UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

Report No. 52-16033-01/93-02

License No. 52-16033-01 Docket No. 030-11155

Licensee: Hospital Metropolitano
Río Piedras, Puerto Rico

Inspection Conducted: December 15, 17 and 29, 1993, and February 16 and April 19, 1994

Inspector: _____ 5/5/94
H. Bermúdez, Sr. Radiation Specialist Date Signed

Approved By: _____ 5/5/94
C. Hosey, Chief Date Signed
Nuclear Materials Inspection Section
Nuclear Materials Safety and Safeguards Branch
Division of Radiation Safety and Safeguards

SUMMARY

Scope:

This special, unannounced inspection of activities conducted under NRC License No. 52-16033-01 included a review of the circumstances surrounding a reported brachytherapy misadministration and the implementation of the licensee's quality management program as applicable to the licensee's brachytherapy operations.

Results:

The inspection revealed that the misadministration was caused by patient intervention in the procedure, in combination with the failure of two nurses to follow an emergency procedure. The failures to follow the emergency procedure and to take effective corrective action to prevent the recurrence of a previously identified violation appear to result from the fact that, although licensee personnel were trained as required, some personnel had a significant lack of awareness regarding radiation safety practices in the handling of hospitalized patients undergoing therapy with licensed materials. Such weakness significantly contributed to the misadministration because the nurses involved in the incident failed to take appropriate action after discovering that radioactive sources had been dislodged and were under the control of the patient.

Within the scope of the inspection, the following apparent violations were identified:

- Failure to notify the Radiation Safety Officer, the physician and the medical physicist of an emergency, a repeat finding from an NRC inspection conducted on April 10, 22-23, 1992.

- Failure of licensee personnel to wear a film badge when entering the room of a patient undergoing implant brachytherapy.

- Failure to evaluate the radiation exposures of personnel who entered the room of a patient undergoing implant brachytherapy without wearing a film badge.

- Failure to submit to the NRC and the patient a written report of a misadministration within 15 days of its discovery.

Report Details

1. Persons contacted

M. Acevedo, Dosimetrist
Z. Alvarado, Nurse
J. Díaz, M.D., Radiation Safety Officer
M. Friger, M.D., Physician
S. Gómez, Consultant
* M. Maldonado, Executive Administrator
* A. Miranda, M.D., Medical Director
* L. Ortiz, Director of Nursing
M. Rodríguez, Associate Director of Nursing
J. Ubiñas, M.D., Authorized User Physician
C. Weigle, Oncology Center's Quality Assurance Coordinator

Other licensee employees contacted included technologists and administrative personnel.

* Attended exit interview.

2. Program Scope and Licensee Organization

License No. 52-16033-01 was originally issued on July 15, 1975, and was most recently amended and renewed on June 10, 1991. The license allows the use of certain radiopharmaceuticals in the practice of diagnostic and therapeutic nuclear medicine. The license also allows the possession and use of radioactive sealed sources for brachytherapy treatments. Nuclear medicine activities were conducted by the licensee's Nuclear Medicine Institute and brachytherapy activities were conducted by the licensee's Radiation Oncology Center (ROC), both contractors of the licensee. The Radiation Safety Officer (RSO) was the Chief of Nuclear Medicine, the practicing authorized user for nuclear medicine activities and the chairman of the licensee's Radiation Safety Committee.

The licensee had been performing approximately 2-3 brachytherapy procedures per month which required patient hospitalization. At the time of the inspection, the licensee scheduled the use of the rooms in which the patients were hospitalized primarily based on availability of any room appropriate for brachytherapy on any floor of the hospital. The licensee's nursing staff were permanently assigned to a particular floor of the hospital. Under these conditions, any particular nurse or other individual permanently assigned to a floor may not deal with brachytherapy patients for long periods of time.

