

The inspector should ensure, during observation and by direct measurement, that the radiation levels in unrestricted areas are within the limits of 10 CFR 20.105(b). The limits are 2 mR in any 1 hour or 100 mR per 7 consecutive days, whichever is more restrictive. For this regulation, occupancy is not a factor. The inspector may

ask the licensee to spot-check radiation levels in selected areas using the licensee's own instrumentation. However, readings of radiation levels using the licensee's instruments shall not be considered as valid. The inspector must use his/her own instruments that have been calibrated, source checked prior to leaving the regional office and checked upon return to see if the calibration is valid.

By definition, surveys of radioactive materials or radiation areas are supposed to be done before the fact, not after an individual gets exposed. If practicable, observe how licensees conduct surveys to determine the adequacy of surveys, particularly during the conduct of radiography operations. Also, note the types of instruments used, and whether they are designed for the type of radiation being measured.

During the physical operations review (facility walkthrough) observe that proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Randomly observe labeling on packages or other containers to determine that proper information is recorded such as isotope, quantity, and date of measurement. 10 CFR 20.204 provides exceptions to posting caution signs, primarily for medical institutions. Some types of licenses, such as those for teletherapy rooms, radiography (fixed or permanent facilities), and irradiator operations also require signals or alarms, both visible and audible.

The inspector should examine these to determine operability. In addition, during the walkthrough examine locations where notices (NRC Form 3) to workers are posted. These should be located so that employees may examine them on their way to and from work locations.

f. Packaging and Transportation

References:

10 CFR Part 71	Packaging and Transportation of Radioactive Material.
49 CFR Parts 170-199	Use Inspection Procedure No. 86740, "Transportation" as applicable.

g. Waste Handling

Use Inspection Procedure No. 84850, "Radioactive Waste Management -Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

h. Performance Evaluation Factors R

Use performance evaluation factors (PEFs) to assess the potential for degraded safety performance in priority 1, 2, and 3 licensees. See Inspection Procedure 87101 for requirements and guidance regarding PEFs. R R R R

02.03 Physical Plant Facilities and Equipment

General. Most of the following line items are found in license applications and will vary, depending on the type of licensed activity, and may not be all inclusive. These items should be inspected during the facility tour (operations review). Other items may be identified in the regulations and also may be repeated in the license application for implementation of the requirements.

References:

10 CFR 20.3(17)	Unrestricted area.
10 CFR 20.202(b)(2)	Radiation area.
10 CFR 20.202(b)(3)	High radiation area.
10 CFR 20.207	Storage and control of licensed material in unrestricted areas.
10 CFR 34.21	Limits on levels of radiation for radiographic exposure devices and storage containers.
10 CFR 34.29	Permanent radiographic installations.
10 CFR 35.632-647	Teletherapy requirements. R
10 CFR 34.41	Security. R

Review and verify that the equipment and the physical facility promote safe conduct of the licensed activity. The facility and equipment should conform to that described in the license application and the equipment should be operable. Systems, subsystems, and equipment important to the safe handling of materials and protection of operating personnel and the public should be (1) examined for operability and (2) designed to carry out intended functions.

Examine records of the most recent five-year teletherapy maintenance program. Some specific items which may need maintenance include the the following, although these are not the only items to be serviced.* R R R

a. Field-light Cord Reel. R
b. Source drawer solenoids. R
c. Low air pressure switch. R
d. Air hoses and fittings. R
e. Treatment timer. R

*May not be applicable to all types of units. R

02.04 Radiation Protection

Use Inspection Procedure 83822 "Radiation Protection" as applicable.

02.05 Radioactive Effluents and Waste Disposal

Regulatory references and license applications:

10 CFR 20.106 Radioactivity in effluents to unrestricted areas.
10 CFR 20.301 General requirement.
10 CFR 20.302 Method for obtaining approval of proposed disposal procedures.
10 CFR 20.305 Treatment of disposal by incineration.
10 CFR 20.306 Disposal of specific wastes.
10 CFR 20.401 Records of surveys, radiation monitoring, and disposal.
10 CFR 30.51 Records.
Other applicable license conditions. R

Review and verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within the limits established by the license and other regulatory requirements and are ALARA.

Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records. Randomly select procedures for both liquid and airborne systems and verify that the procedural steps are being followed. The verification should be made by whatever means are available; i.e., perform an observation of an operation, a review of selected records, etc.

02.06 Confirmatory Measurements

Compare/verify on a sampling basis survey results or data that are used by the licensee to show compliance with the regulations or license conditions. Examples of confirmatory measurements are:

a. physical surveys, using the region's own instrumentation.
b. split samples, etc.

02.07 Required Scope of Selected Materials Inspections

The attachments contain standard formats for recording the results of inspections of radiography, well logging, irradiator, industrial/academic, nuclear medicine and teletherapy licensees. Individual topics define the required scope of inspection for NRC inspections of these types of licensees. R

87100-03 INSPECTION GUIDANCE

General. All inspections should include a mix of records and procedures review, observations, confirmatory measurements, and discussions with personnel involved in the "hands on" work.

03.01 Program Administration

a. The regulatory requirements related to the organization and administration of the licensed program will be contained in license conditions. The organization should be examined to verify that the responsibilities and authorizations of designated individuals comply with license conditions.

b. The inspection is a verification of implementation of the required program. In the review to verify implementation, the inspector should pay attention to the scope of the programs; frequency of licensee audits; the use of qualified auditors; procedure for recording and reporting deficiencies to management; methods and completion of followup actions by management; and the policy regarding announced and unannounced audits.

c. No guidance. R

d. In verifying the implementation of the approved or required training program, pay attention to completion of requirements related to: initial training, periodic retraining, on-the-job training, and tests and examinations of trainees (if applicable).

e. Regulatory requirements related to procedures will be contained in license conditions. It is necessary to verify that operating and emergency procedures have been developed, are adequate and functional, and have been reviewed and approved by management.

f. No guidance.

g. No guidance.

03.02 Authorized Materials, Uses, and Users

General. Authorized materials, uses, and users are generally described and authorized by the license, or as otherwise authorized in 10 CFR Part 33.

a. Receipt and transfer of materials should generally be detailed in procedures sufficient to provide assurance of compliance with regulatory requirements. Specific requirements are set forth in 10 CFR 20.205. It is necessary to assure that only authorized persons are involved in the transfer and receipt of materials.

The frequency of inventories is dictated by need or as specifically set forth in certain parts of 10 CFR or in license conditions. License inventories can be used for two purposes: (1) to track the use of material, and (2) to verify that the licensee is only receiving materials authorized in the amounts listed in the license.

b. No guidance.

c. No guidance.

d. Various strategies for control of materials should be in place. These are generally defined by procedures and should ensure that use is limited to authorized users and that secure storage is provided.

e. No guidance.

f. Specific guidance is set forth in Inspection Procedure 86740.

g. Specific guidance is set forth in Inspection Procedure 84850.

h. Follow the guidance on PEFs in Inspection Procedure 87101. R

03.03 Physical Plant Facilities and Equipment. Descriptions of the physical plant are generally found in the applications for a license and subsequert amendments that are usually tied down to a license condition. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. The facility should include utilities and other services sufficient to cope with emergencies, such as loss of power, loss of contamination control, etc.

Plant equipment is generally described in documents as noted above. Plant equipment should be appropriate to the scope of the licensed program. Processing equipment, associated process control equipment and ventilation and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use.

For the five-year maintenance of teletherapy units, critical repairs and maintenance may be recommended by service representatives, but might not be completed by the licensee. Talk to licensee representatives about about any needed repairs, and get commitments to complete repairs immediately. R R R R R R

03.04 Radiation Protection. Specific guidance is set forth in NRC Inspection Procedure 83822.

03.05 Radioactive Effluents and Waste Disposal. Review the reports and records for obvious mistakes, anomalous measurements, trends, missing data (compare the recorded data with the requirements), and verify the accuracy of the data in the report or record with the licensee if any of these aspects are identified or suspected. R

R

03.06 Confirmatory Measurements Confirmatory measurements should be in sufficient scope to verify survey results or data as found in the licensee's records. Examples: radiation levels in an unrestricted area; airflow to process or fume hoods; and air samples in process areas.

87100-04 ADDITIONAL REFERENCES

Program Administration (Section 03.01) R

RG 7.1 Administrative Guide for Packaging and Transporting Radioactive Material.
RG 7.7 Administrative Guide for Verifying Compliance With Packaging Requirements for Shipments of Radioactive Materials.
RG 8.2 Administrative Practices in Radiation Monitoring.
RG 8.10 Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable.
RG 8.13 Instruction Concerning Prenatal Radiation Exposure.
RG 8.15 Acceptable Programs for Respiratory Protection.
RG 8.18 Information Relative to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable.
RG 10.1 Compilation of Reporting Requirements for Persons Subject to NRC Regulations.
RG 10.2 Guidance to Academic Institutions Applying for Specific Byproduct Materials Licenses of Limited Scope.
RG 10.3 Guide for the Preparation of Applications for a Special Nuclear Material License of Less Than Critical Mass Quantities.
RG 10.5 Applications for Type A Licenses of Broad Scope.
RG 10.6 Guide for the Preparation of Applications for Use of Sealed Sources and Devices for the Performance of Industrial Radiography.
RG 10.7 Guide for the Preparation of Applications for Licenses for Laboratory Use of Small Quantities of Byproduct Material.
RG 10.8 Guide for the Preparation of Applications for Medical Programs.
RG 10.9 Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators.
DRAFT RG Guide for the Preparation of Applications for Licenses in Medical Teletherapy Programs.

Authorized Materials, Uses, and Users (Section 03.02)

RG 6.1 Leak Testing Radioactive Brachytherapy Sources.
RG 7.2 Packaging and Transporting of Radioactively Contaminated Biological Materials.
RG 7.3 Procedures for Picking up and Receiving Packages of Radioactive Material.
RG 7.4 Leakage Tests on Packages for Shipment of Radioactive Materials.
RG 8.21 Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.

Physical Plant Facilities and Equipment (Section 03.03)

RG 3.2 Efficiency Testing of Air-Cleaning Systems Containing Devices for Removal of Particles.
RG 8.1 Radiation Symbol.
RG 8.5 Immediate Evacuation Signal.

Radiation Protection (Section 03.04)

RG 8.3 Film Badge Performance Criteria.
RG 8.4 Direct-Reading and Indirect-Reading Pocket Dosimeters.
RG 8.6 Standard Test Procedures for Geiger-Mueller Counters.
RG 8.7 Occupational Radiation Exposure Records System.
RG 8.9 Acceptable Concepts, Models, Equations, Assumptions for a Bioassay Program.
RG 8.14 Personnel Neutron Dosimeters.
RG 8.15 Acceptable Programs for Respiratory Protection.
RG 8.20 Applications of Bioassay for I-125 and I-131.
RG 8.21 Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.
RG 8.23 Health Physics Surveys at Medical Institutions.
RG 8.25 Calibration and Error Limits of Air Sampling Instruments for Total Volume of Air Sampled.
RG 8.28 Audible Alarm Dosimeters.

Radioactive Effluents and Waste Disposal (Section 03.05)

RG 4.15 Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment.
RG 7.1 Administrative Guide for Packaging and Transporting Radioactive Material.
RG 7.4 Leakage Tests on Packages for Shipment of Radioactive Materials. Requirements for Shipments of Radioactive Materials.
RG 7.5 Administrative Guide for Obtaining Exemptions From Certain NRC Requirements Over Radioactive Material Shipments.
RG 7.7 Administrative Guide for Verifying Compliance with Packaging.

Information Notices Issued by NRC R

IN 84 -01 Continuous Supervision of Irradiators R
IN 85 -07 Contaminated Radiography Source Shipments R
IN 85 -29 Use of Unqualified Sources in Well Logging R
Applications R
IN 85 -36 Malfunction of a Dry-Storage, Panoramic, R
Gamma Exposure Irradiator R
IN 85 -46 Clarification of Several Aspects of Removable R
Radioactive Surface Contamination Limits for R
Transport Packages R
IN 85 -54 Teletherapy Unit Malfunction R

IN 85 -61	Misadministrations to Patients Undergoing Thyroid Scans	R R
IN 85 -70	Teletherapy Unit Full Calibration and Qualified Expert Requirements (10 CFR 35.23 and 10 CFR 35.24)	R R
IN 86 -31	Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges	R R
IN 86 -31	Unauthorized Transfer and Loss of Control of Industrial Nuclear Gauges	R R
IN 86 -59	Increased Monitoring of...Patients with Implanted Coratomic, Inc. Model C-100 & C-101 Nuclear-Powered Cardiac Pacemakers	R R R
IN 86 -67	Portable Moisture/Density Gauges:...Incidents and Common Violations of Requirements for Use, Transportation & Storage	R R R
IN 86 -83	Rupture of Nominal 40-Millicurie Iodine-125 Brachytherapy Seed Causing Significant Spread of Radioactive Contamination	R R R
IN 86 -86	Clarification of Requirements for Fabrication and Export of Certain Previously Approved Type B Packages	R R R
IN 86 -96	Leak Testing Iodine-125 Sealed Sources in Lixi, Inc. Imaging Devices and Bone Mineral Analyzers	R R
IN 87 -18	Unauthorized Service on Teletherapy Units by Non-Licensed Maintenance Personnel	R R
IN 85 -61	Misadministration to Patients Undergoing Thyroid Scans	R R
IN 87 -29	Recent Safety-Related Incidents at Large Irradiators	R R
IN 87 -31	Blocking, Bracing, and Securing of Radioactive Materials Packages in Transportation	R R
IN 87 -37	Compliance with the General License Provisions of 10 CFR Part 31	R R
IN 87 -45	Recent Safety-Related Violations of NRC Requirements by Industrial Radiography Licensees	R R R
IN 87 -47	Transportation of Radiography Devices	R
IN 87 -55	Portable Moisture/Density Gauges: Recent Incidents of Portable Gauges Being Stolen or Lost	R R R
IN 88 -02	Lost or Stolen Gauges	R
IN 88 -07	Inadvertent Transfer of Licensed Material to Uncontrolled Locations	R R
IN 88 -10	Materials Licensees: Lack of Management Controls over Licensed Programs	R R
IN 88 -16	Identifying Waste Generators in Shipments of Low-Level Waste to Land Disposal Facilities	R R R
IN 88 -18	Malfunction of Lockbox on Radiography Device	R
IN 88 -32	Prompt Reporting to NRC of Significant Incidents Involving Radioactive Material	R R
IN 88 -33	Recent Problems Involving the Model Spec 2-T Radiographic Exposure Device	R R

