U. S. NUCLEAR REGULATORY COMMISSION

REGION II

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Report No.:	45-23645-01NA/97-03
Licensee:	Department of the Navy
Locations:	Jacksonville Drug Lab Jacksonville, Florida Washington, D.C.
Dates:	March 12, 1997 March 19, 1997
Inspector:	Jay L. Henson, Radiation Specialist
Approved by:	Thomas R. Decker, Chief Materials Licensing/Inspection Branch 1 Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Department of the Navy
NRC Inspection Report 45-23645-01NA/97-03

This special, announced inspection was conducted to examine the licensee's program for the transportation of radioactive material and the events that lead to the delivery of a package leaking its radioactive contents. The package was shipped from the Navy Drug Screening Laboratory in Jacksonville, Florida (NAVDRUGLAB JAX) and delivered by Federal Express to the U.S. Air Force (USAF) Drug Screening Laboratory at Brooks Air Force Base (BAFB), San Antonio, Texas. The Navy Radiation Safety Committee (NRSC) issued Navy Radioactive Materials Permit (NRMP) No. 09-68850-61NP to NAVDRUGLAB JAX for the use of iodine-125 (I-125) in amounts as needed for in vitro laboratory testing procedures. NAVDRUGLAB JAX uses radioimmunoassay test kits containing up to 250 microcuries of I-125 for detection of drugs in human urine.

On February 28, 1997, NAVDRUGLAB JAX shipped a package containing three radioimmunoassay test kits by Federal Express to the USAF Drug Screening Laboratory at BAFB, San Antonio, Texas. Three 500 milliliter bottles of a radioactive reagent, each of which were reported to have contained 125 microcuries of I-125, were included in the package with six bottles of nonradioactive reagents. When the package was delivered to the laboratory at BAFB on March 3, 1997, the recipient noticed that the bottom surface of the package was wet. The BAFB Radiation Safety Officer (RSO) opened the package and determined that two of the bottles containing I-125 and one other 500 milliliter bottle containing a nonradioactive reagent were broken. The BAFB RSO also determined that the Federal Express truck, the truck driver's shoe, other packages in the truck, and the facility surfaces where the leaking package had been placed by the driver while on BAFB, were contaminated.

The inspection included discussions with cognizant NAVDRUGLAB JAX personnel, review of documents, and direct observations of activities associated with the packaging of radioimmunoassay test kits for shipment. The inspection also included telephonic interviews of the NAVDRUGLAB RSO, who was not present during the inspection, and with the BAFB RSO and Federal Express RSO.

Management Oversight

The inspection indicated that management oversight of the use of licensed material was inadequate as supported by the following examples: (1) NAVDRUGLAB JAX management did not ensure that employees who prepared packages of licensed material for shipment were trained on how to package licensed material for shipment and did not provide procedures to these employees describing how to properly package licensed material for shipment; (2) the RSO for the NAVDRUGLAB JAX was not aware that the NAVDRUGLAB JAX shipped licensed material to other drug laboratories; and (3) Personnel from the Navy Environmental Health Center, the Navy organization responsible for the review of permit applications and inspection of the permittee, were not aware that licensed materials were shipped by the NAVDRUGLAB JAX.

Transportation of Licensed Material

During the inspection, four apparent violations were identified regarding the transportation of the package that was shipped to the BAFB:

1. Failure of the package to maintain its integrity as a whole when subjected to the effects that may arise under normal conditions of transport as required by 49 CFR 173.421(a)(1) and 173.410.

2. Failure of the nonfixed (removable) radioactive surface contamination on the external surface of the package to remain below specified limits during transport as required by 49 CFR 173.421(a)(3) and 173.443(a)(1).

3. Failure to include the required certification notice with the package as required by 49 CFR 173.421(a)(6) and 173.422.

4. Failure to provide function-specific training concerning the transportation requirements for the package to the individual who prepared the package for transportation as required by 49 CFR 172.704(2)(i).

Transfer of Licensed Material

An apparent violation concerning the failure to properly verify that the receiver of radioactive material was authorized to receive the material prior to transferring the material as required by 10 CFR 30.41 was identified during the inspection.

