NUCLEAR MEDICINE PROGRAMS

PROGRAM APPLICABILITY: 2800

2800/029-01 OBJECTIVES

01.01 To determine that licensed activities are conducted safely.

01.02 To determine that licensed activities are conducted in compliance with applicable U.S. Nuclear Regulatory Commission (NRC) regulatory requirements.

01.03 To focus material inspections on risk and licensee's program performance (outcome). Licensee performance is directly related to selected Focus Elements (FEs) that are required to be inspected by this temporary instruction (TI).

01.04 To enhance inspection efficiency while performing an effective inspection and minimizing impact on licensees' operations and resources.

NOTE: Under no circumstances will an NRC Inspector knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent and unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy. Discussion of the inspector's observations of work activities with the workers and interviews with the workers should not occur during the preparation for, or delivery of medical treatment. Inspector's interviews should not be conducted in the presence of the patient.

2800/029-02 BACKGROUND

The purpose of this TI is to implement Nuclear Material Safety and Safeguards (NMSS) initiatives to streamline the inspection process by focusing the inspection efforts on radiological safety. This TI applies only to nuclear medicine programs licensed in accordance with 10 CFR 35.100, 35.200, and 35.300, involving use of unsealed material. (Programs that include additional areas, such as 10 CFR 35.400 or 35.500, involving use of sealed sources for diagnosis or therapy, are not to be inspected under this TI.) Since most nuclear medicine operations involving use of unsealed

material, when conducted with basic safety precautions, are inherently of low radiological risk, a limited number of safety-based and outcome-oriented FEs were chosen to be verified by the inspector. To perform effective inspections, and minimize potential impacts on licensees' resources, the extent and the depth of the verification of the FEs should be commensurate with the potential radiological risk involved with the licensee's program. In examining specific requirements for FE verification, note that some requirements may be associated with several FEs.

To effectively implement this TI, the inspector should shift the primary focus of inspection effort from a detailed examination of the licensee's processes, policies, and procedures, to a review of program outcomes, through verification of FEs. If the FEs' desired outcomes are not achieved, the inspector then should examine the licensee's processes, policies, and procedures. Such examination should include additional, more detailed interviews of the licensee's staff; observation of the licensee's activities; and performance of independent measurements and assessments. Identifying the causes and root-causes that may have contributed to the licensee's failure to achieve the desired performance outcome, while principally the responsibility of the licensee, is a goal of such an inspection-related examination. On the other hand, if the desired outcomes were achieved by the licensee, in a given area, no further inspection effort would be expended in this area.

FEs will be used as a metric to assess licensee performance. Performance is adequate if the FEs are met. Failure to meet an FE indicates that licensed activities are not being conducted safely, warranting increased regulatory scrutiny.

For nuclear medicine program inspections, the specific desired outcomes for the FEs, as listed in Section 03.03, and the inspection approach utilized in this TI, reflect the overarching desired outcome of maintaining safety, by minimizing the number of:

overexposures of workers or members of the general public;
misadministrations;
unauthorized offsite releases or losses of licensed material; and
unauthorized uses of licensed material.

The performance goals being developed for the nuclear materials safety strategic arena are:

- foremost, maintaining safety and safeguards and protecting the environment;
- reducing unnecessary regulatory burden on stakeholders;
- increasing public confidence;
- more effective, efficient, and realistic activities and decisions.

The specific desired outcomes for the FEs reflect all of these performance goals.

The inspector should look at licensee performance since last inspection.

2800/029-03 INSPECTION REQUIREMENTS

03.01 FEs

The inspector will verify that the NRC-licensed nuclear medicine activities are conducted safely and in compliance with the applicable NRC requirements through examination of program performance

results and outcomes. The inspector should determine that the licensee has achieved the desired outcomes for the FEs. The inspector's verification of the FEs would be achieved through review of the NRC nuclear material events database (NMED); observation of ongoing activities; interviews with personnel; independent measurements; and a selective review of licensee's records (sampling, in accordance with current inspection guidance). The extent and depth of the inspector verification of the FEs are commensurate with the potential risk associated with licensee operations and the inspector's initial findings regarding the FEs. The FEs to be inspected are:

Adequate Program Surveillance and Corrective Action
Knowledgeable Staff and Management
Occupational and Public Doses within Regulatory Limits
Adequate Security and Control of Licensed Material
Use of Licensed Material Only as Authorized
Radiopharmaceutical Administrations Conforming to the Physician's Written Directives

03.02 Entrance Briefing

After arriving on site, the inspector should inform licensee's management and radiation safety staff, including the Radiation Safety Officer (RSO), if available, of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical.