IN 88 -52	Failure of Intrauterine Tandem of Fletcher Suit Applicator Brachytherapy Devices During Patient Treatment	R R R
IN 88 -53	Licensee Violations of NRC Regulations, Which Led to Medical Diagnostic Misadministrations	R R
IN 88 -66	Industrial Radiography Inspection and Enforcement	R
IN 88 -90	Unauthorized Removal of Industrial Nuclear Gauges	R
IN 88 -93	Teletherapy Events	R
IN 88 -100	Memorandum of Understanding Between NRC and OSHA Relating to NRC-Licensed Facilities (53 FR 43950, October 31, 1988)	R R R
IN 89 -13	Alternate Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites	R R
IN 89 -25	Unauthorized Transfer of Ownership or Control of Licensed Activities	R R
IN 89 -34	Disposal of Americium Well-Logging Sources	R
IN 89 -35	Loss and Theft of Unsecured Licensed Material	R
IN 89 -46	Confidentiality of Exercise Scenerios	R
IN 89 -60	Maintenance of Teletherapy Units	R

END

APPENDICES:

A.	Medical Teletherapy Inspection Field Notes	R
B.	Nuclear Medicine Inspection Field Notes	R
C.	Well Logging Inspection Field Notes	R
D.	Industrial Radiography Inspection Field Notes	R
E.	Industrial/Academic Inspection Field Notes	R
F.	Commercial Irradiator Inspection Field Notes	R

APPENDIX A

MEDICAL TELETHERAPY INSPECTION FIELD NOTES*
Region ___

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority:

Program Code:

( ) 02300 - Teletherapy - Human Use
( ) Other -

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection: ( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
( ) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

* All areas indicated in field notes are not required to be addressed during each inspection

1. ORGANIZATION

a. Organizational structure meets license requirements. [L/C] ( ) Y ( ) N

Remarks.

b. Use by authorized individuals. [35.960 and 35.22(b)(2)] ( ) Y ( ) N

Remarks.

c. Radiation Safety Officer

(1) Appointed [35.21(a) and 35.900] ( ) Y ( ) N
(2) Fulfills duties per [35.21(b)] ( ) Y ( ) N
(3) Has sufficient authority per [35.23] ( ) Y ( ) N

Remarks.

d. Visiting Authorized User ( ) N/A

(1) Has written permission [35.27(a)(1)] ( ) Y ( ) N
(2) Has copy of license on file [35.27(a)(2)] ( ) Y ( ) N
(3) Performs only those procedures authorized on visitor's license [35.27(a)(3)] ( ) Y ( ) N
(4) Uses material under licensee's license for sixty days per year or less [35.27(b)] ( ) Y ( ) N
(5) Records maintained 3 years after last visit [35.27(c) ( ) Y ( ) N

Remarks.

2. INSPECTION HISTORY

a. Last inspection conducted on _____

b. Violations or deviations were identified ( ) Y ( ) N

c. Response letter or 591 dated _____

d. Violations from previous inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status

e. Any previous violations not corrected ( ) Y ( ) N

Explain.

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use ( ) Y ( ) N

b. If so, list location(s) inspected ( ) N/A

c. List those individuals contacted during inspection

*Indicates presence at exit meeting

d. Briefly describe scope, including type of teletherapy unit, source activity, frequency of use, staff size, etc.

e. Radiation safety program changes pursuant to [35.31] ( ) Y ( ) N ( ) N/A
f. Records of changes maintained [35.31(b)] ( ) Y ( ) N

Remarks.

4. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections are conducted ( ) Y ( ) N ( ) N/A

(1) Audits conducted by _____

(2) Frequency _____

Remarks.

b. Audits are required by license condition ( ) Y ( ) N
c. Records maintained ( ) Y ( ) N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] ( ) Y ( ) N

Remarks.

b. Training program implemented [35.610] ( ) Y ( ) N

(1) Operating procedures [35.610(a)(1)] ( ) Y ( ) N
(2) Emergency procedures [35.610(a)(2)] ( ) Y ( ) N
(3) Retraining required [L/C] ( ) Y ( ) N
(4) Retraining implemented ( ) Y ( ) N
(5) Records maintained ( ) Y ( ) N

Remarks.

c. Supervision of individuals by authorized user in accordance with [35.25] ( ) Y ( ) N

Remarks.

d. Teletherapy Physicist

(1) Named on license [L/C] ( ) Y ( ) N
(2) Certified per [35.961(a)] OR meets requirements in [35.961(b)] ( ) Y ( ) N

Remarks.

6. FACILITIES

a. Facilities as described in license application ( ) Y ( ) N
b. Access to teletherapy room controlled per [35.613(a)] ( ) Y ( ) N
c. Console keys controlled adequately ( ) Y ( ) N
d. Facility provided with electrical interlock system [35.615(b)] ( ) Y ( ) N
e. Facility equipped with functioning beam condition indicator light [35.615(c)] ( ) Y ( ) N
f. Facilty provided with system to permit continuous observation of patient [35.615(e)] ( ) Y ( ) N
g. Unit is restricted to certain source head orientations and/or gantry angles [L/C] ( ) Y ( ) N ( ) N/A
h. Unit ceases to operate in restricted orientation(s) [L/C] ( ) Y ( ) N ( ) N/A

Remarks.

7. EQUIPMENT

a. Licensee has calibrated dosimetry system available for use [35.630(a)] ( ) Y ( ) N

b. Dosimetry system calibrated by NIST (formerly NBS) or an AAPM accredited lab within previous two years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per [35.630(a)(2)] ( ) Y ( ) N

c. Records maintained ( ) Y ( ) N

Remarks.

b. Survey instruments

(1) Appropriate operable survey instruments possessed per [35.620] ( ) Y ( ) N

(2) Calibration performed as required in [35.51] ( ) Y ( ) N

(3) Records maintained [35.51(d)] ( ) Y ( ) N

(4) Proper operation checked with check source per [35.51(c)] ( ) Y ( ) N

Remarks.

c. Facility equipped with permanent radiation monitor [35.615(d)] ( ) Y ( ) N

(1) Monitor provides visible notice of malfunction resulting in exposed source and is observable upon entry into teletherapy room [35.615(d)(1)] ( ) Y ( ) N

(2) Monitor equipped with backup power supply [35.615(d)(2)] ( ) Y ( ) N

(3) Monitor is checked each day of use prior to treatments [35.615(d)(3)] ( ) Y ( ) N

(4) Records of monitor checks maintained [35.615(d)(4)] ( ) Y ( ) N

(5) If monitor malfunctioned, was survey meter used [35.615(d)(5)] ( ) Y ( ) N ( ) N/A

(6) Monitor was repaired/replaced promptly [35.615(d)(6)] ( ) Y ( ) N ( ) N/A

Remarks.

8. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive materials used in accordance with current procedures [L/C] ( ) Y ( ) N

Remarks.

b. Individuals understanding of current procedures is adequate

(1) in general operating procedures ( ) Y ( ) N
(2) in emergency procedures ( ) Y ( ) N

Remarks.

9. MATERIALS

a. Isotope, chemical form, quantity and use as authorized [L/C and 35.600] ( ) Y ( ) N

Remarks.

b. Possession and use of depleted uranium as shielding as authorized ( ) Y ( ) N ( ) N/A

Remarks.

c. Leak tests and Inventory

(1) Leak tests performed per [35.59(b) and (c)] ( ) Y ( ) N
(2) Inventory perfromed per [35.59(g)] ( ) Y ( ) N
(3) Leak tests records in microcuries ( ) Y ( ) N
(4) Leak test/inventory records signed by RSO ( ) Y ( ) N
(5) Records maintained ( ) Y ( ) N

Remarks.

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Transfer of licensed material per [30.41] ( ) Y ( ) N ( ) N/A
b. Records maintained [30.51(a)] ( ) Y ( ) N ( ) N/A

Remarks.

11. TELETHERAPY SERVICING

a. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.647(a)] ( ) Y ( ) N

NOTE: The inspector should determine that the licensee has arranged for needed service identified during the inspection. Examples of important components requiring periodic replacement are as follows:

(1) field light cord reel
(2) source drawer solenoids
(3) low air pressure switch
(4) air hoses and fittings
(5) treatment timer

Remarks.

b. Service performed by persons specifically authorized to do so [35.647(b)] ( ) Y ( ) N

Remarks.

c. Any other work performed is in accordance with [35.605] ( ) Y ( ) N ( ) N/A

Remarks.

12. RADIATION SURVEYS FOR TELETHERAPY FACILITIES

a. Surveys conducted around source head (with source off) and in adjacent areas to treatment room (with source on) [35.641(a)]

(1) Prior to first patient treatment ( ) Y ( ) N
(2) After new source installation ( ) Y ( ) N ( ) N/A
(3) After any changes in room shielding, location of the unit within room, or use of the unit such that radiation levels outside the room could increase ( ) Y ( ) N ( ) N/A

b. Records maintained ( ) Y ( ) N
c. Survey reports submitted to NRC per [35.645] ( ) Y ( ) N

Remarks.

13. TELETHERAPY CALIBRATION

a. Licensee utilizes one of the proper procedures for full calibrations [35.632(d)] ( ) Y ( ) N

b. Licensee utilizes

( ) SCRAD procedures
( ) TG-21 procedures

Remarks.

c. Full calibration

(1) Performed prior to first use on patients [35.632(a)(1)] ( ) Y ( ) N
(2) At intervals not to exceed one year [35.632(a)(3)] ( ) Y ( ) N
(3) Whenever spot-checks indicate output differs from expected by ±5% [35.632(a)(2)(i)] ( ) Y ( ) N ( ) N/A

(4) After source exchange, relocation, and major repair or modification [35.632(a)(2)(ii) and (iii)] ( ) Y ( ) N ( ) N/A

Remarks.

d. Full calibrations performed with properly calibrated instrument (see Section 7(a)) ( ) Y ( ) N

e. Full calibrations include:

(1) Output measured within ±3% of expected for the range of field sizes, range of distances, and compensations (wedges, filters, etc.) [35.632(b)(1)] ( ) Y ( ) N
(2) Coincidence of radiation field and field light localizer [35.632(b)(2)] ( ) Y ( ) N
(3) Uniformity of radiation field and beam angle dependence [35.632(b)(3)] ( ) Y ( ) N
(4) Timer constancy and linearity over the range of use [35.632(b)(4)] ( ) Y ( ) N
(5) On-off error [35.632(b)(5)] ( ) Y ( ) N
(6) Accuracy of all measuring and localization devices [35.632(b)(6)] ( ) Y ( ) N

f. Full calibration output corrected mathematically at one month intervals for Co-60 and six month intervals for Cs-137 [35.632(e)] ( ) Y ( ) N

g. Records of full calibrations maintained per [35.632(g)] ( ) Y ( ) N

Remarks.

h. Periodic spot checks

(1) Performed once in each calendar month [35.634(a)] ( ) Y ( ) N
(2) Procedures for spot checks established by teletherapy physicist [35.634(b)] ( ) Y ( ) N

(3) Procedures for spot checks followed ( ) Y ( ) N
(4) Teletherapy physicist reviews results of spot checks within 15 days ( ) Y ( ) N ( ) N/A

Remarks.

i. Spot checks performed with properly calibrated instrument (see Section 7(a)) ( ) Y ( ) N

j. Output spot checks include:

(1) Time, constancy and linearity over the range of use [35.634(a)(1)] ( ) Y ( ) N
(2) On-off error [35.634(a)(2)] ( ) Y ( ) N
(3) Coincidence of radiation field and field light localizer [35.634(a)(3)] ( ) Y ( ) N
(4) Accuracy of all measuring and localization devices [35.634(a)(4)] ( ) Y ( ) N
(5) The output for one typical set of operating conditions [35.634(a)(5)] ( ) Y ( ) N
(6) Difference between measured and expected output [35.634(a)(6)] ( ) Y ( ) N

Remarks.

k. Safety spot checks include checks of:

(1) Interlock systems [35.634(d)(1)] ( ) Y ( ) N
(2) Beam stops and dead-man switches [35.634(d)(2)] ( ) Y ( ) N
(3) Beam condition indicator lights [35.634(d)(3)] ( ) Y ( ) N
(4) Viewing systems [35.634(d)(4)] ( ) Y ( ) N
(5) Treatment room doors, inside and out [35.634(d)(4)] ( ) Y ( ) N
(6) Electrical treatment doors with power shut off [35.634(d)(6)] ( ) Y ( ) N

l. Licensee promptly repaired items found to be not operating properly from safety spot checks and did not use unit until repaired [35.634(e)] ( ) Y ( ) N ( ) N/A

m. Records of spot checks maintained per [35.634(f)] ( ) Y ( ) N

Remarks.

14. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier _____ Frequency _____

b. Supplier is NVLAP - approved ( ) Y ( ) N

c. Reports reviewed by _____ Frequency _____

d. NRC inspector reviewed personnel monitoring records for

period _____ to _____

e. NRC forms or equivalent

(1) NRC-4: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
(2) NRC-5: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
[20.401(a)]

f. List maximum exposures (millirem):

g. Licensee has implemented an ALARA program [35.20] ( ) Y ( ) N

Remarks.

15. NOTIFICATION AND REPORTS

a.	Licensee in compliance with [19.13] (reports to individuals)	( ) Y ( ) N ( ) N/A
b.	Licensee in compliance with [20.402] (theft or loss)	( ) Y ( ) N ( ) None
c.	Licensee in compliance with [20.403] (incidents)	( ) Y ( ) N ( ) None
d.	Licensee in compliance with [20.405] (overexposures)	( ) Y ( ) N ( ) None

Remarks.

16. MISADMINISTRATIONS

a.	Therapeutic misadministrations have occurred	( ) Y ( ) N
b.	Licensee in compliance with reporting therapeutic misadministrations [35.33(a) and (b)]	( ) Y ( ) N ( ) None
c.	Appropriate action taken to prevent recurrence	( ) Y ( ) N
d.	Records maintained [35.33(d)]	( ) Y ( ) N

Remarks.

e.	Licensee has QA program to prevent misadministrations	( ) Y ( ) N
f.	If so, is QA program tied to NRC license	( ) Y ( ) N ( ) N/A
g.	If so, briefly describe QA Program:	( ) N/A

(1)	Secondary checks of dose calculations performed	( ) Y ( ) N
(2)	Secondary checks provide assurance that final treatment plan will provide prescribed dose	( ) Y ( ) N
(3)	Technologist consults with doctor if prescription or orders are unclear	( ) Y ( ) N

(4) QA program is periodically audited ( ) Y ( ) N

Remarks.

17. POSTING AND LABELING

a. NRC-3 "Notice to Workers" posted ( ) Y ( ) N
b. Emergency procedures posted at console [35.610(a)] ( ) Y ( ) N
c. Other posting and labeling per [20.203] ( ) Y ( ) N

Remarks.

18. RECORDKEEPING FOR DECOMMISSIONING

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N
b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

19. INDEPENDENT MEASUREMENTS

a. Survey instrument used _____

b. NRC Serial No. _____

c. Last date of calibration _____

d. Inspector's measurements were compared to licensee's ( ) Y ( ) N

e. Describe the type and results of measurements (Include surveys around source head with source "off" and surveys in areas adjacent to treatment room with source "on") :

20. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee ( ) Y ( ) N

b. Licensee took appropriate action in response to Bulletins, INs, etc. ( ) Y ( ) N

Remarks.

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

22. LIST OF VIOLATIONS

23. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y ( ) N

b. RSO too busy with other assignments ( ) Y ( ) N

c. Insufficient staffing ( ) Y ( ) N

d. Radiation Safety Committee fails to meet or functions inadequately ( ) Y ( ) N

e. Inadequate consulting services or inadequate audits ( ) Y ( ) N

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

APPENDIX B

NUCLEAR MEDICINE INSPECTION FIELD NOTES*
Region ____

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority :

Program Codes:

( ) 02110 - Broad Scope	( ) 02120 - Limited
( ) 02121 - Custom	( ) 02200 - Private Practice - Limited
( ) 02209 - In Vivo	( ) 02201 - Private Practice - Custom
( ) 02210 - Eye Applicator	( ) 02220 - Nuclear Medical Van
( ) 02400 - Veterinary	( ) 02410 - In Vitro
( ) 02500 - Pharmacy	( ) Other -

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection:

( ) Announced	( ) Unannounced
( ) Routine	( ) Special
( ) Initial	( ) Reinspection

Next Inspection Date. _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
( ) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

* All areas indicated in field notes are not required to be addressed during each inspection.

1. ORGANIZATION

a. Organizational structure meets license requirements [L/C] ( ) Y ( ) N

Remarks.

b. Use by authorized individuals [35.22(b)(2)] ( ) Y ( ) N

Remarks.

c. Radiation Safety Committee ( ) N/A

(1) Membership as specified in [35.22(a)(1)] ( ) Y ( ) N
(2) Meetings held quarterly [35.22(a)(2)] ( ) Y ( ) N
(3) Quorums established per [35.22(a)(3)] ( ) Y ( ) N
(4) Has sufficient authority per [35.23] ( ) Y ( ) N
(5) Committee reviews conducted per [35.22(b)] ( ) Y ( ) N
(6) Record of Committee meetings [35.22(a)(4)] ( ) Y ( ) N

Remarks.

d. Radiation Safety Officer

(1) Appointed [35.21(a)] ( ) Y ( ) N
(2) Fulfills duties per [35.21(b)] ( ) Y ( ) N
(3) Has sufficient authority per [35.23] ( ) Y ( ) N

Remarks.

e. Visiting Authorized User ( ) N/A

(1) Has written permission [35.27(a)(1)] ( ) Y ( ) N
(2) Copy of visitor's license on file [35.27(a)(2)] ( ) Y ( ) N
(3) Performs only those procedures authorized on visitor's license [35.27(a)(3)] ( ) Y ( ) N
(4) Uses material under licensee's license for sixty days per year or less [35.27(b)] ( ) Y ( ) N
(5) Records maintained 3 years after last visit [35.27(c)] ( ) Y ( ) N

Remarks.

f. Mobile Nuclear Medicine Service ( ) N/A

(1) Licensee uses mobile nuclear medicine services [35.29] ( ) Y ( ) N
(2) Licensee operates mobile nuclear medicine services [35.29, 35.80] ( ) Y ( ) N

Remarks.

2. INSPECTION HISTORY ( ) N/A - Initial inspection

a. Last inspection conducted on _____

b. Violations or deviations were identified ( ) Y ( ) N

c. Response letter or 591 dated _____

d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status

e. Any previous violations not corrected ( ) Y ( ) N

Explain.

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use ( ) Y ( ) N
b. If so, list location(s) inspected ( ) N/A

c. List those individuals contacted during inspection

*Indicates presence at exit meeting

d. Briefly describe scope, including types of use involving byproduct material, frequency of use, staff size, etc.

e. Radiation safety program changes pursuant to [35.31] ( ) Y ( ) N ( ) N/A
f. Records of changes maintained [35.31(b)] ( ) Y ( ) N ( ) N/A

Remarks.

4. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections are conducted ( ) Y ( ) N ( ) N/A

(1) Audits conducted by _____

(2) Frequency _____

b. Audits are required by license condition ( ) Y ( ) N
c. Records maintained ( ) Y ( ) N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] ( ) Y ( ) N

Remarks.

b. Training program required [L/C] ( ) Y ( ) N ( ) N/A

(1) Training program implemented ( ) Y ( ) N
(2) Retraining program required ( ) Y ( ) N
(3) Retraining program implemented ( ) Y ( ) N
(4) Records maintained ( ) Y ( ) N

Remarks.

c. Supervision of individuals by authorized user in accordance with [35.25] ( ) Y ( ) N

Remarks.

6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application ( ) Y ( ) N

Remarks.

b. Areas for storage and use of RAM

(1) Adequate method used to prevent an unauthorized individual from entering restricted area ( ) Y ( ) N

(2) RAM is secured to prevent unauthorized removal from an unrestricted area [20.207] ( ) Y ( ) N

Remarks.

c. Dose calibrator

(1) Licensee possesses and uses dose calibrator(s) per [35.50(a)] ( ) Y ( ) N ( ) N/A

(2) Constancy checked per [35.50(b)(1)] ( ) Y ( ) N

(3) Linearity tested per [35.50(b)(2)] ( ) Y ( ) N

(4) Accuracy tested per [35.50(b)(3)] ( ) Y ( ) N

(5) Geometry dependence tested per [35.50(b)(4)] ( ) Y ( ) N

(6) Readings mathematically corrected if linearity error is greater than 10% [35.50(d)] ( ) Y ( ) N

(7) Records maintained [35.50(e)] ( ) Y ( ) N

(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(e)] ( ) Y ( ) N

Remarks.

d. Survey instruments

(1) Approriate operable survey instruments possessed per [35.120,220,320,420] or available per [35.520] ( ) Y ( ) N ( ) N/A

(2) Calibration performed as required in [35.51] ( ) Y ( ) N

(3) Records maintained [35.51(d)] ( ) Y ( ) N

(4) Proper operation checked with check source per [35.51(c)] ( ) Y ( ) N

Remarks.

e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60] ( ) Y ( ) N

f. Vials containing RAM properly labeled and shielded per [35.61] ( ) Y ( ) N

Remarks.

7. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive materials used in accordance with current procedures [L/C] ( ) Y ( ) N

Remarks.

b. Individuals' understanding of current procedures is adequate

(1) in general rules for safe use of RAM ( ) Y ( ) N
(2) in emergency procedures ( ) Y ( ) N

Remarks.

8. MATERIALS

a. Licensee uses unit doses ( ) Y ( ) N

b. Licensee uses generators ( ) Y ( ) N

c. Licensee possesses sealed sources or brachytherapy sources per [35.59] ( ) Y ( ) N

d. Isotope, chemical form, quantity and use as authorized [L/C, 31.11, 35.100,200,300,400,500] ( ) Y ( ) N

Remarks.

e. Molybdenum-99 breakthrough ( ) N/A

(1) Test performed per [35.204(b)] ( ) Y ( ) N
(2) Records maintained per [35.204(c)] ( ) Y ( ) N

Remarks.

f. Leak tests and Inventory

(1)	Leak tests performed on sealed sources and brachytherapy sources per [35.59(b)]	( ) Y ( ) N
(2)	Inventory of sealed sources and brachytherapy sources per [35.59(c)]	( ) Y ( ) N
(3)	Leak tests records in microcuries	( ) Y ( ) N
(4)	Leak test/inventory records signed by RSO	( ) Y ( ) N
(5)	Records maintained of leak tests and inventories for 5 years	( ) Y ( ) N

Remarks.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Describe how packages are received and by whom: ( ) N/A

b.	Opening procedures established and followed [20.205(d)]	( ) Y ( ) N
c.	Incoming packages wiped per [20.205(b)]	( ) Y ( ) N
d.	Incoming packages surveyed per [20.205(c)]	( ) Y ( ) N
e.	Transfer(s) performed per [30.41]	( ) Y ( ) N
f.	Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51]	( ) Y ( ) N

Remarks.

10. AREA SURVEYS ( ) N/A

a.	Ambient exposure rate surveys conducted per [35.70(a),(b),(c)]	( ) Y ( ) N
b.	Contamination surveys conducted per [35.70(e),(f)]	( ) Y ( ) N
c.	Trigger levels established [35.70(d), (g)]	( ) Y ( ) N
d.	Exposure rate survey records in mR/hr	( ) Y ( ) N
e.	Contamination survey records in dpm/100 cm^2	( ) Y ( ) N
f.	Records maintained per [35.70(h)]	( ) Y ( ) N

Remarks.

11. RADIOPHARMACEUTICAL THERAPY ( ) N/A

a.	Licensee provides safety instruction [35.310] and implements safety precautions [35.315] or equivalents [L/C]	( ) Y ( ) N
b.	Patient room contamination surveys per [35.315]	( ) Y ( ) N
c.	Release of patients containing radiopharmaceuticals meets [35.75]	( ) Y ( ) N
d.	Thyroid burden measured on individuals involved in dose administrations [35.315(a)(8)]	( ) Y ( ) N
e.	Records maintained	( ) Y ( ) N

Remarks.

12. BRACHYTHERAPY ( ) N/A

a.	Licensee provides safety instruction [35.410] and implements safety precautions [35.415] or equivalent [L/C]	( ) Y ( ) N
b.	Patient surveys performed per [35.406]	( ) Y ( ) N
c.	Release of patients containing permanent implants meets [35.75]	( ) Y ( ) N
d.	Release of patients treated with temporary implants meets [35.404]	( ) Y ( ) N

e. Brachytherapy sources inventoried per [35.406] ( ) Y ( ) N
f. Brachytherapy source storage area surveyed quarterly and record signed by RSO [35.59(h)] ( ) Y ( ) N
g. Records maintained ( ) Y ( ) N

Remarks.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier _____ Frequency _____

b. Supplier is NVLAP - approved ( ) Y ( ) N

c. Reports reviewed by _____ Frequency _____

d. NRC inspector reviewed personnel monitoring records for

period _____ to _____

e. NRC forms or equivalent

(1) NRC-4: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
(2) NRC-5: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
[20.401(a)]

f. List maximum exposures (millirem):

g. Licensee has implemented an ALARA program [35.20] ( ) Y ( ) N

Remarks.

14. PERSONNEL RADIATION PROTECTION - INTERNAL ( ) N/A

a. Potential for exposure of individuals to airborne RAM exists ( ) Y ( ) N
b. Monitoring for airborne radioactivity conducted [20.201(b) to meet 20.103, 35.90, and 35.205] ( ) Y ( ) N

c. Records maintained [20.401, 35.205(d), and L/C] ( ) Y ( ) N
d. Bioassay program implemented as described in correspondence with NRC ( ) Y ( ) N
e. Radioactive gases

(1) Clearance time and safety procedures are posted [35.205(d)] ( ) Y ( ) N
(2) Reusable collection systems checked monthly ( ) Y ( ) N
(3) Ventilation rates checked each six months for negative pressure [35.205(e)] ( ) Y ( ) N

Remarks.