LIST OF PERSONS CONTACTED

Licensee

&RADM J. Totushek, Chairman, Navy Radiation Safety Committee (NRSC)
&CDR P. Blake, Executive Secretary, NRSC
&CAPT R. LaFontaine, Bureau of Medicine and Surgery (BUMED-211)
*&LCDR S. Wolff, Navy Environmental Health Center (NEHC)
*LCDR L. McWhorter, Commanding Officer, Navy Drug Screening Laboratory, Jacksonville, Florida (NAVDRUGLAB JAX)
J. Stanko, Technical Assistant, NAVDRUGLAB JAX
#LT F. Barby, Radiation Safety Officer NAVDRUGLAB JAX and Naval Hospital, Naval Air Station, Jacksonville, Florida (NAS JAX)
HM3 R. Guevara, Radiation Safety Technician, Naval Hospital, NAS JAX
#J. Orr, RSO, Brooks Air Force Base, San Antonio, Texas
#R. Parker, RSO, Federal Express

Nuclear Regulatory Commission

&B. Mallett, Region II
&C. Haney, Nuclear Materials Safety and Safeguards (NMSS)
&S. Woods, NMSS

*Present at outbrief on March 12, 1997
#Interviewed by NRC inspector by telephone
&Present at exit meeting on March 19, 1997

REPORT DETAILS

01. Event Summary (87103)

Through interviews of licensee and other individuals, observations of activities of NAVDRUGLAB JAX, and review of records, the inspector determined the following:

On February 26, 1997, NAVDRUGLAB JAX received a request from the USAF drug laboratory at BAFB to send the USAF laboratory three methamphetamine radioimmunoassay (RIA) test kits. Each test kit included one 500 milliliter (ml) glass bottle of a yellow reagent containing up to 250 microcuries of I-125, one 500 ml glass bottle of a blue, nonradioactive reagent, and one 1250 ml plastic bottle of a second nonradioactive reagent.

On February 28, 1997, a NAVDRUGLAB JAX technical assistant (TA) obtained permission from the Commanding Officer (CO), NAVDRUGLAB JAX to transfer the requested RIA test kits to BAFB. The TA obtained a cardboard box used to ship glass culture tubes from the manufacturer to the NAVDRUGLAB JAX for use in packaging the RIA test kits. He removed the boxes of culture tubes from the box, but left the one inch thick foam pad in the bottom and sides of the box to cushion the RIA test kit bottles. After placing the nine bottles in the box, the TA placed some additional foam pads between and on top of the bottles. The TA sealed the top flaps of the box with duct tape and shipped the box by Federal Express to the USAF drug laboratory at BAFB. When the package was shipped, each of the bottles of radioactive reagent reportedly contained 125 microcuries of I-125.

On March 3, 1997, Federal Express delivered the package to the USAF drug laboratory at BAFB. The drug laboratory RSO noticed that the bottom of the package was wet. When he determined that this was the package sent from the NAVDRUGLAB JAX, he tried to stop the Federal Express driver and he contacted the BAFB RSO. The driver had left the area, but BAFB security personnel located him before he left BAFB and had him return to the drug laboratory.

The BAFB RSO used an EG&G Berthold Model 123 survey meter with a Model LB 6357 probe (100 square centimeters) to survey the driver, truck, other packages, and areas contacted by the package during the delivery process. The BAFB RSO determined that there was no contamination on the driver except for one spot (1000 disintegration per minute/centimeter squared [dpm/cm^2]) on his shoe. The driver's shoes were confiscated for disposal. The levels of contamination on the sidewalk where the driver had placed the box during the delivery process ranged from 100 to 280 dpm/cm^2. The BAFB RSO determined that a large area of the floor inside the truck was contaminated. The levels of contamination ranged from 30 to 1450 dpm/cm^2, with a number of survey points ranging from 600

to 1100 dpm/cm^2. The BAFB RSO also surveyed packages delivered by the driver before he delivered the leaking package to the drug laboratory and determined that two packages had small areas of contamination. The BAFB RSO removed these small areas of contamination from these packages.

The BAFB RSO opened the leaking box and determined that two of the 500 ml bottles containing the I-125 reagent and one of the 500 ml bottles of the blue, nonradioactive reagent were broken. The liquid contents of all three bottles had leaked out and had soaked the bottom of the box.