03.03 Verification of FEs

a. Adequate Program Surveillance and Corrective Action

Desired outcome: Problems associated with maintenance of equipment and radiation safety processes occur infrequently; when they do, they are properly identified and characterized, and effective corrective actions are implemented.

The licensee's ability to identify, correct, and take appropriate action to prevent recurrence of significant program deficiencies is important to inspection and enforcement and to the licensee in providing reasonable assurance that NRC-licensed materials are being used in a safe manner. This FE is to be verified through selective review of licensee audit records or other self-identification activities (e.g., RSO/consultant audits, Radiation Safety Committee (RSC) minutes, annual program reviews, etc.); selective review of radiation survey records; assessment of the adequacy of radiation safety resources (financial and personnel); and through interviews of the licensee's personnel overseeing the radiological safety program, such as licensee's senior management, authorized users (AUs), technologist(s), RSO, and members of the RSC. These personnel should demonstrate clear awareness of the status of materials receipt, control, transfer, storage, use, and disposal, as appropriate. The licensee should communicate to its appropriate personnel the deficiencies and root-causes which it identifies, with corrective actions to prevent recurrence.

In evaluating this FE, the inspector should look specifically at areas identified in Sections 03.03.b through 03.03.f. The inspector should also verify that NRC-identified violations or licensee-identified radiation safety issues have been properly corrected and did not recur, or that appropriate and timely corrective actions are in progress. The inspector should also assess the licensee's response to radiation safety issues and concerns addressed in information notices, bulletins, NRC newsletters, and other similar NRC-published

information provided to the licensee, that, if not properly addressed by the licensee, could result in violations of NRC requirements that would cause the licensee to not meet an FE.

b. Knowledgeable Staff and Management

Desired outcome: Information-based errors, associated with equipment usage and radiation safety processes, do not occur.

The inspector should verify that the licensee's staff is knowledgeable in radiological safety precautions, as applicable to the staff's duties and responsibilities. The licensee's staff should be familiar with the routine operating and emergency procedures necessary to protect itself, other personnel, patients, and members of the public from unnecessary exposure to radiation and/or radioactive materials. The inspector should interview the licensee's staff and directly observe staff performance of work practices and other ongoing activities. Consider the implications of lack of knowledge on other FEs.

The licensee's staff should demonstrate knowledge in: (1) basic radiological safety precautions such as proper use of time, distance, and shielding; (2) the storage, transfer, and use of licensed materials; (3) the applicable provisions of the NRC regulations and license requirements for the protection of personnel from unnecessary exposure to radiation and/or radioactive materials; (4) its responsibility to promptly report to licensee management any condition that may lead to, or cause a violation of, NRC's regulations and licenses, or unnecessary radiation exposure to personnel, patients, and/or members of the public; (5) appropriate response to unusual radiological occurrences or safety equipment malfunctions; (6) proper use of equipment such as dose calibrators, survey meters, well counters; and (7) use of written directives. The extent and depth of the licensee staff knowledge should be commensurate with the level of potential risk (i.e., use of diagnostic unit doses of technetium-99m vs. use of therapeutic quantities of iodine-131) involved and staff duties and responsibilities.

c. Occupational and Public Doses within Regulatory Limits

Desired outcome: No overexposures of workers or the general public; unnecessary exposure is avoided.

The inspector is to verify that occupational and public doses are maintained below the regulatory limits in 10 CFR Part 20 and in accordance with basic "As Low as is Reasonably Achievable" (ALARA) risk-based principles. Although the inspector is required to verify this FE through examination of outcomes (doses), it is necessary that the licensee's dosimetry program, use of dosimetric devices, dose assessment, and evaluations provide reasonable assurance that occupational and public doses are kept below the applicable regulatory limits and are ALARA. The inspector is to validate the outcome for this FE through observation of work practices, consideration of the quantities and types of material used, review of incidents, personnel interviews, and review of applicable records.