15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y ( ) N
b. Release in accordance with regulatory limits [20.106(a)] ( ) Y ( ) N

Remarks.

c. Describe waste disposal method(s) - solid and liquid:

d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below:

(1) Adequate control of waste in storage is maintained ( ) Y ( ) N
(2) Package is labeled and package integrity is adequately maintained ( ) Y ( ) N
(3) Adequate records of surveys and material accountability are maintained ( ) Y ( ) N

e. Disposal of waste in accordance with regulatory requirements [20.301 and 35.92] ( ) Y ( ) N
f. Decay-in-storage waste disposed per [35.92] ( ) Y ( ) N
g. Records maintained [20.401(b) and 35.92(b)] ( ) Y ( ) N

Remarks.

16. NOTIFICATION AND REPORTS

a.	Licensee in compliance with [19.13] (reports to individuals)	( ) Y ( ) N ( ) N/A
b.	Licensee in compliance with [20.402] (theft or loss)	( ) Y ( ) N ( ) None
c.	Licensee in compliance with [20.403] (incidents)	( ) Y ( ) N ( ) None
d.	Licensee in compliance with [20.405] (overexposures)	( ) Y ( ) N ( ) None

Remarks.

17. MISADMINISTRATIONS

a.	M administrations have occurred	( ) Y ( ) N
	(1) Diagnostic	( ) Y ( ) N
	(2) Therapeutic	( ) Y ( ) N
b.	Licensee in compliance with reporting therapeutic misadministrations [35.33(a),(b)]	( ) Y ( ) N
c.	Licensee in compliance with reporting diagnostic misadministrations, if required [35.33(c)]	( ) Y ( ) N
d.	Appropriate action taken to prevent recurrence	( ) Y ( ) N
e.	Records maintained [35.33(d)]	( ) Y ( ) N

Remarks.

18. POSTING AND LABELING

a. NRC-3 "Notice to Workers" posted ( ) Y ( ) N
b. Other posting and labeling per [20.203] ( ) Y ( ) N

Remarks.

19. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM ( ) Y ( ) N
b. If so, describe shipment content and method:

c. Licensee is aware of 10 CFR 61 requirements ( ) Y ( ) N ( ) N/A
d. Licensee classifies and characterizes waste ( ) Y ( ) N ( ) N/A
e. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A
(2) Package type used _____
(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A
(4) For special form sources, performance test record on file [173.476(a)] ( ) Y ( ) N ( ) N/A
(5) Packages properly labeled [172.403, 173.441] ( ) Y ( ) N ( ) N/A
(6) Packages properly marked [173.200] ( ) Y ( ) N ( ) N/A
(7) Proper shipping papers prepared and used [172.200-204] ( ) Y ( ) N ( ) N/A

Remarks.

25. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a.	Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight	( ) Y ( ) N
b.	RSO too busy with other assignments	( ) Y ( ) N
c.	Insufficient staffing	( ) Y ( ) N
d.	Radiation Safety Committee fails to meet or functions inadequately	( ) Y ( ) N
e.	Inadequate consulting services or inadequate audits	( ) Y ( ) N

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

APPENDIX C

WELL LOGGING INSPECTION FIELD NOTES*
Region ____

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____ ____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority :

Programs Codes:
( ) 03110 - BPM/SNM Tracer and Sealed Sources
( ) 03111 - BPM/SNM Sealed Sources Only
( ) 03112 - BPM Tracers Only
( ) Other -

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection:
( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date. _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No Violations, Clear 591 or letter issued
( ) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

* All areas indicated in field notes are not required to be addressed during each inspection.

1. ORGANIZATION

a. Briefly describe management structure:

b. Individuals identified as responsible for radiation safety still hold those positions ( ) Y ( ) N

Remarks:

2. INSPECTION HISTORY ( ) N/A - Initial inspection

a. Last inspection conducted on _____

b. Violations or deviations were identified ( ) Y ( ) N

c. Response letter or 591 dated _____

d. Violations from Previous Inspection:

Requirement	Violation	Corrective Action Taken (Y/N)	Status

e. Any previous violations not corrected ( ) Y ( ) N

Explain:

3. SCOPE OF PROGRAM (Number of people, rate of use or quantities on hand, places and frequency of use, type, quantity and use as authorized, proper users) [39.13(b)]

4. INTERNAL AUDITS OR INSPECTIONS

Audits conducted per [39.13(d)] or application: ( ) Y ( ) N

If "Yes":

a. By whom _____

b. Frequency _____ Announced _____ Unannounced _____

c. Scope _____

_____

_____

_____

_____

d. Records maintained ( ) Y ( ) N

e. Records reviewed ( ) Y ( ) N

f. Period reviewed: _____

Remarks:

[Inspection should include interviews with audited well-logging supervisors as well as with the managers performing audits.]

5. TRAINING, ANNUAL REVIEWS, INSTRUCTIONS TO WORKERS [10 CFR 39.13(b)]

a. Training program specified in L/C or application ( ) Y ( ) N

[Inspection should verify records of test results, including field exams of supervisors. [39.13(b) and 39.61]]

b. Describe scope of training program:

c. Annual reviews conducted. Records maintained. ( ) Y ( ) N
[39.13(b) and 39.61]

d. Period reviewed: _____

Remarks (percent completed, tests results, etc.):

e. Training provided, but not covered above, such as on-the-job training ( ) Y ( ) N

Remarks:

f. Instructions to workers in accordance with 19.12 and 39.61(a)(2) ( ) Y ( ) N

Remarks:

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Operating and Emergency Procedures [10 CFR 39.63]

(1) Required by L/C or application	( ) Y ( ) N
(2) Procedures reviewed	( ) Y ( ) N
(3) Appeared adequate	( ) Y ( ) N

b. Equipment, such as remote handling tools and gloves, available and used ( ) Y ( ) N

c. Changes in procedures since last inspection ( ) Y ( ) N

d. If changes made, were they authorized? ( ) Y ( ) N ( ) N/A

Remarks:

7. INSTRUMENTATION [10 CFR 39.33]

a. Type(s) of radiation survey instruments on hand as per L/C, application or equivalent ( ) Y ( ) N

If "No," list changes:

b. Capability and availability of radiation survey instruments adequate for program [39.33(a),(b)] ( ) Y ( ) N

c. Instruments calibrated per [39.33(c)] ( ) Y ( ) N

Remarks:

8. MATERIALS

a. Radioactive material locked and secured to prevent unauthorized removal from:

(1) Restricted area [39.31(b)] ( ) Y ( ) N
(2) Unrestricted area [20.207] ( ) Y ( ) N

b. Licensed material not stored with explosives [39.31(b)(1)] ( ) Y ( ) N

c. Method of control appears generally adequate ( ) Y ( ) N

Remarks:

9. FACILITIES

a. Facilities (or field office) described in letter or application ( ) Y ( ) N
b. Facilities (or field office) or temporary job sites inspected ( ) Y ( ) N
c. Materials stored only at locations authorized by the license ( ) Y ( ) N

Remarks:

10. POSTING AND LABELING

a. Posting and labeling in accordance with [20.203, 39.31] ( ) Y ( ) N
b. Uranium sinker bars properly labeled or stamped [39.49] ( ) Y ( ) N

Remarks:

11. RECEIPT AND TRANSFER OF MATERIAL

a. Procedures for picking up and receiving packages [20.205(b),(c)] ( ) Y ( ) N

(1) Incoming shipments monitored ( ) Y ( ) N
(2) Records of monitoring maintained [20.401(b)] ( ) Y ( ) N
(3) Records reviewed by NRC inspector ( ) Y ( ) N
(4) Period reviewed: _____

b. Procedures for opening packages [20.205(d)] ( ) Y ( ) N

c. Records of receipt, transfer and inventory of material available [30.51(a), 40.61(a), 70.51(b)(1)] ( ) Y ( ) N

(1) Records reviewed by NRC inspector ( ) Y ( ) N
(2) Period reviewed: _____

d. Packages on hand meet labeling requirements [49 CFR 172.403] ( ) Y ( ) N

e. Reports to Commission required by L/C or regulation were submitted ( ) Y ( ) N

f. Semiannual physical inventory conducted [39.37] ( ) Y ( ) N

Remarks.

12. PERSONNEL RADIATION PROTECTION - EXTERNAL [10 CFR 39.65]

a. Film or TLD badge supplier: _____

b. Badge exchange frequency: _____

c. Reports reviewed by: _____

d. Records reviewed for period _____ to _____ by NRC inspector

e. NRC forms or equivalent:

(1) NRC-4 [20.102(b)] ( ) Y ( ) N Complete: ( ) Y ( ) N

(2) NRC-5 [20.401(a)] ( ) Y ( ) N Complete: ( ) Y ( ) N

(3) Maximum exposures (mrem):

f. Pocket dosimeters used ( ) Y ( ) N

(1) Type used: _____

(2) Frequency of recharging: _____

(3) Frequency of reading: _____

g. Direct radiation surveys of restricted and/or unrestricted areas being made [39.67] ( ) Y ( ) N

(1) Records of surveys being maintained ( ) Y ( ) N

(2) Records of surveys reviewed ( ) Y ( ) N

(3) Period reviewed: _____

Remarks:

13. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material or other internal hazard exists ( ) Y ( ) N

(1) If "Yes," does program for monitoring and control exist? ( ) Y ( ) N ( ) N/A

(2) Programs for monitoring and control appear adequate ( ) Y ( ) N ( ) N/A

b. Smear surveys being conducted [20.201(b)] ( ) Y ( ) N

(1) Records of smear surveys reviewed ( ) Y ( ) N

(2) Period reviewed: _____

(3) Records appeared adequate ( ) Y ( ) N

(4) Methods of performing and analyzing smears appear adequate ( ) Y ( ) N

c. Bioassay program required [39.45] ( ) Y ( ) N

(1) If "Yes," was bioassay program reviewed? ( ) Y ( ) N ( ) N/A
(2) Bioassay program appears adequate ( ) Y ( ) N ( ) N/A

Remarks:

14. LEAK TESTS OF SEALED SOURCES [10 CFR 39.35]

a. Conducted as required ( ) Y ( ) N

b. Records of leak tests maintained ( ) Y ( ) N

c. Period reviewed: _____

d. Records of leak tests appear adequate ( ) Y ( ) N

Remarks:

15. UTILIZATION RECORDS [10 CFR 39.39]

a. Records contain all pertinent information ( ) Y ( ) N

Remarks:

16. RADIOACTIVE WASTE CONTROL

a. Radioactive material unintentionally released to groundwater or aquifers and sanitary sewer system ( ) Y ( ) N

b. Exemption granted for unintentional releases [39.45(b)] ( ) Y ( ) N

c. Records of releases or radioactive effluents maintained [20.401] ( ) Y ( ) N

d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below:

(1) Adequate control of waste in storage is maintained ( ) Y ( ) N

(2) Package is labeled and package integrity is adequately maintained ( ) Y ( ) N

(3) Adequate records of surveys and material accountability are maintained ( ) Y ( ) N

e. Proper disposal records maintained for decay-in-storage wastes ( ) Y ( ) N

Remarks:

17. DESIGN AND PERFORMANCE CRITERIA FOR SEALED SOURCES [10 CFR 39.41]

a. Sources meet design criteria ( ) Y ( ) N

Remarks:

18. INSPECTION, MAINTENANCE, AND OPENING OF SOURCES OR SOURCE HOLDERS [10 CFR 39.43]

a. Licensee has program for inspection and maintenance of equipment ( ) Y ( ) N

b. Equipment inspected both daily and semiannually ( ) Y ( ) N

c. Records of inspection maintained ( ) Y ( ) N

d. Stuck sources in source holders or repair, opening, modification done only by persons specifically licensed ( ) Y ( ) N

e. Use of radioactive markers in wells only if individual markers contain quantities of licensed material not exceeding exempt quantities [39.47] ( ) Y ( ) N

Remarks:

19. DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS [10 CFR 39.73]

a. Utilization records and other documents located at field stations as required by regulation ( ) Y ( ) N

Remarks:

20. DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOB SITES [10 CFR 39.75]

a. Documents and records maintained at job sites as required by regulation ( ) Y ( ) N

Remarks:

21. NOTIFICATION OF INCIDENTS AND LOST SOURCES; ABANDONMENT PROCEDURES FOR IRRETRIEVABLE SOURCES [10 CFR 39.77]; SOURCE RECOVERY MONITORING REQUIREMENTS. [10 CFR 39.69(c)]

a. Contamination checks made during source recovery operations ( ) Y ( ) N

b. NRC notified of ruptured sources ( ) Y ( ) N

c. NRC notified of abandoned sources ( ) Y ( ) N

d. Abandoned wells properly placarded ( ) Y ( ) N

e. Procedures for using sealed sources in wells without surface casing [39.51] ( ) Y ( ) N

Remarks:

22. TRANSPORTATION [10 CFR 71.5(a) and 49 CFR 171-189]

a. Licensee makes shipments of RAM ( ) Y ( ) N

b. Shipments are:

( ) delivered to common carriers

( ) transported in licensee's own private vehicle

( ) both

( ) no shipments since last inspection

Remarks.

Complete only if shipments made since last inspection:

c. Shipments

(1) Authorized packages used [173.415,416]	( ) Y ( ) N ( ) N/A
(2) Package type used _____	
(3) For DOT-7A packages, performance test record on file [173.415(a)]	( ) Y ( ) N ( ) N/A
(4) For DOT-55 packages, use is approved by NRC [173.416(a)]	( ) Y ( ) N ( ) N/A
(5) Other Type B packages used are approved [173.416(a)]	( ) Y ( ) N ( ) N/A
(6) Licensee has COCs on file with NRC [71.12(c)(1)]	( ) Y ( ) N ( ) N/A
(7) Licensee has a QA program approved by NRC [71.12(b)]	( ) Y ( ) N ( ) N/A
(8) For special form sources, performance test record on file [173.476(a)]	( ) Y ( ) N ( ) N/A
(9) Packages properly labeled [172.403, 173.441]	( ) Y ( ) N ( ) N/A
(10) Packages properly marked [173.200]	( ) Y ( ) N ( ) N/A
(11) Proper shipping papers prepared and used [172.200-204]	( ) Y ( ) N ( ) N/A
(12) Shipping papers readily accessible during transport [177.817(e)]	( ) Y ( ) N ( ) N/A
(13) Vehicles placarded as necessary [172.500, 504]	( ) Y ( ) N ( ) N/A
(14) Cargo blocked and braced [177.842(d)]	( ) Y ( ) N ( ) N/A
(15) Any incidents reported to DOT [171.15-16]	( ) Y ( ) N ( ) None

Remarks.

23. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 19.13 (reports to individuals) ( ) Y ( ) N ( ) N/A

b. Licensee in compliance with 20.405 (overexposure) ( ) Y ( ) N ( ) None

c. Licensee in compliance with 20.403 (incidents) ( ) Y ( ) N ( ) None

d. Licensee in compliance with 20.402 (theft or loss) ( ) Y ( ) N ( ) None

Remarks:

24. POSTING OF NOTICES

a. Licensee in compliance with 19.11(a) or (b) ( ) Y ( ) N

b. Licensee in compliance with 19.11(c) ( ) Y ( ) N

Remarks:

25. BULLETINS AND INFORMATION NOTICES

a. List applicable Bulletins and Information Notices issued during current year:

b. Bulletins, Information Notices, etc. received by licensee ( ) Y ( ) N

c. Licensee took appropriate action in response to Bulletins and Information Notices ( ) Y ( ) N

Remarks:

26. ENVIRONMENTAL MONITORING PROGRAM

a. Environmental Monitoring Program required ( ) Y ( ) N

b. If Environmental Monitoring Program is required:

(1) Records reviewed ( ) Y ( ) N ( ) N/A
(2) Period reviewed: _____ ( ) N/A
(3) Records appeared adequate ( ) Y ( ) N ( ) N/A

Remarks:

c. If Environmental Monitoring Program is not required, briefly describe any existing program:

27. CONFIRMATORY MEASUREMENTS

a. Confirmatory measurements made by inspector ( ) Y ( ) N

If "Yes," answer the following:

b. Survey instrument used: _____

c. NRC Serial No.: _____

d. Last date of calibration: _____

e. Inspector's measurements were compared to licensee's ( ) Y ( ) N

f. Describe the type and results of the confirmatory measurements:

28. RECORDKEEPING FOR DECOMMISSIONING ( ) N/A

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

29. INDEPENDENT INSPECTION EFFORT

Remark on type of independent inspection effort conducted:

30. SECURITY

a. Direct surveillance maintained by logging supervisor/designee when source is not below ground or in shipping container ( ) Y ( ) N

Remarks:

31. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

32. LIST OF VIOLATIONS

33. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y ( ) N

b. RSO too busy with other assignments ( ) Y ( ) N

c. Insufficient staffing ( ) Y ( ) N

d. Radiation Safety Committee fails to meet or functions inadequately ( ) Y ( ) N ( ) N/A

e. Inadequate consulting services or inadequate audits ( ) Y ( ) N ( ) N/A

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

APPENDIX D

INDUSTRIAL RADIOGRAPHY INSPECTION FIELD NOTES*
Region ___.

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority:

Program Codes: ( ) 03310 - Fixed
( ) 03320 - Temporary

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection: ( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
( ) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

* All areas indicated in field notes are not required to be addressed during each inspection.

1. ORGANIZATION

a. Briefly describe the organizational structure:

b. Organizational structure meets license requirements. [L/C] ( ) Y ( ) N

c. Radiographers and Assistants named in license ( ) Y ( ) N

d. List radiography personnel:
(Indicate if they are radiographers or assistants)

2. INSPECTION HISTORY

a. Last inspection conducted on _____

b. Violations or deviations were identified ( ) Y ( ) N

c. Response letter or 591 dated _____

d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status

e. Any previous violations not corrected ( ) Y ( ) N

Explain.

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use ( ) Y ( ) N

b. If so, list location(s) inspected ( ) N/A

c. List those individuals contacted during inspection

*Indicates presence at exit meeting

d. Briefly describe scope, including types of equipment, types of use involving byproduct material, frequency of use, staff size, etc.

4. OPERATING AND EMERGENCY PROCEDURES

a. Licensee maintains current procedures [34.32] ( ) Y ( ) N

b. Procedures contain all information specified in [34.32] ( ) Y ( ) N

c. Procedures are approved by NRC [34.11] ( ) Y ( ) N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] ( ) Y ( ) N

b. Parts 19, 20 , and 34; the license; and Operating and Emergency Procedures furnished to all radiographers and assistants [34.31(a)(2),(b)(1)] ( ) Y ( ) N

Remarks.

c. Training program required [L/C, 34.31] ( ) Y ( ) N

(1) If so, briefly describe training program:

(2) Training program implemented ( ) Y ( ) N
(3) Written tests completed by all radiographers and assistants [34.31(a)(4), (b)(3)] ( ) Y ( ) N
(4) Oral tests [34.31(b)(3)] ( ) Y ( ) N
(5) Inspector reviewed test results ( ) Y ( ) N
(6) All radiographers completed on-the-job training ( ) Y ( ) N
(7) Retraining program required ( ) Y ( ) N
(8) Retraining program implemented ( ) Y ( ) N
(9) Records maintained [34.31(c)] ( ) Y ( ) N

Remarks.

6. INTERNAL AUDITS OR INSPECTIONS

a. Audits or inspections of each radiographer and assistant are conducted per [34.11(d)] ( ) Y ( ) N
b. Equipment check prior to use each day [34.28(a)] ( ) Y ( ) N
c. Equipment inspection and maintenance performed at 3-month intervals per procedures [34.28(b)] ( ) Y ( ) N

d. Records maintained. ( ) Y ( ) N

Remarks.

7. FACILITIES

a. Permanent radiographic installation [34.2] ( ) N/A

(1) High Radiation Area entrances and exits controlled in accordance with [20.203(c)] ( ) Y ( ) N
(2) Entrance controls are of type described in [34.29(a)] ( ) Y ( ) N

If YES, complete (a)-(e) below: ( ) N/A
[34.29(b)]

(a) Visible and audible signals warn of radiation ( ) Y ( ) N
(b) Visible signal actuates when source is exposed ( ) Y ( ) N
(c) Audible signal actuates if entry is attempted when source is exposed ( ) Y ( ) N
(d) System tested at 3-month intervals ( ) Y ( ) N
(e) Records maintained ( ) Y ( ) N

Remarks.

b. Temporary High Radiation Area entry controlled in accordance with [20.203(c)(4) and 34.41] ( ) Y ( ) N ( ) N/A

c. Field location

(1) Field work authorized [L/C] ( ) Y ( ) N ( ) N/A
(2) Field inspection conducted ( ) Y ( ) N ( ) N/A

NOTE: If inspector performs field inspection, a separate radiography field audit report should be completed and attached to these field notes.

d. Storage Area

(1) Storage facilities as described in license [L/C] ( ) Y ( ) N
(2) Sources locked in devices [34.22] ( ) Y ( ) N
(3) Devices secured to prevent tampering or unauthorized removal [34.23] ( ) Y ( ) N

Remarks.

8. MATERIALS AND EQUIPMENT

a. Descibe any special equipment used by licensee: (shields, collimators, etc.)

b. Radiographic exposure devices and storage containers meet radiation level limits per [34.21] (new rule eff. 01/10/90) ( ) Y ( ) N

c. During radiographic operations, sources are locked in shielded position each time source is returned to that position [34.22(a)] ( ) Y ( ) N

d. All sealed sources not fastened to or contained in a radiographic exposure device are tagged per [34.25(e)] ( ) Y ( ) N

Remarks.

e. Leak tests

(1) Leak test method approved [34.25(c)] ( ) Y ( ) N

(2) Model of leak test kit _____

(3) Leak tests performed at intervals not to exceed six months [34.25(b)] ( ) Y ( ) N

(4) Records maintained [34.25(c)] ( ) Y ( ) N

f. Inventory

(1) Quarterly physical inventories conducted [34.26] ( ) Y ( ) N

(2) Inventories contain all required information [34.26] ( ) Y ( ) N

(3) Materials possessed as authorized by license [L/C] ( ) Y ( ) N

(4) Procurement and use in accordance with license [L/C] ( ) Y ( ) N

(5) Most recent BPM inventory conducted on _____

Source Changer Model #	Activity	Isotope	Source S/N	Camera Model and S/N

Remarks.

g. Utilization logs.

(1) Utilization logs maintained [34.27] ( ) Y ( ) N

(2) Logs contain all required information [34.27] ( ) Y ( ) N

Remarks.

9. INSTRUMENTATION

a. Describe the type and number of survey instruments possessed by the licensee:

b. Instruments are capable of measuring 2 mR/hr through 1 R/hr [34.24] ( ) Y ( ) N

c. Operable and calibrated survey instruments available and used on each job [34.43(a)] ( ) Y ( ) N

d. Calibration performed at intervals not to exceed three months [34.24] ( ) Y ( ) N

e. Records maintained [34.24] ( ) Y ( ) N

Remarks.

10. RADIATION SURVEYS

a. Area or facility surveys conducted to show compliance with 20.105 [20.201(b)] ( ) Y ( ) N

b. Records maintained [20.401(b)] ( ) Y ( ) N

c. Survey after each exposure, including guide tube and entire circumference of device [34.43(b)] ( ) Y ( ) N

d. Survey of device when placed in storage, including entire circumference of device [34.43(c)] ( ) Y ( ) N

e. Records maintained of final survey made when devices are stored for day [34.43(d)] ( ) Y ( ) N

Remarks.

11. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier _____ Frequency _____

b. Supplier is NVLAP - approved ( ) Y ( ) N

c. Reports reviewed by _____ Frequency _____

d. License exposure limit: ( ) 1.25 rem/qtr ( ) 3 rem/qtr

e. NRC inspector reviewed personnel monitoring records for

period _____ to _____

f. NRC forms or equivalent

(1) NRC-4: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A

NOTE: NRC-4 must be completed PRIOR to individual receiving more than 1.25 rem per calendar quarter.

(2) NRC-5: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
[20.401(a)]

g. List maximum exposures (millirem):

h. Each individual is assigned a pocket dosimeter, an alarm ratemeter (eff. 1/10/91), and a film badge/TLD [34.33(a)] ( ) Y ( ) N

Remarks.

i. Pocket dosimeters

(1) Type _____

(2) Range _____

(3) Recharged at start of each shift [34.33(a)] ( ) Y ( ) N

(4) Daily readings recorded [34.33(b)] ( ) Y ( ) N

(5) Dosimeters checked for response (±30%) at intervals not to exceed one year [34.33(c)] ( ) Y ( ) N

j. Alarm ratemeters (eff. 01/10/91)

(1) Type _____

(2) Range _____

(3)	Alarm checked at start of each shift [34.33(f)(1)]	( ) Y ( ) N
(4)	Alarm preset at 500 mr/hr [34.33(f)(2)]	( ) Y ( ) N
(5)	Alarm ratemeters calibrated (±20%) at intervals not to exceed one year [34.33(f)(4)]	( ) Y ( ) N

Remarks.

12. NOTIFICATION AND REPORTS

a.	Licensee in compliance with [19.13] (reports to individuals)	( ) Y ( ) N ( ) N/A
b.	Licensee in compliance with [20.402] (theft or loss)	( ) Y ( ) N ( ) None
c.	Licensee in compliance with [20.403] AND [34.30 - eff. 01/10/91] (incidents)	( ) Y ( ) N ( ) None
d.	Licensee in compliance with [20.405] AND [34.30 - eff. 01/10/91] (overexposures)	( ) Y ( ) N ( ) None
e.	Annual reports furnished to NRC per [20.407]	( ) Y ( ) N
f.	Termination reports furnished to NRC per [20.408]	( ) Y ( ) N

Remarks.

13. POSTING AND LABELING

a. Radiation Areas properly posted [20.203(b)] ( ) Y ( ) N
b. High Radiation Areas properly posted [20.203(c)(1)] ( ) Y ( ) N
c. Use or storage areas posted "Caution - Radioactive Materials" [20.203(e)(1)] ( ) Y ( ) N
d. Containers or devices properly labeled [20.203(f)] ( ) Y ( ) N
e. NRC-3 "Notice to Workers" is posted [19.11] ( ) Y ( ) N
f. Parts 19 and 20 and license are posted or a notice indicating where documents can be examined is posted [19.11] ( ) Y ( ) N

Remarks.

14. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Procedures established and followed for picking up, receiving, and opening packages [20.205(d)] ( ) Y ( ) N

b. Incoming packages wiped per [20.205(b)] ( ) Y ( ) N

c. Incoming packages surveyed per [20.205(c)] ( ) Y ( ) N

d. Shipment of sources since last inspection ( ) N/A

(1) Used container authorized by license [L/C] ( ) Y ( ) N
(2) Shipping papers and package labeling properly completed [71.5] ( ) Y ( ) N
(3) Transfer(s) performed per [30.41] ( ) Y ( ) N

e. Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51] ( ) Y ( ) N

Remarks.

15. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM ( ) Y ( ) N

b. Shipments are:

( ) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

Remarks.