Federal Express performed surveys on the two aircraft used to transport the package from NAVDRUGLAB JAX to BAFB and reported that they had determined that there was no contamination present in either aircraft. Federal Express also surveyed their terminal where the driver obtained the package for delivery to BAFB and determined there was no contamination present at this site. It appeared that the bottles broke after they were placed on the truck for delivery to BAFB.

Personnel from the Texas Department of Health, Bureau of Radiation Control (BRC), responded to this event and participated in the survey and remediation of the contamination. The Federal Express truck was decontaminated, but the remaining levels of contamination after this effort remained at or slightly above the limits for release of the truck for unrestricted use. The Texas BRC staff authorized Federal Express to return the truck to the Federal Express parking area and restricted the use of the truck until March 18, 1997, to allow for decay of the remaining contamination.

02. Management Oversight (87100)

Through interviews of licensee and other individuals, observations of activities of NAVDRUGLAB JAX, and review of records, the inspector determined the following:

The Navy Master Materials License (NMML) authorizes the Navy Radiation Safety Committee (NRSC) to issue permits to users of radioactive material within the Navy, and to oversee those uses through auditing. The NRSC maintains oversight of certain uses of radioactive materials through the Navy Environmental Health Center (NEHC), which handles the permitting program and conducts periodic audits of permittees.

The NRSC issued Permit No. 09-68850-61NP to the NAVDRUGLAB JAX for the use of I-125 for in vitro laboratory testing procedures in amounts as needed. The NAVDRUGLAB JAX uses radioimmunoassay test kits containing up to 250 microcuries of I-125 for detection of drugs in human urine.

Based upon discussions with the NAVDRUGLAB JAX CO, the inspector determined that the CO was aware that the laboratory occasionally (once or twice per year) transferred RIA test kits to other Department of Defense drug screening laboratories. The CO was also aware that the TA packaged the RIA test kits and shipped them by Federal Express when the kits were transferred to other laboratories. Through discussions with

the shipment of the RIA test kits and that the CO was not aware of the method that the TA used in preparing packages of RIA test kits for shipment. The CO was also not familiar with the DOT requirements regarding the training required of employees who package radioactive material for transportation by a commercial carrier.

The inspector also asked the CO if a periodic physical inventory was performed of the licensed material at the laboratory. The CO stated that they do maintain a log book that includes the number of kits received, used, transferred and disposed, but that a periodic physical inventory is not performed.

The RSO for the NAVDRUGLAB JAX permit was assigned to the Navy Hospital at the NAS, Jacksonville, where he also serves as the RSO. Activities performed by the RSO or a member of his staff at the NAVDRUGLAB JAX included preparing the permit application and procedures, performing ambient dose rate and contamination surveys, monitoring waste disposal activities including storage and effluent releases, performing quarterly bioassays, annual training and radiac calibration. The NAVDRUGLAB JAX RSO also met with the NAVDRUGLAB JAX CO on a quarterly basis to review the status of the radiation protection program. The RSO stated that the NAVDRUGLAB JAX had experienced two minor spills in the last 18 months and that since 1994, when he became the RSO, all of the bioassays performed on the laboratory staff indicated that no one had any uptakes of I-125.

The inspector asked the RSO if a periodic, physical inventory of the RIA test kits was performed by him, or his staff. The RSO responded that neither he nor his staff conduct a periodic physical inventory of the licensed materials in use at NAVDRUGLAB JAX. The RSO or his staff do obtain information regarding the number of RIA test kits used and the number that are disposed down the sanitary sewer system. He said he obtains this information to monitor the laboratory's compliance with effluent release requirements. The inspector also asked the RSO if he or his staff reviewed the log book NAVDRUGLAB JAX maintains to document their use, transfer and disposal of the RIA kits. The RSO responded that neither he nor his staff review this log book and that they rely upon staff at the laboratory to provide information on the number of kits used and disposed of. The inspector asked the RSO if he was aware that the NAVDRUGLAB JAX occasionally transferred licensed material to other laboratories. The RSO stated that he was not aware of these transfers.

The most recent renewal application for this permit was submitted to NEHC for review on July 10, 1995. The inspector reviewed this application and determined that NAVDRUGLAB JAX did not include any reference or procedure describing the transfer of RIA test kits to other laboratories or the transportation of the kits. The NRSC issued the most recent amendment to this permit on September 29, 1996. The

inspector determined that none of the correspondence regarding the licensed activities conducted at NAVDRUGLAB JAX contained any reference or procedure to the transfer and transportation of RIA test kits to other laboratories.