The extent and depth of inspection efforts should be commensurate with the risk involved.

d. Adequate Security and Control of Licensed Material

Desired outcome: No losses or unauthorized releases of licensed material with potential to deliver or result in overexposures.

The inspector is to verify that NRC-licensed materials are not stolen or lost and are appropriately controlled. The inspector should examine the licensee's receipt, use, inventory, transfer, and disposal of radioactive materials. The inspector should verify the licensee's performance by observations, interviews with licensee personnel, and examination of the following: radioactive material (RAM) inventory; RAM security and control measures; ordering, receipt, use, and transfer of RAM; and proper shipping and disposal of RAM. The extent of RAM security and control measures required by 10 CFR 20.1801 and 20.1802, as implemented by the licensee, should be commensurate with the degree of potential risk associated with the loss of materials.

The inspector should verify that no material was inappropriately released or removed from the site and that patients to whom radiopharmaceuticals were administered were released in accordance with the requirements of 10 CFR 35.75, license conditions, and the licensee's procedures. The licensee's instructions to the patient should be clear in order to minimize radiation doses to the public when the patient is released, in accordance with the requirements of 10 CFR 35.75.

e. Use of Licensed Material Only as Authorized

Desired outcome: No unauthorized activities with licensed material having significant and credible potential for affecting safety.

The inspector should verify that licensed materials are used by or under the supervision of individuals authorized by the license. The licensee should demonstrate that the types and quantities of materials used, locations of use, and modalities are in accordance with the regulatory requirements and license conditions. The inspector should verify that reasonable controls are being implemented by the licensee through the RSO, RSC, and AU, to ensure proper use of licensed materials.

The inspector, through observations of ongoing activities, interviews with personnel, and review of the records, should verify that no unauthorized use of materials occurred.

f. Radiopharmaceutical Administrations Conforming to the Physician's Written Directives

Desired outcome: Maintenance of an effective Quality Assurance program, to avoid misadministrations.

The inspector is to verify that the licensee's quality management program is effective. The inspector should determine whether any misadministrations, as defined in 10 CFR Part 35, have occurred. The licensee's AUs, technologist(s) and other staff involved in dose prescription, preparation, and administration should have a clear understanding that doses are to be administered to patients as directed by the AUs. The inspector should verify that the licensee's actions and performance would minimize the probability of: (1) administering the wrong material; (2) administering material to the wrong individual; (3)

administering material via the wrong route of administration; and (4) differences between administered and prescribed dosages of greater than 20 percent and, for either sodium iodide I-125 or I-131, in excess of 1.1 megabecquerels (30 microcuries).

The inspector should verify that misadministrations are properly identified, recorded, and evaluated, and that notifications and reports are submitted as required by 10 CFR 35.33.

2800/029-04 INSPECTION GUIDANCE

For each of the FEs, the Inspection Record for this TI (Appendix A) includes elements to examine and consider in deciding whether or not the FE has been met. These "second-tier" items are not the only elements to be assessed in the decision process for a particular FE, but are representative of those that should be considered. The depth of review associated with elements of a given FE will vary from one inspection to another, reflecting the nature of onsite observations, interviews, and selective, limited, review of records, in accordance with current guidance on records sampling.

Failure to meet any "second-tier" item can result in a violation: minor; Severity Level (SL) IV (cited or non-cited); or higher. If the violation is an SL III, or higher, the associated FE cannot be met.

There is no direct relationship between the number of SL IV violations identified and failure to meet an FE. The issue is whether there is a significant and credible potential for affecting safety; if there is, then the inspector should consider that the FE has not been met. In questionable situations, relative to an FE being met, or not, because of the "second-tier" SL IV violations identified, the inspector should, while still onsite, consult with Regional Management, if possible. (A Form-591 should not be given to the licensee onsite if one or more FEs have not been met. See Section 05, "Enforcement.")

For guidance in deciding whether an issue brought to light in the inspection should result in an SL IV violation or should be classified as minor, see Section 05.01, "Use of Form 591."