Complete only if shipments made since last inspection:

c. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A

(2) Package type used _____

(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A

(4) For DOT-55 packages, use is approved by NRC [173.416(a)] ( ) Y ( ) N ( ) N/A

(5) Other Type B packages used are approved [173.416(a)] ( ) Y ( ) N ( ) N/A

(6) Licensee has COCs on file with NRC [71.12(c)(1)] ( ) Y ( ) N ( ) N/A

(7) Licensee has a QA program approved by NRC [71.12(b)] ( ) Y ( ) N ( ) N/A

(8) For special form sources, performance test record on file [173.476(a)] ( ) Y ( ) N ( ) N/A

(9) Packages properly labeled [172.403, 173.441] ( ) Y ( ) N ( ) N/A

(10) Packages properly marked [173.200] ( ) Y ( ) N ( ) N/A

(11) Proper shipping papers prepared and used [172.200-204] ( ) Y ( ) N ( ) N/A

(12) Shipping papers readily accessible during transport [177.817(e)] ( ) Y ( ) N ( ) N/A

(13) Vehicles placarded as necessary [172.500, 504] ( ) Y ( ) N ( ) N/A

(14) Cargo blocked and braced [177.842(d)] ( ) Y ( ) N ( ) N/A

(15) Any incidents reported to DOT [171.15-16] ( ) Y ( ) N ( ) None

Remarks.

16. RECORDKEEPING FOR DECOMMISSIONING ( ) N/A

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

17. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee ( ) Y ( ) N

b. Licensee took appropriate action in response to Bulletins, INs, etc. ( ) Y ( ) N

Remarks.

18. INDEPENDENT MEASUREMENTS

a. Survey instrument used _____

b. NRC Serial No. _____

c. Last date of calibration _____

d. Inspector's measurements were compared to licensee's ( ) Y ( ) N

e. Describe the type and results of measurements:

19. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

20. LIST OF VIOLATIONS

21. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y ( ) N

b. RSO too busy with other assignments ( ) Y ( ) N

c. Insufficient staffing ( ) Y ( ) N

d. Radiation Safety Committee fails to meet or functions inadequately ( ) Y ( ) N ( ) N/A

e. Inadequate consulting services or inadequate audits ( ) Y ( ) N ( ) N/A

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

APPENDIX E

INDUSTRIAL/ACADEMIC INSPECTION FIELD NOTES*
Region ____

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority:

Program Code(s):

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection:
( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date _____ ( ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
( ) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date _____
(Signature)

Approved: _____ Date _____
(Signature)

* All areas indicated in field notes are not required to be addressed during each inspection.

1. ORGANIZATION

a. Briefly describe the organizational structure:

b. Organizational structure meets license requirements. [L/C] ( ) Y ( ) N

Remarks.

c. Licensee is required to have a Radiation Safety Committee ( ) Y ( ) N

(1) If so, does RSC fulfill license requirements [L/C] ( ) Y ( ) N
(2) Records maintained ( ) Y ( ) N

Remarks.

d. Radiation Safety Officer

(1) Authorized on license [L/C] ( ) Y ( ) N
(2) Fulfills duties as RSO ( ) Y ( ) N

Remarks.

2. INSPECTION HISTORY ( ) N/A - Initial inspection

a. Last inspection conducted on _____

b. Violations or deviations were identified ( ) Y ( ) N

c. Response letter or 591 dated _____

d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status

e. Any previous violations not corrected ( ) Y ( ) N

Explain.

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use ( ) Y ( ) N

b. If so, list location(s) inspected ( ) N/A

c. List those individuals contacted during inspection

*Indicates presence at exit meeting

d. Briefly describe scope, including types of use involving byproduct material, frequency of use, staff size, etc.

4. INTERNAL AUDITS OR INSPECTIONS

a. Audits are required by license condition ( ) Y ( ) N
b. Audits or inspections are conducted ( ) Y ( ) N

(1) Audits conducted by _____
(2) Frequency _____

c. Records maintained. ( ) Y ( ) N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] ( ) Y ( ) N

Remarks.

b. Training program required [L/C] ( ) Y ( ) N

(1) If so, briefly describe training program:

(2) Training program implemented ( ) Y ( ) N
(3) Retraining program required ( ) Y ( ) N
(4) Retraining program implemented ( ) Y ( ) N
(5) Records maintained ( ) Y ( ) N

Remarks.

6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application [L/C] ( ) Y ( ) N

Remarks.

b. Areas for storage and use of RAM

(1) Adequate method used to prevent an unauthorized individual from entering restricted area ( ) Y ( ) N

(2) RAM is secured to prevent unauthorized removal from an unrestricted area [20.207] ( ) Y ( ) N

Remarks.

c. Survey instruments ( ) N/A

(1) Appropriate operable survey instruments possessed ( ) Y ( ) N

(2) Calibration performed as required ( ) Y ( ) N

(3) Records maintained ( ) Y ( ) N

Remarks.

7. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive materials used in accordance with current procedures [L/C] ( ) Y ( ) N

b. Individuals understanding of current procedures is adequate [L/C]

(1) in general rules for safe use of RAM ( ) Y ( ) N
(2) in emergency procedures ( ) Y ( ) N

Remarks.

8. MATERIALS

a. Isotope, chemical form, quantity and use as authorized [L/C] ( ) Y ( ) N

Remarks.

b. Leak tests and Inventory

(1) Leak tests of sealed sources performed as required [L/C] ( ) Y ( ) N
(2) Inventory of RAM performed as required [L/C] ( ) Y ( ) N
(3) Records maintained ( ) Y ( ) N

Remarks.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Describe how packages are received and by whom: ( ) N/A

b. Opening procedures established and followed [20.205(d)] ( ) Y ( ) N
c. Incoming packages wiped per [20.205(b)] ( ) Y ( ) N
d. Incoming packages surveyed per [20.205(c)] ( ) Y ( ) N
e. Transfer(s) performed per [30.41] ( ) Y ( ) N
f. Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51] ( ) Y ( ) N

Remarks.

10. AREA SURVEYS ( ) N/A

Briefly describe area survey requirements and licensee's implementation [L/C]:

11. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier _____ Frequency _____

b. Supplier is NVLAP - approved ( ) Y ( ) N

c. Reports reviewed by _____ Frequency _____

d. NRC inspector reviewed personnel monitoring records for

period _____ to _____

e. NRC forms or equivalent

(1) NRC-4: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
(2) NRC-5: ( ) Y ( ) N Complete: ( ) Y ( ) N ( ) N/A
[20.401(a)]

f. List maximum exposures (millirem):

16. ENVIRONMENTAL MONITORING PROGRAM

a. Licensee has implemented an environmental monitoring program [L/C] ( ) Y ( ) N

b. Records maintained ( ) Y ( ) N

Remarks.

c. Briefly describe the licensee's environmental monitoring program:

17. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM ( ) Y ( ) N

b. Shipments are:

( ) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

Remarks.

Complete only if shipments made since last inspection:

c. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A

(2) Package type used _____

(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A

(4)	For DOT-55 packages, use is approved by NRC [173.416(a)]	( ) Y ( ) N ( ) N/A
(5)	Other Type B packages used are approved [173.416(a)]	( ) Y ( ) N ( ) N/A
(6)	Licensee has COCs on file with NRC [71.12(c)(1)]	( ) Y ( ) N ( ) N/A
(7)	Licensee has a QA program approved by NRC [71.12(b)]	( ) Y ( ) N ( ) N/A
(8)	For special form sources, performance test record on file [173.476(a)]	( ) Y ( ) N ( ) N/A
(9)	Packages properly labeled [172.403, 173.441]	( ) Y ( ) N ( ) N/A
(10)	Packages properly marked [173.200]	( ) Y ( ) N ( ) N/A
(11)	Proper shipping papers prepared and used [172.200-204]	( ) Y ( ) N ( ) N/A
(12)	Shipping papers readily accessible during transport [177.817(e)]	( ) Y ( ) N ( ) N/A
(13)	Vehicles placarded as necessary [172.500, 504]	( ) Y ( ) N ( ) N/A
(14)	Cargo blocked and braced [177.842(d)]	( ) Y ( ) N ( ) N/A
(15)	Any incidents reported to DOT [171.15-16]	( ) Y ( ) N ( ) None

Remarks.

18. RECORDKEEPING FOR DECOMMISSIONING ( ) N/A

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

Remarks.

12. PERSONNEL RADIATION PROTECTION - INTERNAL ( ) N/A

a. Potential for exposure of individuals to airborne RAM exists ( ) Y ( ) N
b. Monitoring for airborne radioactivity conducted [20.201(b) to meet 20.103] ( ) Y ( ) N
c. Records maintained [20.401 and L/C] ( ) Y ( ) N

d. Briefly describe licensee's monitoring system for airborne radioactivity [L\C]

e. Bioassay program implemented as described in correspondence with NRC ( ) Y ( ) N

Remarks.

13. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y ( ) N
b. Release in accordance with regulatory limits [20.106(a)] ( ) Y ( ) N

Remarks.

c. Describe waste disposal method(s) - solid and liquid:

d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below:

(1) Adequate control of waste in storage is maintained ( ) Y ( ) N
(2) Package is labeled and package integrity is adequately maintained ( ) Y ( ) N
(3) Adequate records of surveys and material accountability are maintained ( ) Y ( ) N

e. Disposal of waste in accordance with regulatory requirements [20.301] ( ) Y ( ) N
f. Records maintained [20.401(b)] ( ) Y ( ) N

Remarks.

14. NOTIFICATION AND REPORTS

a. Licensee in compliance with [19.13] (reports to individuals) ( ) Y ( ) N ( ) N/A
b. Licensee in compliance with [20.402] (theft or loss) ( ) Y ( ) N ( ) None
c. Licensee in compliance with [20.403] (incidents) ( ) Y ( ) N ( ) None
d. Licensee in compliance with [20.405] (overexposures) ( ) Y ( ) N ( ) None

Remarks.

15. POSTING AND LABELING

a. NRC-3 "Notice to Workers" is posted [19.11] ( ) Y ( ) N
b. Parts 19 and 20 and license are posted or a notice indicating where documents can be examined is posted [19.11] ( ) Y ( ) N
c. Other posting and labeling per [20.203] ( ) Y ( ) N

Remarks.

19. INDEPENDENT MEASUREMENTS

a. Survey instrument used _____

b. NRC Serial No. _____

c. Last date of calibration _____

d. Inspector's measurements were compared to licensee's ( ) Y ( ) N

e. Describe the type and results of measurements:

20. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee ( ) Y ( ) N

b. Licensee took appropriate action in response to Bulletins, INs, etc. ( ) Y ( ) N

Remarks.

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

22. LIST OF VIOLATIONS

23. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ( ) Y ( ) N

b. RSO too busy with other assignments ( ) Y ( ) N

c. Insufficient staffing ( ) Y ( ) N

d. Radiation Safety Committee fails to meet or functions inadequately ( ) Y ( ) N ( ) N/A

e. Inadequate consulting services or inadequate audits ( ) Y ( ) N ( ) N/A

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

APPENDIX F

COMMERCIAL IRRADIATOR INSPECTION FIELD NOTES
REGION _____

Inspection Report No. _____ License No. _____

Licensee (name and address) Docket No. _____

_____
_____
_____
_____

Licensee Contact _____ Telephone No. _____

Last Amendment No. _____ Date of Amendment _____

Priority : Program Code:

Date of Last Inspection _____

Date of This Inspection _____

Type of Inspection : ( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial ( ) Reinspection

Next Inspection Date _____ ( ) Normal ( ) Extended ( ) Reduced

Summary of Findings and Action:

( ) No violations, Clear 591 or regional letter issued
( ) Violations, 591 or Regional letter issued
( ) Previous Violations ( ) Action ( ) No Action

Inspector : _____ Date _____
(Signature)

Approved : _____ Date _____
(Signature)

1. ORGANIZATION

a. Management Structure

(1) Plant Manager involved in safety program? [L/C] ( ) Y ( ) N

(2) Plant Manager sets safety goals/objectives? [L/C] ( ) Y ( ) N

(3) Adequate budget and resources are provided to the safety program? ( ) Y ( ) N

(4) Corporate management supports safety through site visits, program reviews, and site support? [L/C] ( ) Y ( ) N

Remarks:

b. Radiation Protection

(1) Radiation protection function is separate from plant operations? [L/C] ( ) Y ( ) N

(2) A corporate policy exists which addresses radiation safety? [L/C] ( ) Y ( ) N

(3) A trained qualified RSO assigned? [L/C] ( ) Y ( ) N

(4) Radiation Protection procedures have been written and approved [L/C] ( ) Y ( ) N

Remarks:

c. Authorized Users

Authorized users are qualified through training ? [L/C] ( ) Y ( ) N

Remarks:

2. LICENSEE INTERNAL AUDITS

a. Does the Radiation Safety Officer (RSO) conduct radiation safety audits? [L/C] ( ) Y ( ) N

Frequency _____

b. Does corporate management conduct audits/reviews? [L/C] ( ) Y ( ) N

Frequency _____

c. Does the licensee conduct annual ALARA reviews? [L/C] ( ) Y ( ) N

d. Are audit and review findings discussed in safety meetings? [L/C] ( ) Y ( ) N

Remarks:

3. INSPECTION HISTORY

a. Were violations, unresolved items or deviations identified in previous inspections? ( ) Y ( ) N

b. Were licensee corrective actions adequate on previous inspection findings? ( ) Y ( ) N

Remarks:

4. TRAINING AND INSTRUCTIONS TO EMPLOYEES

a. Initial Radiation Worker/Operator Training

(1) A formal qualification/training program has been established and implemented. [L/C] ( ) Y ( ) N

(2) Required tests administered, test scores satisfactory, and records retained. [L/C] ( ) Y ( ) N

(3) Training program is adequate for intended purpose and contains sufficient technical depth. [L/C] ( ) Y ( ) N

(4) Management periodically reviews training program implementaion. [L/C] ( ) Y ( ) N

b. Retraining Program

(1) A formal program has been established to retrain radiation workers/ operators. [L/C] ( ) Y ( ) N

