UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

September 30, 2025

EAF-RI-2025-0097

Nina F. Schor, MD, Ph.D.
Deputy Director for Intramural Research
Department of Health & Human Services
National Institutes of Health
21 Wilson Drive, MSC 6780
Bethesda, MD 20892-6780

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS), NATIONAL INSTITUTES OF HEALTH (NIH) - INSPECTION REPORT NO. 030-37773/2025001

Dear Dr. Schor:

This letter refers to our inspection initiated in-office on January 23, 2025, conducted on-site at your Bethesda, Maryland facility on February 7, 2025, and continued with further in-office review until September 4, 2025. The inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel. In addition to the on-site review, the inspector conducted multiple phone interviews with Michael Roberson, former Radiation Safety Officer (RSO), and Teresa Fisher, current RSO of your staff. The enclosed report presents the results of the review. A final exit briefing was conducted telephonically with Dr. Jessica McCormick-Ell, Director, Division of Safety, Commander Alfredo Sancho, Program Manager in Office of Intramural Research, Teresa Fisher, RSO, and others on September 4, 2025.

Based on the results of this review, the NRC identified one apparent violation which is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation, as described in the enclosed inspection report, involved NIH's operation of a cyclotron in a manner that was outside of the operating conditions described in the licensee's application, dated September 24, 2014 (ML14280A513).

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Before the NRC makes its final enforcement decision, we are providing you with an opportunity to (1) respond to the apparent violation addressed in this letter within 30 days of the date of this letter, or (2) request a pre-decisional enforcement conference (PEC or conference). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference.

If you decide to participate in a PEC, please contact Monica Ford at (610) 337-5214 or via email at Monica.Ford@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to An Apparent Violation in NRC Inspection Report 030-37773/2025001; EAF-RI-2025- 0097" and should include: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be mailed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy mailed to Christopher M. Regan, Director (Acting), Division of Radiological Safety & Security, U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road, Suite 102, King of Prussia, PA, 19406-1415, and emailed to R1Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

Please be advised that the characterization of the apparent violation, as well as the number of identified violations described herein may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with Title10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Monica Ford of my staff at (610) 337-5214 or Monica.Ford@nrc.gov.

Sincerely,

Signed by Regan, Christopher
on 09/30/25

Christopher M. Regan, Director (Acting)
Division of Radiological Safety and Security
NRC Region I

Docket No. 030-37773
License No. 19-00296-21

Enclosures:
1. NRC Inspection Report 030-37773/2025001
2. Excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

cc w/Encl:
Teresa Fisher, Radiation Safety Officer
Dr. Liza Lidenberg, Chair, NIH Radiation Safety Committee

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS), NATIONAL INSTITUTES OF HEALTH (NIH) - INSPECTION REPORT NO. 030-37773/2025001 DATED SEPTEMBER 30, 2025

DISTRIBUTION w/encl:

ADAMS	
SECY	RIDSSECYMAILCENTER
OCA	RIDSOCAMAILCENTER
OEMAIL, OEWEB	
MKing, EDO	RIDSEDOMAILCENTER
TSteadham, EDO	
BPham, OE	RIDSOEMAILCENTER
JPeralta, OE	
LSreenivas, OE	
AKock, NMSS	RIDSNMSSOD RESOURCE
CEinberg, NMSS	
MBurgess, NMSS	
AMiller, NMSS	
Enforcement Coordinators	
RII, RIII, RIV (M Kowal;	
D Betancourt-Roldan, B Alferink)	
HPittman, OPA	RIDSOPAMAILCENTER
RFeitel, OIG	RIDSOIGMAILCENTER
DCollins, ORA, RI	
CRegan, DRSS, RI	R1DRSSMAILRESOURCE
MFerdas, DRSS, RI	
MFord, DRSS, RI	
ESpangler, DRSS, RI	
SBurnell, PAO-RI	
SSeeley, SAO-RI	
KBarnes, SAO-RI	
BKlukan, ORA, RI	
LCasey, ORA, RI	

ADAMS ACCESSION NUMBER: ML25232A164

☒ SUNSI Review/		☒ Non-Sensitive ☐ Sensitive			☒ Publicly Available ☐ Non-Publicly Available	
OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	NMSS	OE
NAME	RRagland	MFord	BKlukan	MMcLaughlin	MBurgess	JPeralta/LS
DATE	09/03/2025	09/04/2025	09/04/2025	09/10/2025	09/24/2025	09/12/2025
OFFICE	RI/DRSS					
NAME	CRegan					
DATE	09/30/2025					

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Docket:	030-37773
License:	19-00296-21
Report:	2025001
EA No.:	EAF-RI-2025-0097
Licensee:	Department of Health and Human Services, National Institutes of Health
Locations Inspected:	21 Wilson Drive, MSC 6780 Bethesda, MD 20892-6780
Inspection Dates:	January 23, 2025, telephonically, February 7, 2025, on-site, and continued in-office until September 4, 2025
Inspector:	Randolph C. Ragland, Jr., Senior Health Physicist Commercial, Industrial, R&D and Academic Branch Division of Radiological Safety and Security
Approved By:	Monica Ford, Chief Commercial, Industrial, R&D and Academic Branch Division of Radiological Safety and Security

EXECUTIVE SUMMARY

National Institutes of Health
NRC Inspection Report 030-37773/2025001

Program Overview

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services (HHS), is the nation's medical research agency. It is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body system. The NIH headquarters, known as the "NIH campus," are located in Bethesda, Maryland. NIH possesses three NRC licenses: a medical broad scope license (19-00296-10), an irradiator license (19-00296-17), and a cyclotron license (19-00296-21).

Inspection Findings

On January 23, 2025, NRC Region I learned that NIH was potentially operating their cyclotron with the cyclotron vault door open. This represented a potentially hazardous operating configuration, so NRC opened a reactive inspection. The reactive inspection began telephonically on January 23, 2025, and continued onsite on February 7, 2025.

During the inspection, the RSO explained that he, the lead cyclotron engineer, and two health physics specialists (HPs) had just completed an operational test of the cyclotron running at the lowest power level with the door slightly ajar. The purpose of the test was to obtain radiation survey data to determine if it was possible to run the cyclotron with the vault door open to enable research staff to continue to produce medical and research radioisotopes until the door motor bearings could be repaired. The test required the vault door interlock to be bypassed in order to operate the cyclotron with the vault door open. The RSO stated that the test was terminated when radiation survey data showed that elevated doses would occur in areas adjacent to the vault if the cyclotron is operated at higher power levels. The inspector pointed out that the cyclotron vault door "interlock" that prevents operation of the cyclotron with the door open is described in NIH's NRC License Application dated September 24, 2014, and is referenced in NRC License No. 19-00296-21, Amendment 11, Condition 18.A, which makes it a license requirement, and bypassing the interlock to conduct the test represented an apparent violation of NRC requirements.

Initial Corrective Actions

Following initial identification of the apparent violation, the RSO briefed the cyclotron engineers, the HPs, and NIH's RSC on the license requirement. In addition, the RSO stated that he planned to insert a requirement in the license renewal application that any operation of the cyclotron outside of normal operations (e.g., operating with the shield door open) requires notification and approval from the NRC.

REPORT DETAILS

1. Program Overview

1.1 Background

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services (DHHS), is the nation's medical research agency. It is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on a particular disease or body system. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH headquarters, known as the "NIH campus," are located in Bethesda, Maryland.

NIH possesses three NRC licenses: a medical broad scope license (19-00296-10), an irradiator license (19-00296-17), and an accelerator production (i.e., cyclotron) license (19-00296-21).

NIH possesses three cyclotrons used to produce short-lived radioisotopes for medical and research procedures under NRC license 19-00296-21. On January 22, 2025, one of NIH's GE PETrace cyclotrons experienced a motor bearing failure preventing the 40-ton shield door from easily opening and closing. The failure left the door mainly in place but slightly ajar. In response, researchers asked the radiation safety and cyclotron engineering staff if there was any way to continue isotope production in its current configuration (i.e., with the door slightly ajar) while waiting for the repairs to the cyclotron vault door motor bearings.

On January 23, 2025, NRC Region I learned that NIH was potentially operating their cyclotron with the cyclotron vault door open. This represented a potentially hazardous operating configuration. A reactive inspection began via telephone on January 23, 2025, and continued with an onsite inspection on February 7, 2025.

2. Observations and Findings

2.1 Inspection Scope

Information was gathered through interviews with the previous and current radiation safety officers, health physics specialists (HPs) and cyclotron engineers, and the Chair of the RSC; direct on-site inspections of NIH's Cyclotron Vault No. 2, and reviews of records including NIH NRC license applications, RSC minutes, radiation survey data, and operational records for the cyclotron.

2.2 Observations and Findings

During the telephonic portion of the inspection, the NRC inspector asked the RSO if they had been operating with one of NIH's cyclotrons vault doors open. The RSO reported that when the inspector called, he, the lead cyclotron engineer, and two HPs had just completed an operational test of the cyclotron running at the lowest power level with the door slightly ajar. The RSO stated that the test was terminated when radiation survey data in the adjacent lab showed that elevated doses would occur (i.e., >2 mR/h) if the cyclotron is operated at higher power levels.

The RSO explained that the shield door for NIH's GE PETrace cyclotron in vault No. 2 experienced a motor bearing failure preventing the 40-ton shield door from easily opening and closing and researchers asked the radiation safety and cyclotron engineering staff if there was any way to continue isotope production with the door slightly ajar while they wait on repairs.

Radiation Safety Considerations

The RSO stated that the radiation safety staff and cyclotron engineers devised a plan to safely test and gather radiation survey data to determine if the cyclotron could run at normal power levels with the vault door slightly ajar. The test involved positioning the cyclotron door so there was a 24" opening, bypassing the door interlock/limit switch, evacuating adjacent labs, staging two HPs with radiation survey instruments behind the 40-ton shield door, staging the RSO with survey instruments in an adjacent lab, moving the high radiation area boundaries to the exterior laboratory doors, establishing telephone communications between the cyclotron operator, RSO, and the HPs, and then operating the cyclotron at low-power levels. To take the place of the vault door interlock, the HPs would implement and maintain positive high radiation area access controls authorized by 10 CFR 20.1601(a)(3). During the test, the HPs would stand behind the 40-ton shield door and monitor radiation levels. If radiation levels were low, they would then conduct surveys in other parts of the exterior vault lab; if radiation levels were high, then they would request the cyclotron engineer to terminate the test. When radiation levels reached 2 mrem/h in the adjacent laboratory and the outer radiochemistry door, the RSO extrapolated dose rates to higher power levels and determined that operation of the cyclotron at full power would require them to restrict access in the adjacent lab so they terminated the test. The RSO reported that the dose to the maximally exposed individual (HP) was 3.6 mrem.

The inspector pointed out that the cyclotron vault door "interlock" that prevents operation of the cyclotron with the door open is described in NIH's NRC License Application dated September 24, 2014, and is referenced in NRC License No. 19-00296-21, Amendment 11, Condition 18.A, which makes it a license requirement, and bypassing the interlock to conduct the test represented an apparent violation of NRC requirements.

Root Causes

The RSO stated that the primary root cause of the violation was that he did not consider the one-time low-power test to be a procedural or programmatic change. He assumed that the test as planned could be performed safely using the three fundamental principles of radiation protection which are limiting time, increasing distance, and use of shielding. If the results of the test showed that the radiation levels in the lab were reasonably low, then he would have sought approval from the RSC and eventually request a license amendment from the NRC to allow for a temporary procedural change.

The cyclotron engineer stated that although he was aware that the cyclotron interlock was described in the license application, he relied on the guidance provided by the RSO, who was a full member of the RSC, regarding matters of regulatory compliance. In addition, he did not feel the license application provided specific enough guidance for him to determine what represents a procedural or programmatic change. The HP Specialists stated that they were aware that the cyclotron interlock was described in the license application, but they also relied on the guidance provided by the RSO.

During an interview with the Chair of the RSC, the Chair stated that she and the other members of the RSC were not provided with a briefing prior to the performance of the test. However, she stated that she had great confidence in the RSO's technical knowledge and judgement.

2.2 Apparent Violation

One apparent violation of NRC requirements was identified and appears as follows:

License condition 18A of NRC License No. 19-00926-21, Amendment 11, dated January 2, 2024, requires in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 24, 2014. The application dated September 24, 2014, describes in part the facilities and equipment that are needed to safely work with licensed material. Item 9, "Facilities and Equipment," states in part that the licensee's cyclotron vaults "are safeguarded with interlocks that prevent operation of the cyclotron while the vault door is open" and that the interlock systems are designed to prevent individuals from experiencing potentially high exposure rates while the cyclotrons are running.

Contrary to the above, on January 23, 2025, NIH failed to conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 24, 2014. Specifically, although the application represents that the cyclotron was designed and constructed with an interlock system that only allows operation when the vault door is shut, NIH disabled the vault interlock system and operated the cyclotron with the door open [approximately 24 inches].

2.3 Conclusions

The NRC inspection identified one apparent violation regarding the operation of a cyclotron in a manner that was outside of the operating conditions described in the licensee's application dated September 24, 2014.

3. Corrective Actions

NIH implemented the following corrective actions:

NIH summarized their corrective and preventative actions in an email dated April 29, 2025 (ML25255A293). The cyclotron license renewal application was revised to include explicit language regarding changes to operations including the following statement, "NOTE: ANY OPERATION OF THE CYCLOTRON OUTSIDE OF NORMAL OPERATIONS (E.G., OPERATING WITH THE SHIELD DOOR OPEN) REQUIRES NOTIFICATION AND APPROVAL OF THE NRC."

The cyclotron's protocol with radiation safety was revised to include clear language prohibiting the bypass of safety interlock features.

The following groups received targeted training about this incident and the requirement to contact the NRC prior to implementing programmatic or procedure changes that differ from what is stated, in not only the cyclotron license but all the licenses we have with the NRC:

- NIH cyclotron engineers,
- Members of the NIH RSC including the new RSO, Chair, Deputy Chair, and Management Representative,
- Radiation safety health physicists assigned to the cyclotron,
- Radiation safety health physicists assigned to program areas on the broad scope and irradiator licenses, and
- Radiation Safety Branch Chiefs and the Irradiator Program Manager.

Material from a formal presentation on this topic has been added to the mandatory refresher training that will be launched later this year for all radiation workers on the broad scope license, individuals in the irradiator program, and individuals associated with the cyclotron license.

4. Exit Meeting Summary

On September 4, 2025, a final telephonic exit briefing was conducted with Dr. Jessica McCormick-Ell, Director, Division of Safety, Commander Alfredo Sancho, Program Manager in Office of Intramural Research, Teresa Fisher, RSO, and others on your staff on September 4, 2025. The conversation included a review of the findings presented in this report. Licensee representatives acknowledged the findings and reiterated their commitments to the corrective actions stated in this report.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Licensee

Daniel Watson, Corporate Radiation Safety Officer
Dr. Liza Lindenberg, Chair, NIH Radiation Safety Committed
Mike Roberson, Former Radiation Safety Officer
Teresa Fisher, Current Radiation Safety Officer
Jessica McCormick, Director of Safety
Justen Jensen, Health Physics Specialist
Larry Koenig, Health Physics Team Lead
Kris Kim, Senior Cyclotron Engineer

INSPECTION PROCEDURES USED

87126 – Broad Scope Academic and Research & Development Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-37773 /2025001	AV	The NRC inspection identified one apparent violation regarding the operation of a cyclotron in a manner that was outside of the operating conditions described in the licensee's application dated September 24, 2014.

Closed

None Discussed

None

LIST OF ACRONYMS

ADAMS	Agencywide Documents Access and Management System
AV	Apparent Violation
CFR	*Code of Federal Regulations*
HHS	Department of Health and Human Services
HPs	Health Physics Specialists
NIH	National Institutes of Health
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference
RSO	Radiation Safety Officer
RSC	Radiation Safety Committee

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued in 1996.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS WASHINGTON, D.C. 20555
May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations. In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action.

Nevertheless, the root cause(s) of minor violations must be identified, and appropriate corrective action must be taken to prevent recurrence. If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a pre-decisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a pre-decisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation. It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation. Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent the occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation.

   Typically, such reviews include: Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers. Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

   Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As

each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of a lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

   In evaluating the root causes of a violation and developing effective corrective action, consider the following:

   1. Has management been informed of the violation(s)?

   2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

   3. Have precursor events been considered and factored into the corrective actions?

   4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

   5. Has your staff been adequately trained on the applicable requirements?

   6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

   7. Has your staff been notified of the violation and of the applicable corrective action?

   8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

   9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

   10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

   11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided with sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?