The inspector should consult with regional management on identification of potential wrong-doing issues such as records falsification, material false statements, or willful violation of NRC requirements. When potential wrong-doing is identified by the inspector, even when the licensee's performance regarding the FEs was found acceptable, appropriate regulatory action, including enforcement, documentation of the inspection effort, and communications with the licensee, must be conducted by the regional office.

For each of the individual FEs, specific guidance on how to determine if the FE has or has not been met is provided below.

04.01 Adequate Program Surveillance and Corrective Action

Try to determine if the licensee is proactive in surveillance and corrective actions. (In this context, surveillance is routine examinations, by observations or measurements, of licensed activities,

personnel performance, procedures, and processes, to verify adherence to NRC regulatory requirements, license conditions, and licensee policies and procedures. Surveillance includes audits, but does not equate solely to audits.) The inspector should review licensee surveillance activities and discuss these efforts, their results, and any followup actions with the staff, RSO, and RSC.

04.02 Knowledgeable Staff and Management

- Use interviews, observations of activities, and demonstrations to assess the knowledge of licensee staff who routinely perform licensed activities, as well as those who conduct these activities less frequently. (Unless required for followup on questionable interviews, don't look at training elements such as curricula, examination scores.)

- Attempt to determine the ability of staff to handle new procedures, use of different types of material, new quantities that have been approved on the license, and significant personnel changes. (If the program has changed over time, did staff adjust to the programmatic changes?)

- As part of the evaluation of (applicable) knowledge levels of individuals, consider the implications of lack of knowledge on other FEs.

04.03 Occupational and Public Doses within Regulatory Limits

For 10 CFR 35.100, 35.200, and 35.300 licensees, individual elements to be considered for this FE are more likely to result in SL IV violations than an overall determination that the FE has not been met (i.e., that significant and credible potential for affecting safety is associated with the violations, individually or collectively). Examples of violations likely to be at SL IV, but not prevent the FE from being met, are:

- Lack of bioassay procedures;
- Failure to assign dosimeters; and
- A radiation dose rate in an unrestricted area exceeding 0.02 millisievert (2 millirem) in an hour.

Specific program elements that the inspector should review when assessing the licensee's performance in this area include, but are not limited to:

- External and internal exposure monitoring programs;
- Public dose assessment;
- Patient release and in-patient procedures;
- Protective clothing, equipment, and engineering controls; and
- Effluent releases.

The inspector should also perform independent measurements of ambient dose rates and contamination levels to verify that radiation levels are within acceptable limits.

04.04 Adequate Security and Control of Licensed Material

For violations that involve loss, release, or disposal of licensed material, a determination that the FE has not been met will be required if the amount of licensed material involved in the inspection

findings on any listed ("second tier") element exceeds 10 times the quantity specified in Appendix C to 10 CFR Part 20 and/or it appears that exposures exceeding regulatory limits could have been received by persons in restricted or unrestricted areas.

For security violations that do not involve loss, release, or disposal of licensed material, a determination that the FE has not been met will be required if the amount of licensed material involved in the inspection findings on any listed ("second tier") element exceeds 1000 times the quantity specified in Appendix C to 10 CFR Part 20.

A determination that the FE has not been met can also result from any violation(s) when there is a significant and credible potential for affecting safety, *i.e.,* SL III or higher violations.

04.05 Use of Licensed Material Only as Authorized

A determination that the FE has not been met will be required: 1) if the amount of licensed material involved in a violation of any listed ("second-tier") element exceeds 1000 times the quantity specified in Appendix C to 10 CFR Part 20; 2) for any violation(s) when there is significant and credible potential for affecting safety; 3) for administration to a patient of material that was not authorized for medical use; or 4) if it appears that exposures exceeding regulatory limits could have been received by persons in restricted or unrestricted areas, i.e., SL III or higher violations.

"Second-tier" elements to be considered in determining whether the FE has been met include: authorized users, uses, types and quantities of materials, and locations.

04.06 Radiopharmaceutical Administrations Conforming to the Physician's Written Directives

Applies only to those administrations for which written directives are required under 10 CFR 35.32:

- Any administration of quantities greater than 1.1 megabecquerels (30 microcuries) of either sodium iodide I-125 or I-131; and
- Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

Other "second-tier" elements, relating to the licensee's quality management program and misadministrations, should be examined. A determination that the FE has not been met can result from any violation(s) when there is a significant and credible potential for impacting safety, i.e., SL III or higher violations. Refer to Regulatory Guide 8.33.

2800/029-05 ENFORCEMENT

Use of Form 591, Safety and Compliance Inspection

Minor violations (previously categorized at Severity Level V) are not included in Notices of Violation nor are they documented on Form 591. Section 3.5.c of the Enforcement Manual contains detailed guidance on determining whether a violation is minor. That section is included in this TI, as Appendix B, for reference. In general, issues that represent isolated failures to implement a requirement, without programmatic implications and without safety impact, may be categorized as

minor. Examples of violations that normally should be considered minor include an isolated failure to: perform a routine survey; prepare a record; perform a daily dose calibrator check; or perform an instrument calibration at the exact frequency required.

Non-Cited Violations (NCVs) should be documented in Item 2 of Form 591. To be included on a Form 591, an NCV must meet all of the following criteria: (1) It was identified by the licensee; (2) It could not reasonably be prevented by the licensee's corrective action for a previous violation that occurred within the last two years or two inspections, whichever is longer; (3) It was or will be corrected within a reasonable time, by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence; and (4) It was not willful. In judging the corrective action taken or proposed, the standard is reasonableness (*i.e.*, the licensee's corrective action should be commensurate with the safety significance of the issue). In determining repetitiveness, the fact that a violation repeats is not the only criterion that should be considered. If a violations recurs, it does not necessarily mean that past corrective action was not reasonable or effective. The key is: Did the licensee develop and implement reasonable corrective actions for the previous violation, commensurate with the safety significance, such that at the time the corrective actions were implemented, there was a reasonable expectation that the root causes of the violation would be corrected?

There is no limitation on the number or type of Severity Level IV violations that may be entered on Form 591. However, a Form 591 should not be issued at the site if the inspection results include violations that appear to the inspector to indicate that any one of the FEs was not met. Normally, if an FE was not met, the violations will be issued from the Regional Office in a formal Notice of Violation (NOV).

The number and nature of the violations at a given facility may be an indication that the FE on program surveillance and corrective actions was not met. Judgment is required. If the inspector is uncertain, a Form 591 should not be issued at the site, and the decision will be made after coordinating with Regional Management. If Regional Management decides that the FEs were met, a Form 591 still may be issued from the Regional Office.

In a case where an FE has not been met, Regional Management may decide to add language to the cover letter of a formal NOV to indicate that improved management oversight is warranted. Example language follows:

> "These violations indicate the need for increased and improved management oversight over licensed operations. Consequently, in your reply to this letter, in addition to discussing corrective action for the specific violations, you should also describe actions taken or planned to improve the effectiveness of your management control over licensed activities."

2800/029-06 REPORTING REQUIREMENTS

The Inspection Record associated with this TI (Appendix A) shall be completed for each 10 CFR 35.100, 35.200, and 35.300 licensee inspection carried out during the pilot program.

2800/029-07 COMPLETION SCHEDULE

No change in inspection scheduling will be required for the use of this TI (pilot program). Refer to MC 2800 for scheduling requirements. Adjustments to the inspection frequency for a particular licensee may be deemed appropriate based on the results of using this TI for a regularly scheduled inspection.

2800/029-08 EXPIRATION

This TI shall remain in effect until September 30, 2003.

2800/029-09 CONTACT

Questions regarding this TI should be addressed to Charles Cox, Division of Industrial and Medical Nuclear Safety, NMSS, at 301-415-6755.

2800/029-10 STATISTICAL DATA REPORTING

No change in entering/charging staff hour expenditures or administrative effort to the Regulatory Information Tracking System is required for implementation of this TI during the pilot program. See Section 06, "Reporting Requirements."

2800/029-11 ORIGINATING ORGANIZATION INFORMATION

11.01 Organizational Responsibility. The Rulemaking and Guidance Branch of the Division of Industrial and Medical Nuclear Safety, NMSS, initiated this TI.

11.02 Resource Estimate. Inspections using this TI are not expected to require staff hour expenditures exceeding those required for inspections of these licensees using the current inspection procedure (87115, Nuclear Medicine Programs).