NEHC routinely inspects NAVDRUGLAB JAX for compliance with NRC and Navy regulations. NEHC conducted their most recent inspection of the NAVDRUBGLAB JAX on March 14, 1995. The inspector reviewed the documentation regarding the most recent inspection and found no reference to the transfer and transportation activities performed by the NAVDRUGLAB JAX. As a result of the review of permitting and inspection documentation and from discussions with NEHC personnel, the inspector determined that NEHC was also not aware that the NAVDRUGLAB JAX occasionally transferred RIA test kits to other laboratories.

No violations were identified in this area. However, it appeared that the NRSC, and the NAVDRUGLAB JAX CO and RSO, had not maintained sufficient oversight of the licensed activities performed by the NAVDRUGLAB JAX to ensure that regulatory requirements were met.

03. Transportation Activities (86740)

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.421(a) permits the shipment of certain quantities of radioactive materials as "limited quantity", excepted from the specification packaging, marking, labeling and, if not a hazardous substance or hazardous waste, the shipping paper and certification requirements of subpart H, 49 CFR Part 173, provided the package meets the requirements specified in that part.

Through review of records and discussions with licensee personnel, the inspector determined that on February 28, 1997, the NAVDRUGLAB JAX offered a package containing 375 microcuries of I-125 (a "limited quantity" of radioactive material) for transport by a commercial carrier, and that on March 3, 1997, when Federal Express delivered this package to the recipient at the BAFB, the bottom of the package was wet from its liquid radioactive contents.

a. 49 CFR 173.421(a)(1) requires that each limited quantity package meet the general design requirements of 49 CFR 173.410. 49 CFR 173.410(f) requires, in part, that the package will be capable of withstanding the effects of any acceleration, vibration or vibration resonance that may arise under normal conditions of transport without any deterioration in the integrity of the package as a whole.

Through discussions with personnel from BAFB and Federal Express, the inspector determined that when the package was received at BAFB on March 3, 1997, the bottom of the package was wet. The BAFB RSO opened the package and determined that two of the three glass bottles containing the I-125 reagent were broken and the radioactive contents had soaked the bottom of the box. In discussions with BAFB and Federal Express personnel, and review of pictures provided by the BAFB RSO of the truck and box as received by BAFB, the inspector determined that the package was subjected to the conditions normally incident to transportation and the package did not maintain its integrity as a whole. Failure of the package to withstand the conditions normally incident to transportation without any deterioration in its integrity as a whole was identified as an apparent violation of 49 CFR 173.421(a)(1) and 173.410.

b. 49 CFR 173.421(a)(3) requires that the nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a). 49 CFR 173.443(a)(1) requires, in part, with exceptions not applicable here, that for beta-gamma emitting contaminants, the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment, when averaged over the surface wiped, not exceed 22 disintegrations per minute per square centimeter on any single wiping material at any time during transport.

Through discussions with BAFB personnel, the inspector determined that on March 3, 1997, when the package was delivered at BAFB, the recipient noticed the wet area on the bottom of the package and contacted the BAFB RSO. Based upon discussions with the BAFB RSO and the results of the contamination surveys performed by the BAFB RSO of the Federal Express truck floor, the level of removable contamination that remained on the truck floor surface from the external surface of the package was as high as 1450 dpm/cm^2. The presence of contamination in the Federal Express truck that came from the external surface of the package that exceeded 22 dpm/cm^2 was identified as an apparent violation of 49 CFR 173.421(a)(3) and 173.443(a)(1).

c. 49 CFR 173.421(a)(6) requires that the radioactive material in a "limited quantity" package be otherwise prepared for shipment as specified in accordance with 49 CFR 173.422. 49 CFR 173.422 requires, in part, that packages prepared for shipment under 49 CFR 173.421 be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the following statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910".

The inspector reviewed a copy of the documentation (shipping label) that accompanied the "limited quantity" package the NAVDRUGLAB JAX shipped on February 28, 1997. The inspector also interviewed the NAVDRUGLAB JAX personnel regarding the documentation they prepared for the package and discussed the information included with the package when received at BAFB with the BAFB RSO. Based upon the review and discussions, the inspector determined that the licensee did not include the required confirmatory notice with the package when it was shipped. Failure of the licensee to include this confirmatory notice with the package was identified as an apparent violation of 49 CFR 173.421(a)(6) and 173.422.

d. 49 CFR 172.704(2)(i) requires, in part, that each hazardous materials employee shall be provided function-specific training concerning requirements of subchapter A of Chapter I of Title 49, or exemptions issued under subchapter A of Chapter I, which are specifically applicable ot the functions the employee performs.

The inspector reviewed training records for the individual who packaged the RIA test kits for shipment to BAFB. This individual attended the annual radiation safety training provided by the permit RSO on November 6, 1995 and September 16, 1996. This individual had also attended the two week RSO safety course provided by the Navy's Radiological Affairs Support Office (RASO) in May, 1996. This individual did not obtain a passing grade on the test provided at the end of the RASO course (passing grade was 80%; individual scored 78%). This individual also attended the 40 hour Hazardous Materials Training Course provided at the NAS, Jacksonville, during the week of December 13, 1996 and received a certificate attesting to the successful completion of this course.

The inspector interviewed the individual who packaged the RIA test kits regarding the material included in the different radiation safety training courses he had attended. The individual stated that he had not received any training on how to package a "limited quantity" of radioactive material for shipment. The only transportation specific training he remembered receiving was in the RASO RSO course. He said that the training was specific for the transportation requirements associated with large radioactive sources, such as radiography sources, and did not include a discussion on the transportation requirements for a "limited quantity" radioactive material package.

Failure of the licensee to provide function-specific training related to the transportation requirements for a "limited quantity" radioactive materials package to the individual who packaged the RIA test kits shipped on February 28, 1997, was identified as an apparent violation of 49 CFR 172.704(2)(i).

04. Radioactive Material Transfers (87100)

10 CFR 30.41 requires, in part, that no licensee transfer byproduct material except to a person authorized to receive such byproduct material under the terms of a specific or general license issued by the Commission or an Agreement State and that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. 10 CFR 30.41(d) specifies acceptable methods for this verification.

The inspector reviewed the licensee's records of use, transfers, and disposals. The licensee maintained a log book which listed each RIA kit the licensee had received. When a RIA test kit was used, the individual removing the kit from storage entered his/her initials and date of use. If the kit was disposed, the individual entered his/her initials and the date of disposal. If the kit was transferred to another laboratory, the person transferring the material entered the date and the laboratory to which the material was sent. The inspector reviewed the records from January 1, 1995, to March 12, 1997. The inspector noted that the licensee had transferred RIA test kits to the Navy Drug Screening Laboratory, in San Diego, California, on July 14, 1995, the Navy Drug Screening Laboratory, in Great Lakes, Illinois, on May 15, 1996, and to the USAF Drug Screening Laboratory, BAFB, San Antonio, Texas, on February 28, 1997.

The inspector asked the NAVDRUGLAB JAX CO and staff how they verified that the laboratories to which they had transferred RIA test kits were authorized to receive this licensed material. The CO stated that since all the laboratories were a part of the Department of Defense Drug Screening Program, she assumed that they were all authorized to receive the material. The inspector asked if the CO or a member of her staff verified that these laboratories were authorized to receive this material by one of the means described in 10 CFR 30.41(d). The CO responded that neither she nor her staff had verified that the laboratories were authorized to receive the RIA test kits as described in 10 CFR 30.41(d).

Failure of the licensee to verify that the laboratories to which it transferred RIA test kits were authorized to receive the licensed material by one of the required methods was identified as an apparent violation of 10 CFR 30.41(d).

EXIT MEETING SUMMARY

An exit meeting was held with licensee representatives, including the NEHC and the NAVDRUGLAB JAX on March 12, 1997. The overall findings from the inspection, including some of the violations were discussed. No dissenting comments were received from the licensee, and the licensee did not specify any

information reviewed during the inspection as proprietary in nature. On March 19, 1997, the NRSC was briefed on the inspection findings and apparent violations during their quarterly meeting. No dissenting comments were received.

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 normally open to public observation. 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 that has not been publicly disclosed; 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, notwithstanding the above normal criteria for opening or closing conferences, with the approval of the Executive Director for Operations, conferences may either be open or closed to the public after balancing the benefit of the public observation against the potential impact on the agency's decision-making process in a particular case.

The NRC will notify the licensee that the conference will be open to public observation. 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, (3) a toll-free electronic bulletin board at 800-952-9676, and on the World Wide Web at the NRC Office of Enforcement homepage (www.nrc.gov/OE). In addition, the NRC normally 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 may observe but not participate in the conference. It is noted that the purpose of conducting open conferences is not to maximize public attendance, but rather to provide the public with opportunities to be informed of NRC activities consistent 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. The open conference will be terminated if disruption interferes with a successful conference. NRC's Predecisional Enforcement Conferences (whether open or closed) normally will be held at the NRC's Regional offices or in NRC Headquarters Offices and not in the vicinity of the licensee's facility.

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.

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.

NRC ENFORCEMENT PROGRAM

The Commission has developed an enforcement program and Enforcement Policy to support the NRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement action should be used as a deterrent to emphasize the importance of compliance with regulatory requirements, and to encourage prompt identification and prompt, comprehensive correction of violations.

Violations are identified through inspections and investigations. All violations are subject to civil enforcement action and may also be subject to criminal prosecution. After an apparent violation is identified, it is assessed in accordance with the Commission's Enforcement Policy. The Policy is published as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions," to provide widespread dissemination. Because it is a policy statement and not a regulation, the Commission may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

There are three primary enforcement sanctions available: Notices of Violation, civil penalties, and orders. A Notice of Violation (NOV) summarizes the results of an inspection, identifies a requirement and how it was violated, and formalizes a violation pursuant to 10 CFR 2.201. A civil penalty is a monetary fine issued under authority of section 234 of the Atomic Energy Act. That section provides for penalties of up to $100,000 per violation per day; but that amount has been adjusted by the Debt Collection Improvement Act of 1996 to be $110,000. NOVs and civil penalties are issued based on violations. Orders may be issued for violations, or in the absence of a violation, because of a public health or safety issue.

The Commission's order issuing authority is broad and extends to any area of licensed activity that affects the public health and safety. Orders modify, suspend, or revoke licenses or require specific actions by licensees or individuals. As a result of a rulemaking in 1991, the Commission's regulations now provide for issuing orders to individuals who are not themselves licensed.

The first step in the enforcement process is assessing the severity of the violation. Severity Levels range from Severity Level I, for the most significant violations, to Severity Level IV for those of more than minor concern. Minor violations are not subject to formal enforcement action. Severity levels may be increased for cases involving a group of violations with the same root cause, repetitive violations, or willful violations.

A predecisional enforcement conference is normally conducted with a licensee before making an enforcement decision if escalated enforcement action (i.e., Severity Level I, II, or III violations, civil penalties or orders) appears to be warranted, and if the NRC concludes that it is necessary or the licensee requests it. If the NRC concludes that a conference is not necessary, it will normally provide a licensee with an opportunity to respond to the apparent violations before making an

enforcement decision. 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. The decision to hold a conference does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. In accordance with the Enforcement Policy, conferences are normally open to the public and held at NRC regional offices. However, the Commission will close conferences under certain circumstances.

Civil penalties are considered for Severity Level III violations and are normally 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.

The NRC imposes different levels of civil penalties based on a combination of the type of licensed activity, the type of licensee, the severity level of the violation, and (1) whether the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past 2 years or past 2 inspections, whichever is longer; (2) whether the licensee should be given credit for actions related to identification; (3) whether the licensee's corrective actions are prompt and comprehensive; and (4) whether, in view of all the circumstances, the matter in question requires the exercise of discretion. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or a base civil penalty escalated by 100%.

If a civil penalty is to be proposed, a written Notice of Violation and Proposed Imposition of Civil Penalty is issued and the licensee has 30 days to respond in writing, by either paying the penalty or contesting it. The NRC considers the response, and if the penalty is contested, may either mitigate the penalty or impose it by order.

If the civil penalty is to be imposed by order, the order is published in the *Federal Register*. Thereafter, the licensee may pay the civil penalty or request a hearing.

In addition to civil penalties, orders may be used to modify, suspend, or revoke licenses. Orders that modify a license may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. The NRC issues a press release with a proposed civil penalty or order.

NOTE: Persons attending open predecisional enforcement conferences are reminded that (1) the apparent violations discussed at open 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 opinion made by NRC employees at open enforcement conferences or the lack thereof, are not intended to represent final determinations or beliefs.