3. Sequence of events surrounding the misadministration

Through interviews with licensee representatives and review of records the inspector determined the following:

At 5:20 p.m. on December 9, 1993, a patient began undergoing a gynecological low-dose-rate brachytherapy treatment for which the Authorized User Physician (AUP) had prescribed a radiation dose of 3000

centigrays (cGy) to a specified point in the treatment site. Dosimetry calculations indicated that the prescribed dose was to be delivered by 5:30 p.m. on December 11, 1993. However, at approximately 7:30 a.m. on December 11, 1993, the patient intervened in the treatment by removing the implant containing the radioactive sources and placing it next to her thigh. The implant contained approximately 1.1 gigabecquerels of radioactivity. Shortly after removing the implant the patient showed it to a nurse who had gone to the patient's room to take vital signs. The nurse recognized the implant and understood there was an unusual situation which needed to be reported and reported it to her supervisor. The nurse's supervisor was experiencing difficulty with another patient in addition to be working on shift turnover matters when she was told of the problem with the brachytherapy implant. As a result of the distraction caused by the heavy workload at the time the incident was reported to her, the nurse supervisor failed to realize the urgent nature of the situation and forgot to make the required notifications she and the supervised nurse had been instructed to make in case of emergencies. On several occasions that morning licensee personnel entered the patient's room without realizing that the radioactive sources were exposed because the sources were covered by bed linen and the patient did not notify them that the sources were on the bed. During that time, the nurse who originally saw the implant assumed that her supervisor had made the required notifications and neglected to follow up to ensure that the notifications were made. Approximately two and a half hours after the patient removed the implant the AUP entered the patient's room for a routine check and discovered that the implant was outside the patient's body. After properly accounting for the sources and storing them, the AUP examined and interviewed the patient and decided to terminate the treatment. The AUP's decision to terminate the treatment was made on the basis that the patient was a threat to herself and others, and that the combination of the external beam irradiation to which the patient had been subjected prior to the implant and the implant dose received made the overall treatment of the patient clinically adequate. Calculations of the actual radiation dose delivered to the intended treatment site were made and the AUP revised the written directive to reflect the lower dose delivered. The licensee's evaluation of the incident indicated that the maximum dose to the skin of the patient's thigh, assuming that the implant remained in the same location for three hours, was 572 cGy.

4. Causes of the misadministration

Pursuant to 10 CFR 35.2, "misadministration" means, in part, a brachytherapy radiation dose involving the wrong treatment site. The fact that the skin of the patient's thigh was not intended to receive a therapeutic radiation dose makes the incident a misadministration. Through interviews with licensee representatives and review of records the inspector determined that the cause of the misadministration was patient intervention in the treatment, in combination with the failure of the two nurses to follow established procedures by failing to make the required notifications. The inspector also determined that the cause of the failure to make the required notifications was a

significant lack of awareness regarding radiation safety practices in the handling of hospitalized patients undergoing therapy with licensed materials. The inspector further determined that the such lack of awareness was caused by the licensee's personnel infrequent handling of hospitalized patients undergoing therapy with licensed materials and the ineffectiveness of the licensee's training program in addressing this issue.

5. Consequences

The AUP indicated to the inspector that the brachytherapy treatment was subsequent to surgery and the delivery of 5000 cGy by external beam irradiation. The AUP indicated that, based on the history of the case, the delivery of anywhere between 2000 and 3000 cGy to the treatment site would make the treatment clinically adequate. Dosimetry calculations showed that the treatment site received approximately 2270 cGy. The licensee's position was that the underdose at the treatment site will not have negative effects on the patient and the dose of up to 572 cGy to the skin of the thigh will not result in skin damage.

The NRC's medical consultant reviewed this case and discussed it with the AUP. Based on the reviews and discussions, the NRC's medical consultant determined that the dose delivered to the treatment site was sufficient to treat the patient's condition. The NRC's medical consultant concluded that the treatment goals were achieved, although the brachytherapy dose to the treatment site was lower than originally planned. Regarding the unplanned exposure to the thigh, the NRC's medical consultant indicated that the calculated maximum dose received was not expected to result in acute or late effects. Furthermore, through discussions with the AUP on April 19, 1994, the NRC's medical consultant determined that the patient had a normal examination with no evidence of acute or late sequelae. [See the NRC's medical consultant's reports dated February 16 and April 19, 1994, attached to this report.]