APPENDICES:

A - "Nuclear Medicine Inspection Record"
B - "Guidance on Determining Whether a Violation Is Minor"

END

APPENDIX A

NUCLEAR MEDICINE INSPECTION RECORD
(TEMPORARY INSTRUCTION 2800/029)

Region ___

Inspection record No._____ License No. _____

Licensee (Name and Address): Docket No. _____

_____

_____

_____

Location (Authorized Site) Being Inspected:

_____

Licensee Contact: _____ Telephone No. _____

Priority: _____ Program Code: _____

Date of Last Inspection: _____ NMED/Event No(s).:_____
Date of This Inspection: _____ _____

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

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

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s) _____ Date _____
(Sign Name)

_____
(Print Name)

Approved _____ Date _____
(Sign Name)

_____
(Print Name)

PART I-LICENSE INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations including NCVs; Confirmatory Action Letters; and orders)

2. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that the NRC nuclear material events database, regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

PART II - INSPECTION DOCUMENTATION

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all focus elements are to be addressed during each inspection.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations. NOTE: *Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy.*

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

2. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

4. OTHER:
(e.g., posting and labeling)

PART III - FOCUS ELEMENTS

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS
YES ___ NO___

(Adequate program reviews, including corrective actions for licensee findings and NRC- identified violations; resources [financial and personnel] dedicated to the program; recurring problems; radiation safety officer [RSO] present; RSO authority and effectiveness; radiation safety committee involvement [if required]; management support of program; radioactive material surveys)

2. KNOWLEDGEABLE STAFF AND MANAGEMENT YES ___ NO___

(Use by qualified and knowledgeable individuals; safe work practices; all levels of management possess sufficient knowledge to provide effective oversight of the program)

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS

YES ___ NO___

(Offsite contamination events; effective event response; trending as low as reasonably achievable; release pursuant to 10 CFR 35.75; substantial potential for overexposure; monitoring and dose assessment program; release for unrestricted use; notification)

4. ADEQUATE SECURITY AND CONTROL OF LICENSED MATERIAL YES ___ NO___

(Security and control measures commensurate with the hazard of the material involved; inventory; proper ordering, receipt and transfer of RAM; RAM in unrestricted/uncontrolled area; proper shipping; loss of RAM; proper disposal; notification)

5 USE OF LICENSED MATERIAL ONLY AS AUTHORIZED YES ___ NO___

(Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users)

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES YES ___ NO___

(Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records)

PART IV - POST- INSPECTION ACTIVITIES

1. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer, and/or State Liaison Officer)

2. OTHER:

END

APPENDIX B

GUIDANCE ON DETERMINING WHETHER A VIOLATION IS MINOR
(From NRC Enforcement Manual, NUREG-BR-0195, Rev 2)

Minor violations (previously categorized at Severity Level V) are not the subject of formal enforcement action and are not usually described in inspection reports. To the extent such violations are described, they are noted as minor violations. (See Section 3.7 for additional guidance on documenting minor violations in inspection reports.)

Such violations normally are characterized by (1) having no actual impact and little or no potential for impact on safety, (2) being isolated, not evidencing programmatic deficiencies, and (3) relating to licensee administrative limits rather than to NRC regulatory limits. When an inspector identifies a violation, the determination of whether the violation is minor should consider the following questions:

- Does the violation have any actual impact (or any realistic potential for impact) on safety?
- Does the violation suggest a programmatic problem that could have a realistic potential safety or regulatory impact?
- Could the violation be viewed as the possible precursor to a significant event?
- If inadvertently left uncorrected, would this violation become a more significant safety and regulatory concern?
- Are there associated circumstances that add regulatory concern to this violation (e.g., apparent willfulness, licensee refusal to comply, management involvement, etc.)?

If the answer to all of these questions is "no," the violation should be considered a minor violation. If, on the other hand, the answer to any one of these questions is "yes," the violation should not be considered a minor violation.

An isolated record-keeping failure may be a minor violation. However, where record-keeping problems interfere in the ability to monitor or audit activities or identify performance problems, the failures are more significant and should not be considered a minor violation.

Where a licensee does not take corrective action or repeatedly or willfully commits a minor violation, such that a formal response is necessary, the matter should be categorized at least at Severity level IV.