(2) Retraining records are retained and reflect adequate program implementation. [L/C] ( ) Y ( ) N

c. General Training

(1) Instruction to workers provided [19.12] ( ) Y ( ) N

(2) Instruction provided to ancillary personnel (security, custodial, maintenance, etc.) [L/C] ( ) Y ( ) N

Remarks:

5. RADIATION PROTECTION PROCEDURES

a. Have operating and emergency evacuating procedures been developed and implemented? [L/C] ( ) Y ( ) N

b. Are manufacturer's instructions for devices used and available? [L/C] ( ) Y ( ) N

c. Does the licensee maintain a logbook for recording operational data? [L/C] ( ) Y ( ) N

d. Is access controlled to high radiation areas? [20.203(c)]

(1) postings ( ) Y ( ) N
(2) locks/barriers ( ) Y ( ) N
(3) interlocks ( ) Y ( ) N

e. Are interlocks checked periodically for operability? [L/C] ( ) Y ( ) N

f. Are interlocks designed such that it is difficult to tamper or intentionally defeat them? [L/C] ( ) Y ( ) N

g. Are restricted areas established, posted, and properly controlled? [20.203] ( ) Y ( ) N

h. Are security measures in place to control or protect materials in storage? [20.207] ( ) Y ( ) N

i. Is entrance key attached to hand held survey meter? [L/C] ( ) Y ( ) N

Remarks:

6. MATERIALS, FACILITIES, AND INSTRUMENTS

a. Is the licensee in possession of the authorized type, quantity, and form of material? [L/C] ( ) Y ( ) N

b. Are the materials being used as authorized? [L/C] ( ) Y ( ) N

c. Are appropriate survey meters on hand and operable? [L/C] ( ) Y ( ) N

d. Are survey meters calibrated at the required frequency? [L/C] ( ) Y ( ) N

e. Are fixed process or area monitors operable and calibrated at the required frequency? [L/C] ( ) Y ( ) N

f. Is source shroud in place and in good repair? [L/C] ( ) Y ( ) N

g. Type of irradiator: ( ) carrier ( ) tote ( ) pallet

h. Manufacturer and model: _____

_____

_____

i. Mode of operation: ( ) continuous ( ) batch

Remarks:

7. SOURCE LOADING AND UNLOADING

a. Are procedures developed and implemented [L/C] ( ) Y ( ) N

b. Are transfers of byproduct material proper? [30.41] ( ) Y ( ) N

c. Are labels and packaging material appropriate? [71.5] ( ) Y ( ) N

d. Are records of receipt, transfer, storage survey, and monitoring maintained? [30.51] ( ) Y ( ) N

e. Does licensee know the position (by serial number and activity) of all sources? [L/C] ( ) Y ( ) N

Remarks:

8. PERSONNEL PROTECTION - EXTERNAL

a. Personnel monitoring control; minimize exposures, control of accumulated dose [20.101,102,104,202] ( ) Y ( ) N

b. Dosimetry supplier: _____

c. Frequency of exchange: _____

d. Type of dosimeters: _____

e. Maximum exposures (W.B. and extremity) :

f. Number of persons monitored: _____

g. Surveys conducted [20.201] ( ) Y ( ) N

h. Frequency, results, records [20.401] _____

_____

_____

i. Levels in Unrestricted Areas [20.105] _____

Remarks:

9. LEAK TESTS/SOURCE INTEGRITY EVALUATIONS

a. Are leak tests and/or source integrity evaluations conducted? [L/C] ( ) Y ( ) N

(1) Are the tests conducted at regular intervals? [L/C] ( ) Y ( ) N

(2) Is the testing method sufficient to detect leakage or source integrity problem? [L/C] ( ) Y ( ) N

b. Is a water chemistry program established and procedures developed? [L/C] ( ) Y ( ) N

(1) Have chemical parameters and sampling frequency been identified? [L/C] ( ) Y ( ) N

(2) Have appropriate limits and action levels been established? [L/C] ( ) Y ( ) N

(3) Does the chemical sampling program include the following? [L/C]

- ° total and suspended solids (conductivity) ( ) Y ( ) N
- ° pH ( ) Y ( ) N
- ° pool clarity ( ) Y ( ) N
- ° chlorides/fluorides ( ) Y ( ) N

c. Is the pool cleanup and cooling system operated as designed? ( ) Y ( ) N

d. Are demineralizers used for pool cleanup? [L/C] ( ) Y ( ) N

(1) Are demineralizers always in operation or are they used intermittently? [L/C] ( ) Y ( ) N

(2) Are radiation monitors placed on or adjacent to the demineralizer? [L/C] ( ) Y ( ) N

(3) Are alarm set points established for those monitors? [L/C] ( ) Y ( ) N

(4) Does the monitor alarm in the control room? [L/C] ( ) Y ( ) N

e. Are records maintained of leak tests and source integrity? [L/C] ( ) Y ( ) N

Remarks:

10. RELEASE OF EFFLUENTS [20.106]

Does licensee evaluate:

a. water leakage from pool? ( ) Y ( ) N
b. effluent from regeneration of demineralizer? ( ) Y ( ) N
c. pool sediment? ( ) Y ( ) N
d. release of demineralizer to nonlicensed service company? ( ) Y ( ) N

Remarks:

11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM ( ) Y ( ) N

b. Shipments are:

( ) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

Remarks.

Complete only if shipments made since last inspection:

c. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A

(2) Package type used _____

(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A

(4) For DOT-55 packages, use is approved by NRC [173.416(a)] ( ) Y ( ) N ( ) N/A

(5)	Other Type B packages used are approved [173.416(a)]	( ) Y ( ) N ( ) N/A
(6)	Licensee has COCs on file with NRC [71.12(c)(1)]	( ) Y ( ) N ( ) N/A
(7)	Licensee has a QA program approved by NRC [71.12(b)]	( ) Y ( ) N ( ) N/A
(8)	For special form sources, performance test record on file [173.476(a)]	( ) Y ( ) N ( ) N/A
(9)	Packages properly labeled [172.403, 173.441]	( ) Y ( ) N ( ) N/A
(10)	Packages properly marked [173.200]	( ) Y ( ) N ( ) N/A
(11)	Proper shipping papers prepared and used [172.200-204]	( ) Y ( ) N ( ) N/A
(12)	Shipping papers readily accessible during transport [177.817(e)]	( ) Y ( ) N ( ) N/A
(13)	Vehicles placarded as necessary [172.500, 504]	( ) Y ( ) N ( ) N/A
(14)	Cargo blocked and braced [177.842(d)]	( ) Y ( ) N ( ) N/A
(15)	Any incidents reported to DOT [171.15-16]	( ) Y ( ) N ( ) None

Remarks.

12. NOTIFICATIONS AND REPORTS

a.	To individuals [19.13]	( ) Y ( ) N
b.	Overexposures, excessive levels and concentrations, incidents [20.403,405]	( ) Y ( ) N ( ) None
c.	Personnel exposures and monitoring termination reports [20.407,408]	( ) Y ( ) N ( ) None
d.	Theft or loss of licensed material [20.402]	( ) Y ( ) N ( ) None

Remarks:

13. POSTING OF NOTICES

a. Parts 19 and 20, license and documents, procedures, and Notices of Violations [19.11] ( ) Y ( ) N

b. Form NRC-3 [19.11] ( ) Y ( ) N

Remarks:

14. EMERGENCY PREPAREDNESS

a. Has an emergency plan and general implementing procedures been developed? [L/C] ( ) Y ( ) N

b. Has the plan been coordinated with appropriate offsite support authorities? (e.g. local government, emergency medical, state health authorities) [L/C] ( ) Y ( ) N

c. Are notification procedures adequate and up to date? ( ) Y ( ) N

d. Are management, RSO, and offsite authorities listed on the notification procedure? [L/C] ( ) Y ( ) N

e. Are licensee employees trained in emergency response activities? [L/C] ( ) Y ( ) N

f. Are drills conducted? [L/C] ( ) Y ( ) N

If "Yes," are the drills critiqued? ( ) Y ( ) N

g. Are offsite officials involved in drills and training? [L/C] ( ) Y ( ) N

Remarks:

15. PRODUCT MONITORING

a. Has the licensee established a program for periodically monitoring irradiated products for potential contamination? [L/C] ( ) Y ( ) N

If "Yes," does the program include:

(1) direct radiation surveys? [L/C] ( ) Y ( ) N

(2) removable contamination surveys? [L/C] ( ) Y ( ) N

b. Have action limits been established for product contamination levels? [L/C] ( ) Y ( ) N

c. Are the licensee's survey techniques and methods sensitive enough to detect the established contamination level? [L/C] ( ) Y ( ) N

Remarks:

16. RECORDKEEPING FOR DECOMMISSIONING

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

17. NRC CONFIRMATORY MEASUREMENTS [10 CFR 20.105,201] ( ) N/A

a. Meter used:

b. Calib. Date: _____

c. Serial No: _____

d. Describe measurements taken and results:

18. INDEPENDENT INSPECTION EFFORT

Scope of program: (Results)

19. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

20. LIST OF VIOLATIONS

f. Licensee makes return shipments of radiopharmacy doses ( ) Y ( ) N ( ) N/A

(1) If YES, licensee assumes responsiblity of all shipper requirements ( ) Y ( ) N

(2) If NO, describe arrangements made between licensee and radiopharmacy as to performance of shipper responsibilities:

20. RECORDKEEPING FOR DECOMMISSIONING

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

b. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks.

21. INDEPENDENT MEASUREMENTS

a. Survey instrument used _____

b. NRC Serial No. _____

c. Last date of calibration _____

d. Inspector's measurements were compared to licensee's ( ) Y ( ) N

e. Describe the type and results of measurements:

22. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee ( ) Y ( ) N

b. Licensee took appropriate action in response to Bulletins, INs, etc. ( ) Y ( ) N

Remarks.

23. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

24. LIST OF VIOLATIONS

21. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) _____ _____ _____

Inspector _____

Inspection Date _____

a.	Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight	( ) Y ( ) N
b.	RSO too busy with other assignments	( ) Y ( ) N
c.	Insufficient staffing	( ) Y ( ) N
d.	Radiation Safety Committee fails to meet or functions inadequately	( ) Y ( ) N ( ) N/A
e.	Inadequate consulting services or inadequate audits	( ) Y ( ) N ( ) N/A

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

17

ATTACHMENT A DRAFT

INTERIM FIELD NOTES

QUALITY MANAGEMENT (QM) PROGRAM

[Note - "Yes" and "No" answers may indicate a "Weakness (W)" or "Substantial Weakness (SW)" based on their significance. If the question is not applicable, indicate "NA"]

1. GENERAL

a. License number(s):_____

b. Docket number(s):_____

c. Last inspection date(s):_____

d. Current inspection date(s):_____

2. MODALITIES

a. Procedures the licensee performs:

(1) Teletherapy	Y	N
(2) Gamma Stereotactic Radiosurgery	Y	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N
(4) All Other Brachytherapy	Y	N
(5) NaI I-125 or I-131 >30 microCi	Y	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N

3. PROGRAM

a. Licensee has a written QM program, as applicable, that covers all policies/procedures that require a written directive and program review [35.32(a) and (b)(1)] Y N (SW)

b. Written QM program and certification (for existing licensee) submitted to NRC [35.32(f)(2)] Y N
Date_____

c. Recent version with latest modifications submitted to NRC [35.32(e)] Y N
Date_____

Remarks:

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4. SUPERVISION

a. Supervised individual(s) instructed in the QM program applicable to the modality of use [35.25(a)(1)] Y N (SW)

(1) If any individual(s) has not received training, document their name and position. Additionally, briefly describe the reasons as stated by the individual, the RSO, and the supervising authorized user:

Remarks:

5. SAMPLING

a. Determine the number of administrations to sample and review:	Total Admin.	Target* Sample	No. Reviewed
* Refer to Appendix: Table I and II			
(1) Teletherapy	_____	_____	_____
(2) Gamma Stereotactic Radiosurgery	_____	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy	_____	_____	_____
(4) All Other Brachytherapy	_____	_____	_____
(5) NaI I-125 or I-131 >30 microCi	_____	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5)	_____	_____	_____

Remarks:

6. OBJECTIVES

[Note - Under each modality for Section 6 (Objectives 1 and 2), 1 miss is considered as "Satisfactory (S)", 2 misses indicates a "Weakness (W)", and 3 or more misses indicates a "Failure (F)" or "Substantial Weakness (SW)"]

OBJECTIVE 1

a. How many written directives, as applicable, were missing for the following administrations [35.32(a)(1) and (d)(1)]:

	Misses	S,W,SW
(1) Teletherapy	_____	_____
(2) Gamma Stereotactic Radiosurgery	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy	_____	_____
(4) All Other Brachytherapy	_____	_____
(5) NaI I-125 or I-131 >30 microCi	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5)	_____	_____

Remarks:

b. How many written directives, as applicable, did not contain the following required information [35.2]:

	Misses	S,W,SW
(1) Teletherapy (total dose, dose per fraction, treatment site, and overall treatment period)	_____	_____
(2) Gamma Stereotactic Radiosurgery (target coordinates, collimator size, plug pattern, and total dose	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy (radioisotope, treatment site, and total dose)	_____	_____
(4) All Other Brachytherapy:		
(a) Prior to implantation (radioisotope, number of sources, and source strengths)	_____	_____
and		
(b) After implantation, but prior to completion of procedure (radioisotope, treatment site, and total source strength and exposure time (or, total dose)	_____	_____
(5) NaI I-125 or I-131 >30 microCi (dosage)	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5) - (radiopharmaceutical, dosage, and route of administration)	_____	_____

Remarks:

c. Are exceptions to written directives documented [footnote to 35.32(a)(1)]:

	Misses	S.W.SW
(1) Written revisions	_____	_____
(2) Oral revisions	Y	N
(3) Oral directives	Y	N

Remarks:

OBJECTIVE 2

a. Prior to each administration, does the licensee use more than one method to verify the patient's identity as the individual named in the written directive [35.32(a)(2)]:

	Misses	S.W.F
(1) Teletherapy	_____	_____
(2) Gamma Stereotactic Radiosurgery	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy	_____	_____
(4) All Other Brachytherapy	_____	_____
(5) NaI I-125 or I-131 >30 microCi	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5)	_____	_____

Remarks:

OBJECTIVE 3

a. Does the licensee implement procedures for verifying that the final plans of treatment and related calculations are in accordance with the respective written directives [35.32(a)(3)]:

(1) Teletherapy	Y	N (SW)
(2) Gamma Stereotactic Radiosurgery	Y	N (SW)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (SW)
(4) All Other Brachytherapy	Y	N (SW)

Remarks:

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b. Does the licensee implement procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations) [35.32(a)(3)]:

(1) Teletherapy	Y	N (W)
(2) Gamma Stereotactic Radiosurgery	Y	N (W)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (W)
(4) All Other Brachytherapy	Y	N (W)

Remarks:

c. Has the licensee implemented procedures for performing acceptance testing (based on licensee's specific needs and applications) on each treatment planning or dose calculating computer program that could be used for dose calculations [35.32(a)(3)]:

(1) Teletherapy	Y	N (W)
(2) Gamma Stereotactic Radiosurgery	Y	N (W)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (W)
(4) All Other Brachytherapy	Y	N (W)

Remarks:

OBJECTIVE 4

a. Does the licensee implement procedures to verify, before administering each radiation dose or radiopharmaceutical dosage, that the specific details of the administration are in accordance with the written directive [35.32(a)(4)]:

(1) Teletherapy	Y	N (SW)
(2) Gamma Stereotactic Radiosurgery	Y	N (SW)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (SW)
(4) All Other Brachytherapy	Y	N (SW)
(5) NaI I-125 or I-131 >30 microCi	Y	N (SW)
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N (SW)

Remarks:

OBJECTIVE 5

a. Does the licensee implement procedures to identify and evaluate any unintended deviations (e.g., mistakes, errors, or omissions) from the written directive [35.32(a)(5)]:

(1) Teletherapy	Y	N (SW)
(2) Gamma Stereotactic Radiosurgery	Y	N (SW)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (SW)
(4) All Other Brachytherapy	Y	N (SW)
(5) NaI I-125 or I-131 >30 microCi	Y	N (SW)
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N (SW)

Remarks:

(a)(1) Briefly describe the licensee's monitoring and evaluation process used to identify unintended deviations (e.g., errors, mistakes, or omissions) from the written directive:

(i) Teletherapy

(ii) Gamma Stereotactic Radiosurgery

(iii) High-Dose-Rate Remote Afterloading Brachytherapy

(iv) All Other Brachytherapy

(v) NaI I-125 or I-131 >30 microCi

(vi) Therapeutic Radiopharmaceutical Other Than (v)

b. Did the licensee identify and evaluate any unintended deviations (e.g., mistakes, errors, or omissions) from the written directive since the last inspection [35.32(a)(5)]:

(1) Teletherapy	Y	N
(2) Gamma Stereotactic Radiosurgery	Y	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N
(4) All Other Brachytherapy	Y	N
(5) NaI I-125 or I-131 >30 microCi	Y	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N

Remarks:

c. Describe any unintended deviations from the written directive, identified by yourself, that occurred even though the policies/procedures in the licensee's QM program were followed [35.32(a)(5)]:

(1) Teletherapy

(2) Gamma Stereotactic Radiosurgery

(3) High-Dose-Rate Remote Afterloading Brachytherapy

(4) All Other Brachytherapy

(5) NaI I-125 or I-131 >30 microCi

(6) Therapeutic Radiopharmaceutical Other Than (5)

d. Does the licensee implement procedures to ensure appropriate (corrective) action is taken after any unintended deviations from the written directive are identified and evaluated [35.32(a)(5)]:

(1) Teletherapy	Y	N (W)
(2) Gamma Stereotactic Radiosurgery	Y	N (W)
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N (W)
(4) All Other Brachytherapy	Y	N (W)
(5) NaI I-125 or I-131 >30 microCi	Y	N (W)
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N (W)

Remarks:

7. RECORDABLE EVENTS AND MISADMINISTRATIONS

a. Did the licensee identify any recordable events since the last inspection [35.32(c) and 35.2]: Y N

Remarks:

b. Does the licensee implement procedures to evaluate and respond to each recordable event within 30 days after discovery [35.32(c)]: Y N

(1) Assemble relevant facts including the cause, Y N
and
(2) Identify corrective action to prevent recurrence, Y N
and
(3) Retain a record of (1) and (2) Y N

Remarks:

c. Were any recordable events identified by yourself that the licensee failed to identify [35.32(c) and 35.2]:

(1) Teletherapy	Y (W)	N
(2) Gamma Stereotactic Radiosurgery	Y (W)	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y (W)	N
(4) All Other Brachytherapy	Y (W)	N
(5) NaI I-125 or I-131 >30 microCi	Y (W)	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y (W)	N

Remarks:

d. Did the licensee report any misadministrations since the last inspection [35.33(a)]: Y N

If "Yes," answer the following:

(1) Did licensee notify NRC within next calendar day after discovery [35.33(a)(1)], Y N
and
(2) Submit written report to NRC within 15 days after discovery [35.33(a)(2)], Y N
and
(3) Written report contains required information, including

(a) Licensee's name and prescribing physicians's name Y N

and

(b) Brief description of event and why event occurred Y N

and

(c) Effect on patient Y N

and

(d) Improvements needed and actions taken to prevent recurrence Y N

and

(e) Whether patient or responsible relative (or guardian) was notified Y N

and

(f) If patient was not notified, why not Y N

and

(g) If patient was notified, what information was provided Y N

(3) Did licensee notify referring physician within 24 hours after discovery [35.33(a)(3)] Y N

and

(4) Did licensee notify patient* within 24 hours after discovery [35.33(a)(3)] Y N

*Note: Referring physician may choose to inform the patient in lieu of licensee notification, or not inform the patient based on medical judgement

If licensee did not notify patient:

(a) Did referring physician inform patient Y N

If referring physician did not inform patient:

(b) Did referring physician believe telling patient would be harmful Y N

If "Yes," gather as much information as possible from the licensee concerning the rationale or reasons for the referring physician's decision**

**Note: Refer to Manual Chapter 1360 for guidance regarding use of a medical consultant to evaluate the referring physicians decision not to inform the patient

Remarks:

e. If patient was notified, did licensee furnish written report to patient within 15 days after discovery of misadministration [35.33(a)(4)]: Y N

(1) Copy of report submitted to NRC Y N

or

(2) Brief description of event and consequences as they may affect patient, including a statement that report sent to NRC can be obtained from licensee Y N

Remarks:

f. Record of each misadministration maintained by licensee for five years [35.33(b)] Y N

g. Record of each misadministration contains required information [35.33(b)], including

(1) Names of all individuals involved Y N

and

(2) Patient's social security number or identification number if one assigned Y N

and

(3) Brief description of event and why event occurred Y N

and

(4) Effect on patient Y N

and

(5) Improvements needed and actions taken to prevent recurrence Y N

Remarks:

h. Did the licensee identify any misadministrations that were not subsequently reported [35.33(a)]: Y (SF) N

If "Yes," briefly describe the reasons given by the RSO, supervising authorized user, and any other involved individuals for not reporting

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i. Were any misadministrations identified by yourself that the licensee failed to identify [35.2 and 35.33]:

(1) Teletherapy	Y (SF)	N
(2) Gamma Stereotactic Radiosurgery	Y (SF)	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y (SF)	N
(4) All Other Brachytherapy	Y (SF)	N
(5) NaI I-125 or I-131 >30 microCi	Y (SF)	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y (SF)	N

Remarks:

8. RECORDS

[Note - Under each modality for Section 8, 1 miss is considered as "Satisfactory (S)", 2 misses indicates a "Weakness (W)", and 3 or more misses indicates a "Failure (F)"]

a. How many times did the licensee prepare a written directive, but failed to maintain a record for the following administrations [35.32(d)(1)]:

	Misses	S,W,F
(1) Teletherapy	_____	_____
(2) Gamma Stereotactic Radiosurgery	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy	_____	_____
(4) All Other Brachytherapy	_____	_____
(5) NaI I-125 or I-131 >30 microCi	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5)	_____	_____

Remarks:

b. How many times did the licensee fail to retain a record of each administered radiation dose or radiopharmaceutical dosage for the following administrations [35.32(d)(2)]:

	Misses	S,W,F
(1) Teletherapy	_____	_____
(2) Gamma Stereotactic Radiosurgery	_____	_____
(3) High-Dose-Rate Remote Afterloading Brachytherapy	_____	_____
(4) All Other Brachytherapy	_____	_____
(5) NaI I-125 or I-131 >30 microCi	_____	_____
(6) Therapeutic Radiopharmaceutical Other Than (5)	_____	_____

Remarks:

9. PERIODIC REVIEWS

a. How many times did the licensee fail to conduct a review of the QM program at intervals no greater than 12 months [35.32(b)(1)]: _____

b. When was the last review performed:
Date_____

c. Did the review include each applicable program area [35.32(b)(1)]:

(1) Teletherapy	Y	N
(2) Gamma Stereotactic Radiosurgery	Y	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N
(4) All Other Brachytherapy	Y	N
(5) NaI I-125 or I-131 >30 microCi	Y	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N

Remarks:

d. Did the licensee evaluate each review to determine the effectiveness of the QM program [35.32(b)(2)]: Y N

If "No," describe the reasons given by the RSO, supervising authorized user, and other responsible individuals for the failure to evaluate each review

e. Based on the evaluation of each review, did the licensee, if required, make modifications to meet Objectives 1 - 5 in Section 6 [35.32(b)(2)]: Y N

If "Yes," briefly describe the modifications

If "No," describe the reasons given by the RSO, supervising authorized user, and other responsible individuals for the failure to make necessary modifications

f. Did the licensee retain records of each review, including the evaluation and findings [35.32(b)(3)]: Y N

If "No," describe the reasons given by the RSO, supervising authorized user, and other responsible individuals for the failure to retain a record

g. Did the review include, for each applicable program area, an evaluation of the following:

(1) A representative sample of patient administrations [35.32(b)(i)] Y N

and

(2) All recordable events [35.32(b)(ii)] Y N

and

(3) All misadministrations [35.32(b)(iii)] Y N

If "No," describe the reasons given by the RSO, supervising authorized user, and other responsible individuals for the failure to include an evaluation of (1) - (3)

10. MODIFICATIONS

a. Did the licensee choose to make modifications to the QM program to increase the program's efficiency (provided effectiveness not decreased) [35.32(e)]: Y N

If "Yes," were the modifications furnished to the NRC within 30 days after modification was made [35.32(e)]: Y N

If "No," describe the reasons given by the RSO, supervising authorized user, and other responsible individuals for the failure to furnish the modification

11. RESULTS OF REVIEW

a. Briefly describe the overall implementation of the QM Program and summarize the inspection findings:

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APPENDIX

1. TARGET SAMPLE

Use Table I to determine approximately how many administrations to sample and review (target sample) for each modality listed (e.g., NaI I-125 or I-131 >30 microCi) in Section 6: Objective 1.a - c, and Section 8.a - b of the Interim Field Notes. Record this information in Section 5.a.

Table I

IF	THEN
Total Administrations Are	Target Sample Is
1 to 10	All
11 to 100	10
>100	10%

2. FURTHER SAMPLING

Use Table II to determine approximately how many more administrations to sample and review (new target sample) for each modality listed in Section 6: Objective 1.a - c, and Section 8.a - b of the Interim Field Notes if two or more misses* are identified in the target sample (Table I). Record this information in Section 5.a.

Table II

IF	AND	THEN
Total Administrations Are	Trigger Level Is	New Target Sample Is
1 to 50	2 or > misses	All
51 to 100	2 or > misses	50
>100	2 or > misses	50%

*Misses are defined as omissions or failures to meet specific requirements in the objective.

ADDENDUM DRAFT

INTERIM FIELD NOTES

QUALITY MANAGEMENT (QM) PROGRAM

[Note - "Yes" and "No" answers may indicate a "Weakness (W)" or "Substantial Weakness (SW)" based on their significance. If the question is not applicable, indicate "NA"]

1. GENERAL

a. License number(s):_____

b. Docket number(s):_____

c. Last inspection date(s):_____

d. Current inspection date(s):_____

2. MODALITIES

a. Procedures the licensee performs:

(1) Teletherapy	Y	N
(2) Gamma Stereotactic Radiosurgery	Y	N
(3) High-Dose-Rate Remote Afterloading Brachytherapy	Y	N
(4) All Other Brachytherapy	Y	N
(5) NaI I-125 or I-131 >30 microCi	Y	N
(6) Therapeutic Radiopharmaceutical Other Than (5)	Y	N

3. PROGRAM

a. Licensee has a written QM program, as applicable, that covers all policies/procedures that require a written directive and program review [35.32(a) and (b)(1)] Y N (SW)

b. Written QM program and certification (for existing licensee) submitted to NRC [35.32(f)(2)] Y N
Date_____

Remarks:

4. SUPERVISION

a. Supervised individual(s) instructed in the QM program applicable to the modality of use [35.25(a)(1)] Y N (SW)

(1) If any individual(s) has not received training, document their name and position. Additionally, briefly describe the reasons as stated by the individual, the RSO, and the supervising authorized user:

Remarks: