U. S. NUCLEAR REGULATORY COMMISSION

REGION II

Docket Nos.:	030-19134, 999-90002 and 999-90002
License No.:	52-16345-02MD
Report Nos.:	52-16345-02MD/96-01, 999-90002/96-03 and 999-90002/96-04
Licensee:	Diagnostic Photon Corporation
Other Entities:	Syncor Overseas, Ltd. and Syncor International Corporation
Location:	Carolina, Puerto Rico
Dates:	July 26 and 29, 1996, onsite
Inspector:	Héctor Bermúdez, Senior Radiation Specialist
Approved by:	John P. Potter, Chief Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Diagnostic Photon Corporation, Syncor Overseas, Ltd. and
Syncor International Corporation
NRC Inspection Report Nos. 52-19134-02MD/96-01, 999-90002/96-03
and 999-90002/96-04

This special, announced inspection was conducted to review the control and conduct of licensed activities at the Diagnostic Photon Corporation's (DPC's) radiopharmacy located in Carolina, Puerto Rico. This included a review of the licensed radiation safety program. The inspection was conducted because the President of DPC had reported on June 28 and July 3, 1996, that Syncor International Corporation (SIC) had taken control of licensed activities. The inspection included direct observation of activities in progress, discussions with cognizant DPC and Syncor Overseas, Ltd. (SOL) representatives, review of documents, and review of the organization and scope of the DPC's program.

Within the scope of the inspection, six apparent violations of NRC requirements were identified. The apparent violations involved: (1) the apparent transfer of control of licensed activities on the part of DPC without prior NRC consent, (2) the apparent failure of SIC to obtain a valid NRC license prior to possessing, using and distributing byproduct materials in Puerto Rico, (3) the apparent failure of SOL to obtain a valid NRC license prior to possessing, using and distributing byproduct materials in Puerto Rico, (4) the failure of DPC to notify NRC of the credentials of appointed Authorized Nuclear Pharmacists within 30 days of their beginning work, (5) the failure of DPC to train personnel on the requirements of its operating and emergency procedures and license, and (6) the use by DPC of unauthorized operating procedures.

LIST OF PERSONS CONTACTED

Licensee

*J. Caamaño, M.D., President and Radiation Safety Officer
N. Oldham, Alternate Radiation Safety Officer
*A. González Géigel, Esq., Licensee's Counsel

Syncor Overseas, Ltd.

R. Green, Pharmacist
#F. Peña, Office Manager
#J. Simon, Pharmacist

Syncor International Corporation
#F. Peña, Office Manager
#J. Simon, Pharmacist

* By telephone during both the inspection and exit interview
# Represented both Syncor International Corporation and Syncor Overseas, Ltd. during the exit interview with SOL on July 29, 1996

REPORT DETAILS

1. Background

License No. 52-16345-02MD was originally issued to DPC on July 27, 1983, and was most recently amended on April 18, 1995. As a result of rulemaking, on March 1, 1996, the license's expiration date was extended to April 30, 2005. The license authorizes the possession and use of byproduct materials for the preparation and distribution of radioactive drugs (radiopharmaceuticals) to authorized recipients in accordance with conditions specified therein. The license also authorizes the preparation and distribution to authorized recipients of therapeutic iodine-131 radiopharmaceuticals but such activities have never been conducted at the licensee's facility (pharmacy).

On February 6, 1996, DPC entered into a Management Agreement (Agreement) with SIC which was effective on March 1, 1996. The Agreement specified that SIC would have control over the management and operation of the DPC pharmacy and SIC's use of DPC's licenses. The Agreement also committed DPC's management to promptly sign applications for any and all of its licenses, and allowed SIC to make all decisions related to the pharmacy and to conduct all affairs as SIC deems appropriate. In addition, the Agreement specified that DPC's President, who is the designated Radiation Safety Officer (RSO) on the NRC license, was to be retained as a consultant and that all other DPC employees, including the Alternate RSO designated on the NRC license, were to become employees of SIC.

2. Circumstances Leading to the Inspection

In early March 1996, DPC's President advised the NRC that he had recently allowed SIC to manage his pharmacy pending a potential transfer of the business and all applicable federal and local permits. He requested an inspection at that time to make sure SIC was properly conducting licensed activities under his license. After discussions with the inspector, it was determined that, due to the short time that SIC had been involved in DPC's operation and the lack of negative safety-significant information available, an inspection was not warranted at that time. DPC's President was informed that NRC believed it would be prudent to delay any inspection for approximately three months and that it was important that he carefully monitor the transition in operations.

On March 25, 1996, DPC requested an amendment to its license. The letter referenced the Agreement and mentioned a pending transfer of the license to SIC. On June 14, 1996, SIC personnel replied to questions raised by the NRC in a May 15, 1996 letter regarding the requested amendment. The reply addressed, among others, the use of new labels and transport containers and a bioassay program related to the intended use of iodine-131. The reply further stated "We are aware that changes requested may not be implemented until final approval is received from your agency." The letter indicated a place for signature, but was not signed by the President of DPC. NRC replied to SIC's June 14, 1996

letter by indicating that its letter seeking a license amendment must be signed by the President of DPC in order for NRC to continue its review of the amendment request. On June 28, 1996, DPC's President indicated during a telephone conversation with NRC that he had not signed the letter because he was not sure that iodine-131 could be handled safely at his facility.

During the same June 28, 1996 conversation, the NRC inquired about the status of DPC operations to determine whether an inspection was warranted at that time. DPC's President indicated that: (1) he had lost control over licensed activities, (2) he did not like the way in which activities were being conducted at his facility, and there was little he could do to rectify the situation, (3) there was too much turnover of dispensing pharmacists and their credentials were unknown to him, and (4) he wished that NRC inspect his facility as soon as possible. The NRC then spoke with SIC's lead representative on site, who faxed Region II a copy of the Agreement. The SIC representative indicated that he used the Agreement as his basis for justifying his actions involving his control over the pharmacy. The SIC representative indicated that such actions included the implementation of the NRC-licensed program.

On July 3, 1996, NRC, Region II, after legal and technical review of the Agreement, telephoned DPC's President and informed him that it appeared that, since March 1, 1996, DPC had been in violation of 10 CFR 30.34(b), which prohibits the transfer of control of an NRC license without prior NRC consent. The President was informed that if neither he, as the RSO, nor the Alternate RSO designated on the license, were in control of licensed activities, there was no valid license under which SIC was operating. The President indicated that he would try to regain control of licensed activities at his facility.

On July 16, 1996, SIC assigned its interest in the Agreement to Syncor Overseas, Ltd. (SOL), Citco Building, Wickhams Cay, P.O. Box 662, Road Town, Tortola, British Virgin Islands. On July 19, 1996, SOL, requested NRC to transfer DPC's NRC license to their name and that a new RSO be named. NRC's response to this request is discussed in Section 4 of this report.

On July 22, 1996, DPC's Alternate RSO was escorted out of the facility by SOL personnel with instructions that she not return to the facility. On or about the same date, SOL personnel changed the locks of all entrance doors to the facility and did not provide keys to DPC's President. Since then, DPC's President/RSO has not had keys to the facility and the Alternate RSO named on the license has been prohibited from entering the building.

The inspector conducted an onsite inspection on July 26 and 29, 1996.

3. Inspection Results

3.1 Observations and Findings Regarding DPC

3.1.1 Control of Licensed Activities

10 CFR 30.34(b) provides that no license issued by the Commission, nor any right under a license, be transferred, either voluntarily or involuntarily, directly or indirectly, through the transfer of control of a license to any person unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the Atomic Energy Act and gives its consent in writing.

As part of the inspector's attempt to ascertain who was in control of licensed activities, the inspector determined the following:

a. From review of records and discussions with SOL representatives, between March 1 and July 16, 1996, and between July 16 and July 29, 1996, SIC and SOL, respectively, rotated pharmacists who practiced at various SIC pharmacies located on the mainland into DPC at a frequency of approximately once every two weeks. During telephone discussions with DPC's President, the President indicated he continued to be unable to ascertain the qualifications of the pharmacists who were dispensing at his facility because he did not want to create conflicts. The inspector indicated that it was his responsibility to ascertain the qualifications of the pharmacists and the President indicated he would try to do so. SOL representatives stated that it was SIC and SOL who designated the nuclear pharmacists during their respective periods of operation, not DPC.

b. The pharmacist representing SOL the weeks of July 15 and 22, 1996, stated to the inspector on July 26, 1996, that he used SIC's Operations Manual for the conduct of licensed activities and that he had not received training on DPC's operating and emergency procedures. The pharmacist indicated that he felt comfortable that SIC's manual would be at least as thorough as DPC's. While inspecting DPC's packaging, container labels and unit dose containers, the inspector noted that they were not the ones routinely used by DPC but were the ones seen by the inspector to be routinely used at other SIC facilities in the mainland. The inspector also noted that the transport containers and labels in use were the ones for which approval was sought in the June 14, 1996 letter, which is the same letter to which the President of DPC objected because it included references to the use of iodine-131. These issues are discussed further in Section 3.1.3 below.

c. The language in the Agreement assigned SIC to make all decisions related to the pharmacy and conduct all affairs as SIC deems appropriate. Also, SIC would have control over the management and operation of the DPC pharmacy and SIC's use of DPC's license.

This authority was transferred to SOL by SIC on July 16, 1996 without DPC consent. Neither of these assignments of control were consented by the NRC.

d. The DPC RSO and Alternate RSO were restricted from access to the pharmacy. Through discussions with the DPC RSO, Alternate RSO and SOL representatives, the inspector determined that the Alternate RSO was escorted from the facility on July 22 by SOL staff. This action was related to a purchase and gift transfer of thallium-201, a transaction that SOL considered contrary to another agreement between DPC and SIC. SOL representatives stated that the alleged inappropriate transfer of thallium-201 was the reason for changing the locks to the facility. An SOL representative indicated that, if and when DPC's President/ RSO wishes to access the facility to supervise licensed activities as required by his function as RSO, he must be allowed in by SOL personnel without restriction but SOL personnel must be onsite whenever the RSO is present. Through discussions with SOL representatives, the inspector further learned that, during June and July 1996, DPC's RSO seldom frequented the facility to supervise licensed activities. DPC's President stated to the inspector that his lack of attendance was due to his intention to avoid conflicts.

e. As described further in Section 2, the SIC lead representative at the pharmacy, indicated, on June 28, 1996, that the Agreement allowed him to control the pharmacy. The representative indicated this included implementation of NRC-licensed activities.

Based on: (1) the language contained in the Agreement which addresses the transfer of control of the operation of the pharmacy and SIC's use of DPC's licenses, as summarized in Section 1 of this report, (2) the President of DPC's statements during the June 28, and July 3 and 26, 1996 conversations regarding loss of control over licensed activities and his inability to ascertain the credentials of dispensing pharmacists at his facility, (3) the fact that SIC and SOL dictated who the Authorized Nuclear Pharmacists (ANPs) would be, without any input from DPC management, (4) the fact that, at least during the weeks of July 15 and 22, 1996, it was SIC's operating and emergency procedures that were being implemented, not DPC's, (5) the fact that the pharmacist who worked during the weeks of July 15 and 22, 1996 did not receive training on DPC's operating and emergency procedures or the license because it was his understanding that he was to operate under SIC's Operations Manual, (6) the fact that SIC and SOL representatives implemented changes to the licensed program without DPC or NRC approval by changing the labels and transport containers to conform with SIC's standard operating practices, (7) the SIC representative's understanding that the Agreement allowed him to control NRC licensed activities at the pharmacy, (8) the fact that the Alternate RSO was prohibited by SOL from entering the pharmacy (9) the fact that DPC's President and RSO has been denied the keys the pharmacy, and (10) the lack of presence of the RSO during June and July 1996 to supervise licensed activities and his

reliance on SIC and SOL pharmacists, whose credentials are unknown to him, to supervise the licensed program, the inspector concluded that an apparent transfer of control of the NRC license occurred without prior NRC consent.

The transfer of control of the NRC license without the NRC's prior consent was identified as an apparent violation of 10 CFR 30.34(b).

3.1.2 Failure to Submit Credentials of ANPs

10 CFR 32.72(b)(5) requires that a licensee provide the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows the individual to work as an Authorized Nuclear Pharmacist (ANP).

Through discussions with DPC and SOL representatives and reviews of records, the inspector determined that between March 1 and July 29, 1996, DPC allowed six individuals to practice as ANPs. As of the date of this report, DPC has failed to submit to the NRC the credentials of all the individuals who had been allowed to work as ANPs within 30 days of their beginning work. SOL representatives indicated that it was DPC's responsibility to submit the required credentials in a timely manner. DPC's President indicated he was unable to obtain them, and, therefore, he was unable to submit them. The inspector reminded DPC representatives that although control of the license may have transferred, such transfer had not been authorized by the NRC and, therefore, DPC remained the licensee. Based on this, the inspector indicated that DPC was required to comply with the reporting requirement. The failure to submit to the NRC the credentials of individuals designated as ANPs within 30 days of their designation as such was identified as an apparent violation of 10 CFR 32.72(b)(5).

3.1.3 Operating and Emergency Procedures and Personnel Training

Condition 20 of License No. 52-16345-02MD requires that the licensee conduct its program in accordance with the statements and procedures contained in the licensee's application dated December 7, 1988, and letters dated April 20, 1989, March 2, 1994, and April 5, 1995.

10 CFR 19.12 requires, in part, that individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 millirems be instructed in the applicable provisions of Commission regulations and licenses.

As discussed in Section 3.1.1 above, the pharmacist representing SOL the weeks of July 15 and 22, 1996 stated to the inspector on July 26, 1996, that he was operating under SIC's Operating Manual and showed the inspector a copy of the manual. The manual contained procedures and

instruction on how to carry out SIC's operations. The pharmacist also stated that the training program for all new personnel consisted of the standard SIC training manual and videotape, and that it did not include the provisions of DPC's operating and emergency procedures contained in DPC's license. The pharmacist further stated that he had not received training on the licensee's procedures and instructions contained in the licensee's application dated December 7, 1988, and letters dated April 20, 1989, March 2, 1994, and April 5, 1995. This became evident to the inspector when the inspector saw SOL staff supervised by the pharmacist using SIC's transport containers and labels and SOL's shipping papers. DPC's transport containers, labels and shipping papers are described in DPC's license application dated December 7, 1988.

The failure to conduct operations in accordance with the statements and procedures contained in the licensee's application dated December 7, 1988, and letters dated April 20, 1989, March 2, 1994, and April 5, 1995, during the weeks of July 15 and 22, 1996, was identified as an apparent violation of Condition No. 20 of License No. 52-16345-02MD. In addition, the failure of the licensee to train a pharmacist on the operating and emergency procedures contained in the license was identified as an apparent violation of 10 CFR 19.12.

3.2 Findings Regarding SIC and SOL

10 CFR 30.3 requires, with exemptions not applicable here, that no person manufacture, produce, transfer, receive, acquire, own, possess or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations contained in Title 10 of the Code of Federal Regulations (10 CFR).

Based on the discussions in Section 3.1.1 above, the inspector concluded that between March 1 and July 16, 1996, and between July 16 and 29, 1996, SIC and SOL, respectively, conducted activities subject to NRC licensing without a valid NRC license. Specifically, in their respective timeframes, both SIC and SOL used licensed materials and controlled the use of the NRC license issued to DPC without consent of the NRC in violation of the transfer of control provisions specified in 10 CFR 30.34(b). Since the transfer was not approved by the NRC and there was no other license issued to SIC or SOL for use of byproduct materials at the pharmacy, the conduct of activities subject to licensing without a valid NRC license was identified as an apparent violation of 10 CFR 30.3.

4. Developments Subsequent to the Inspection

In response to the NRC onsite inspection findings, a Confirmatory Action Letter (CAL) was issued to SOL on July 29, 1996, confirming SOL's agreement that DPC be in control of the license and that activities be conducted in accordance with DPC's approved radiation safety program. On August 19, 1996, the SOL President, responded to the CAL in writing to the NRC. The letter described restrictions to the DPC RSO on access to the facility. However, it indicated the RSO and DPC held

responsibility and control for the license. The letter informed the NRC that SOL operations in Puerto Rico were being conducted under DPC's license and that DPC's President was afforded all necessary access to the facility to supervise licensed activities as RSO. The NRC determined the access described in the letter allowed adequate control of the DPC license to comply with 10 CFR 30.34, if implemented as described.

On August 8, 1996, the NRC replied to SOL's July 19, 1996 request to transfer DPC's license to their name and to change the RSO. The NRC reply indicated that SOL's request of July 19, 1996 could not be approved because it was not signed by the licensee or a person duly authorized to act on behalf of the licensee.

On July 29, 1996, the NRC wrote a letter to DPC discussing the inspection findings and an apparent violation of 10 CFR 30.34(b). The letter indicated that DPC must maintain control of its NRC licensed activities and provided the results of the July 29 CAL with SOL/SIC. On August 5, 1995, DPC's counsel informed NRC that SOL continued to hinder the DPC RSO from effectively controlling operations conducted under the license without specific examples. NRC replied on August 19, 1996, and requested specific examples.

On August 27, 1996, DPC's President advised NRC that he had recently learned of SOL's July 19, 1996 letter requesting transfer of his license. DPC's President indicated that the NRC staff should disregard such letter since he did not want the transfer of the license to occur or the change in RSO to be made. He also expressed concern that SIC/SOL personnel had been communicating issues directly to NRC relevant to his license without his knowledge. On September 3, 1996, DPC's counsel addressed, in writing, the possibility of litigation with SIC and rescission of the Agreement and other contracts for, among others, the alleged "continued failure to ... cooperate with the transfer of licenses."

On September 12, 1996, SOL applied for a separate license to operate at DPC's facility. On September 18, 1996, SIC/SOL representatives were told by Region II that the license application will be submitted to the NRC Headquarters in Washington, D.C., to evaluate the implications of licensing two separate entities to operate in the same facility.

5. Exit Meeting Summary

An exit interview was held separately with DPC and SOL representatives at the conclusion of the onsite inspection on July 29, 1996. The overall findings from the inspection, including the apparent violations were discussed. No dissenting comments regarding the transfer of control of the license were received from DPC. An additional exit interview via telephone was conducted with DPC's President on September 16, 1996, in which additional apparent violations were discussed as a result of further review of this case. Regarding the rest of the apparent violations DPC's President took exception

discussing his lack of control of licensed activities as specified in Section 3.1.2 above.

The lead SOL representative onsite on July 29, 1996, took exception to the inspection findings involving SIC and SOL. The SOL representative indicated that, if DPC were not in control of licensed activities, SOL would have proceeded with activities they desired to conduct that DPC's President did not want to conduct. The SOL representative indicated that such activities included compounding and distributing therapeutic dosages of iodine-131. Based on this, the lead SOL representative onsite contended that a transfer of control over the license had not occurred, and therefore SIC operated and SOL had been operating under a valid license, DPC's, all along. Regarding the activities that SOL wanted to conduct against the wishes of DPC's President, the inspector noted that SIC/SOL requested NRC to amend the DPC license to allow the changes without consent of DPC. The inspector further indicated that the preponderance of the evidence, the facts as understood by the inspector and the conduct of the parties involved led to the inspector's conclusion that a transfer of control of the NRC license had taken place without NRC's consent.

Proprietary information was reviewed as part of the inspection but is not contained in this report.

ITEMS OPENED AND DISCUSSED

OPENED

96001-01	VIO	UNAUTHORIZED TRANSFER OF CONTROL OF AN NRC LICENSE
96001-02	VIO	FAILURE TO SUBMIT CREDENTIALS OF ANPs WITHIN 30 DAYS OF BEGINNING OF WORK
96001-03	VIO	FAILURE TO INSTRUCT PERSONNEL ON THE REQUIREMENTS OF THE LICENSEE'S LICENSE AND OPERATING AND EMERGENCY PROCEDURES
96001-04	VIO	USE OF UNAUTHORIZED OPERATING PROCEDURES
999-90002/96003-01	VIO	SOL OPERATING WITHOUT A VALID NRC LICENSE
999-90002/96004-01	VIO	SIC OPERATING WITHOUT A VALID NRC LICENSE

2-Sided

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 nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)[1] 60 FR 34381, 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 VII.B.1 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)

[1]Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional 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 predecisional 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 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 particular 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 an auditable record 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 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 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?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

signed by

Elizabeth Q. Ten Eyck, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

signed by

Donald A. Cool, Director
Division of Industrial
and Medical Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Nader L. Mamish, OE
(301) 415-2740
Internet:nlm@nrc.gov

Daniel J. Holody, RI
(610) 337-5312
Internet:djh@nrc.gov

Bruno Uryc, Jr., RII
(404) 331-5505
Internet:bxu@nrc.gov

Bruce L. Burgess, RIII
(708) 829-9666
Internet:blb@nrc.gov

Gary F. Sanborn, RIV
(817) 860-8222
Internet:gfs@nrc.gov

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be categorized at least at a Severity Level IV.

D. Violations of Reporting Requirements

The NRC expects licensees to provide complete, accurate, and timely information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

V. Predecisional Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which escalated enforcement action appears to be warranted, or recurring nonconformance on the part of a vendor, the NRC may provide an opportunity for a predecisional enforcement conference with the licensee, vendor, or other person before taking enforcement action. The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, such as: (1) A common understanding of facts, root causes and missed opportunities associated with the apparent violations, (2) a common understanding of corrective action taken or planned, and (3) a common understanding of the significance of issues and the need for lasting comprehensive corrective action.

If the NRC concludes that it has sufficient information to make an informed enforcement decision, a conference will not normally be held unless the licensee requests it. However, an opportunity for a conference will normally be provided before issuing an order based on a violation of the rule on Deliberate Misconduct or a civil penalty to an unlicensed person. If a conference is not held, the licensee will normally be requested to provide a written response to an inspection report, if issued, as to the licensee's views on the apparent violations and their root causes and a description of planned or implemented corrective action.

During the predecisional enforcement conference, the licensee, vendor, or other persons will be given an opportunity to provide information consistent with the purpose of the conference, including an explanation to the NRC of the immediate corrective actions (if any) that were taken following identification of the potential violation or nonconformance and the long-term comprehensive actions that were taken or will be taken to prevent recurrence. Licensees, vendors, or other persons will be told when a meeting is a predecisional enforcement conference.

A predecisional enforcement conference is a meeting between the NRC and the licensee. Conferences are normally held in the regional offices and are not normally open to public observation. However, a trial program is being conducted to open approximately 25 percent of all eligible conferences for public observation, i.e., every fourth eligible conference involving one of three categories of licensees (reactor, hospital, and other materials licensees) will be open to the public. Conferences will not normally be open to the public if the enforcement action being contemplated:

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of an NRC Office of Investigations report; or

(4) Involves safeguards information, Privacy Act information, or information which could be considered proprietary;

In addition, conferences will not normally be open to the public if:

(5) The conference involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing the exposed individual's name; or

(6) The conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility.

Notwithstanding meeting any of these criteria, a conference may still be open if the conference involves issues related to an ongoing adjudicatory proceeding with one or more intervenors or where the evidentiary basis for the conference is a matter of public record, such as an adjudicatory decision by the Department of Labor. In addition, with the approval of the Executive Director for Operations, conferences will not be open to the public where good cause has been shown after balancing the benefit of the public observation against the potential impact on the agency's enforcement action in a particular case.

As soon as it is determined that a conference will be open to public observation, the NRC will notify the licensee that the conference will be open to public observation as part of the agency's trial program. Consistent with the agency's policy on open meetings, "Staff Meetings Open to Public," published September 20, 1994 (59 FR 48340), the NRC intends to announce open conferences normally at least 10 working days in advance of conferences through (1) notices posted in the Public Document Room, (2) a toll-free telephone recording at 800–952–9674, and (3) a toll-free electronic bulletin board at 800–952–9676. In addition, the NRC will also issue a press release and notify appropriate State liaison officers that a predecisional enforcement conference has been scheduled and that it is open to public observation.

The public attending open conferences under the trial program may observe but not participate in the conference. It is noted that the purpose of conducting open conferences under the trial program is not to maximize public attendance, but rather to determine whether providing the public with opportunities to be informed of NRC activities is compatible with the NRC's ability to exercise its regulatory and safety responsibilities. Therefore, members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings," published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed.

Members of the public attending open conferences will be reminded that (1) the apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at predecisional enforcement conferences, or the lack thereof, are not intended to represent final determinations or beliefs.

Persons attending open conferences will be provided an opportunity to submit written comments concerning the trial program anonymously to the regional office. These comments will be subsequently forwarded to the Director of the Office of Enforcement for review and consideration.

When needed to protect the public health and safety or common defense and security, escalated enforcement action, such as the issuance of an immediately effective order, will be taken before the conference. In these cases, a conference may be held after the escalated enforcement action is taken.

VI. Enforcement Actions

This section describes the enforcement sanctions available to the NRC and specifies the conditions under which each may be used. The basic enforcement sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative actions such as Notices of Nonconformance, Notices of Deviation, Confirmatory Action Letters, Letters of Reprimand, and Demands for Information are used to supplement the enforcement program. In selecting the enforcement sanctions or administrative actions, the NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. Usually, whenever a violation of NRC requirements of more than a minor concern is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, a Notice of Violation or a Notice of Nonconformance is the normal action.

A. Notice of Violation

A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) corrective steps that have been taken and the results achieved; (3) corrective steps that will be taken to prevent recurrence; and (4) the date when full compliance will be achieved. The NRC may waive all or portions of a written response to the extent relevant information has already been provided to the NRC in writing or documented in an NRC inspection report. The NRC may require responses to Notices of Violation to be under oath. Normally, responses under oath will be required only in connection with Severity Level I, II, or III violations or orders.

The NRC uses the Notice of Violation as the usual method for formalizing the existence of a violation. Issuance of a Notice of Violation is normally the only enforcement action taken, except in cases where the criteria for issuance of civil penalties and orders, as set forth in Sections VI.B and VI.C, respectively, are met. However, special circumstances regarding the violation findings may warrant discretion being exercised such that the NRC refrains from issuing a Notice of Violation. (See Section VII.B, "Mitigation of Enforcement Sanctions.") In addition, licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of (1) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders; (2) any requirement for which a license may be revoked; or (3) reporting requirements under section 206 of the Energy Reorganization Act. Civil penalties are designed to deter future violations both by the involved licensee as well as by other licensees conducting similar activities and to emphasize the need for licensees to identify violations and take prompt comprehensive corrective action.

Civil penalties are considered for Severity Level III violations. In addition, civil penalties will normally be assessed for Severity Level I and II violations and knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act.

Civil penalties are used to encourage prompt identification and prompt and comprehensive correction of violations, to emphasize compliance in a manner that deters future violations, and to serve to focus licensees' attention on violations of significant regulatory concern.

Although management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of management involvement may not be used to mitigate a civil penalty. Allowing mitigation in the latter case could encourage the lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

1. Base Civil Penalty

The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, materials, and vendor programs. (Civil penalties issued to individuals are determined on a case-by-case basis.) The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of the penalties take into account a licensee's ability to pay. In determining the amount of civil penalties for licensees for whom the tables do not reflect the ability to pay or the gravity of the violation, the NRC will consider as necessary an increase or decrease on a case-by-case basis. Normally, if a licensee can demonstrate financial hardship, the NRC will consider payments over time, including interest, rather than reducing the amount of the civil penalty. However, where a licensee claims financial hardship, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

2. Civil Penalty Assessment

In an effort to (1) emphasize the importance of adherence to requirements and (2) reinforce prompt self-identification of problems and root causes and prompt and comprehensive correction of violations, the NRC reviews each proposed civil penalty on its own merits and, after considering all relevant circumstances, may adjust the base civil penalties shown in Table 1A and 1B for Severity Level I, II, and III violations as described below.