On the other hand, the failure of the licensee's nurses to make the required notifications resulted in the patient receiving an unintended whole body irradiation to include up to 572 cGy to the skin of the thigh, a significant loss of control of the radioactive sources and unnecessary radiation exposures for the AUP and other licensee personnel who entered the room while the sources were exposed.

6. Licensee's response to the event and corrective actions

Through discussions with licensee representatives and review of records the inspector determined that, upon discovering the implant on the bed, the AUP immediately accounted for the sources, stored them in a shielded container and performed radiation surveys to ensure safe radiological conditions. The AUP then explained to the patient that the sources, when inside the body, were beneficial to her condition but outside the body were potentially harmful, and that the treatment was not delivered as intended. The licensee notified the NRC Operations Center of the misadministration within three hours of its discovery. The AUP notified

the referring physician of the misadministration and discussed the clinical management of the case with him the following morning. The licensee promptly conducted an investigation of the incident and a clinical evaluation of the patient. The licensee's investigation revealed that, contrary to written procedures, licensee personnel had not been wearing their assigned film badges when entering the patient's room. The licensee determined that the failure to make the required notifications and to wear film badges when entering the patient's room were due to the lack of familiarity with established radiation safety procedures on which personnel had been trained. The licensee held a Radiation Safety Committee meeting in which the incident and corrective actions to prevent recurrence were discussed. The licensee decided to dedicate one floor of the hospital for all therapies involving licensed materials to help ensure that nurses assigned to the floor maintain familiarity with operating and emergency procedures. The licensee was also evaluating the need to increase patient awareness regarding non-intervention in procedures.

On December 29, 1993, the licensee indicated that they would revise their emergency procedures for responding to radiological emergencies involving patients undergoing radiopharmaceutical or sealed source therapy to, as a minimum, define what a radiological emergency is and provide examples of situations which must be considered radiological emergencies or which could result in misadministrations. The licensee also indicated that they would develop and implement a retraining program based on the revised emergency procedures for all hospital employees who may be involved in the handling of patients hospitalized while undergoing therapy with licensed materials.

At the time of the inspection, the licensee had not evaluated the exposures of unmonitored individuals who entered the patient's room. Licensee personnel indicated they would evaluate the exposures of those individuals.

7. Regulatory issues

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. The program must include written policies and procedures to meet the following objectives: (1) That, prior to administration, a written directive is prepared for any brachytherapy radiation dose; (2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive; (3) That final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directive; (4) That each administration is in accordance with the written directive; and (5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken. The inspector evaluated the event and the licensee's quality management program applicable to brachytherapy for adequacy in meeting the specified objectives. Through interviews, the inspector verified

that licensee personnel, including members of the nursing staff, had been instructed in the applicable parts of the licensee's quality management program and safety procedures. Also, in addition to the case described in this report, the inspector randomly reviewed with licensee representatives three other brachytherapy cases for adequacy in meeting the objectives specified in 10 CFR 35.32(a). Based on discussions and review of records, the inspector determined that for each of the cases reviewed: (1) a properly documented written directive was prepared prior to the administration of the radiation dose, (2) prior to the administration, at least two independent methods were used to verify the patient's identity as the individual named in the written directive, (3) the final plan of treatment and related calculations were in accordance with the written directive, (4) the licensee verified that the specific details of the administration were in accordance with the written directive, and (5) the licensee had implemented procedures to identify and evaluate unintended deviations from the written directive and to take adequate corrective actions.

Condition 15 of license no. 52-16033-01 requires, in part, that the licensee conduct its program in accordance with the statements and procedures contained in the license application dated July 11, 1989. Item 6 of Attachment 10.15 of the application, "Instructions to Doctors, Nurses and Visitors," requires, in part, that the physician, the RSO and the medical physicist be called in case of an emergency. The failure of the licensee's nurses to make the required notifications after discovering that there was an emergency consisting of the patient being in control of the radioactive sources, causing her whole body to be irradiated, was identified as an apparent violation of Condition 15 of the license. This apparent violation is similar to Violation II.B.1 contained in a Notice of Violation and Proposed Imposition of Civil Penalties issued to the licensee on June 26, 1992.

Item 4 of Attachment 10.15 of the application states, in part, that any person who enters the room of a patient undergoing implant brachytherapy must use a film badge. After reviewing the licensee's investigation report on the misadministration which indicated that personnel entering the room did not wear their film badges, the inspector interviewed licensee representatives to learn how personnel knew about the requirement. The inspector determined that the procedure which requires the use of film badges was part of the patient's chart and was also posted on the door to the room. Licensee personnel also indicated that they were periodically reminded of the requirement during refresher training or upon beginning to handle a brachytherapy patient. However, some personnel had difficulty explaining the purpose of wearing a film badge. Based on the interviews, the inspector agreed with the licensee's conclusion that the failure to wear film badges when entering the therapy room was due to the lack of familiarity with established radiation safety procedures on which personnel had been trained. The failure of licensee personnel to wear film badges when entering the room of a patient undergoing implant brachytherapy was identified as another apparent violation of Condition 15 of the license.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive material or other sources of radiation under a specific set of conditions. As of December 17, 1993, the licensee had not evaluated the exposures of personnel who entered the patient's room without wearing the required film badges. The failure to evaluate radiation exposures of personnel who entered the patient's room without wearing film badges was identified as an apparent violation of 10 CFR 20.201(b).

10 CFR 35.33(a)(2) requires, in part, that the licensee submit to the appropriate NRC Regional Office listed in Appendix D of 10 CFR Part 20, a written report of a misadministration within 15 days of the discovery of the misadministration. 10 CFR 35.33(a)(4) requires, in part, that the licensee also submit to the patient a written report of a misadministration within 15 days of the discovery of the misadministration. For the misadministration that was discovered on December 11, 1993, the licensee did not submit the required written report to the NRC until January 5, 1994, and did not submit the required written report to the patient until January 13, 1994, both intervals in excess of 15 days. The failure to submit the required written misadministration reports to the NRC and the patient in a timely manner was identified as an apparent violation of 10 CFR 35.33(a).

8. Exit interview

The inspection scope and results were summarized in an exit interview with those individuals identified in Section 1 of this report. The inspector reviewed the program areas inspected and discussed in detail the inspection findings. The NRC's enforcement policy was reviewed with licensee representatives. The inspector also discussed the reasons why the NRC will not issue licenses directly to licensee contractors which operate within the licensee's premises, and reminded licensee management that the NRC expects licensee management to be ultimately responsible for all activities conducted under the NRC license. Licensee representatives acknowledged the NRC's concerns regarding the need to better ensure that written procedures will be fully implemented as intended. Licensee representatives did not provide dissenting comments relative to the apparent violations discussed in this report. Proprietary information is not contained in this report.

Enclosure 2

PROPOSED ENFORCEMENT CONFERENCE AGENDA

Hospital Metropolitano

Rio Piedras, Puerto Rico

May 20, 1994 9:00 a.m.

I.	Opening Remarks	NRC and Licensee
II.	NRC Enforcement Policy and Procedure	NRC
III.	Discussion of NRC Concerns	NRC
IV.	Inspection Findings and Apparent Violations	NRC
V.	Causes of Apparent Violations and Corrective Actions	Licensee
VI.	NRC Followup Questions	NRC
VII.	Closing Comments	NRC and Licensee

RADIATION ONCOLOGY

University of Wisconsin School of Medicine

Department of Human Oncology, Timothy J Kinsella MD, *Chairman*
Center for Health Sciences and the University of Wisconsin
Comprehensive Cancer Center, Paul P Carbone MD, *Director*

600 Highland Drive, Madison, Wisconsin 53792-0600 (608) 263 - 8500 FAX (608) 263 - 9167

February 16, 1994

Mr. Charles M. Hosey
U.S. Nuclear Regulatory Commission
Region II
101 Marietta St., N.W.
Atlanta, GA 30323

Dear Mr. Hosey:

Attached is the Medical Consultant Report on the Hospital Metropolitano, Rio Piedras, Puerto Rico, regarding a misadministration of therapy incident. Records were reviewed; the incident has been described; the medical consequence of the exposure have been addressed; and I do agree with the written report submitted by the licensee. If you have any questions, please feel free to contact me (608/263-8500).

Sincerely,

Judith Anne Stitt, M.D.
Associate Professor of Human Oncology AND
Clinical Director, Section of Radiation Oncology

JAS/dtp

Enclosures

COMPLETE FOR MEDICAL MISADMINISTRATION

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to NRC pursuant to 10 CFR 35.33 in the following areas:

a.	Why the event occurred	Y+	N
b.	Effect on the patient	Y+	N
c.	Licensee's immediate actions upon discovery	Y+	N
d.	Improvements needed to prevent recurrence	Y+	N
e.	Licensee's plan for followup of patient	Y+	N
f.	Report submitted to patient or patients responsible relative or guardian	Y+	N

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33), provide the basis for your opinion:

No areas of disagreement.

3. If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with medical ethics?
Y N

If not, comment on why the reason was not valid.

Records indicate that the patient was to be notified of the incident

4. Briefly describe the medical condition of the exposed individual and the cause of the short-term medical care being provided to the individual.

The patient's medical condition will be followed by her attending physician at regular intervals consistent usual management of her endometrial cancer. No changes in the follow-up schedule need to be made as a result of her brachytherapy treatment.

Description of Incident:

On 12-9-93 a patient with adenocarcioma of the endometrium treated with hysterectomy and external beam irradiation received a gynecologic insertion with a 2 cm diameter vaginal cylinder. This was loaded with three 10 mg-eq Cdsium-137 sources (30 milli8curies). The labia were sutured following the insertion. Localization films and dosimetery were performed. A dose of 3000 cGy to a specified point was prescribed.

Sources were loaded on 12-9-93 at 5:30 PM. On 12-11-93 at 7:30 AM the patient notified nursing personnel that the applicator and sources were in her bed next to ther thigh. The duration of the implant was 38 hours.

The radiation therapist and the patient's attending physician determined that because of the patients mental status and prior external beam therapy, the dose received from this brachytherapy insertion was sufficient. No further treatment with isotopes was deemed necessary.

Medical Consequence of Exposure:

The normal tissues that received unplanned dose was the soft tissue of the thigh. The calculated dose received by this region was 572 cGy. No acute or late effects would be expected to ensue from this radiation dose.

The patient received pelvic irradiation with 5,000 cGy external beam therapy with 2270 cGy to the vaginal cuff from the brachytherapy insertion. This dose is sufficient to treat endometrial carcinoma following surgery. Therefore, the treatment goals were achieved, although the brachytherapy dose was lower than originally planned.

Was individual or individual's physician informed of DOE Long-Term Medical Study Program?	Not Stated	Y	N
Would individual like to be included in the Program?	Not Stated	Y	N

Medical Consultant Name: Judith Anne Stitt, MD Report Date: 2/14/94

Signature: [signature]

Licensee Name: Jeanne Ubinas,MD License No. 52-16033-01

Individual's/Patient's Identification No. or Name: Not Stated

Incident Date: 12 / 11 / 93

Individual's/Patient's Physician Name: Jeanne Ubinas,MD

Individuals Contacted During Investigation:

Charles Hosey NRC

Records Reviewed: (General Description)

Incident report from Licensee

NRC Records

Calculated Dose to Individual: 2270 cGy to Vagina

Prescribed Dose (Medical Misadministration Only): 3000 cGy to vagina

Method Used to Calculate Dose: No calculation done-doses stated in licensee's document were reviewed and appear to be correct

Medical Consultant Name: Judith Anne Stitt, MD

Report Date: 4/ 19 / 94
Appended Report

Signature: Judith Stitt, MD.

Licensee Name: Jeanne Ubinas,MD License No. 52-16033-01

Individual's/Patient's Identification No. or Name: Not Stated

Incident Date: 12 / 11 / 93

Individual's/Patient's Physician Name: Jeanne Ubinas,MD

Individuals Contacted During Investigation:

Charles Hosey NRC
Hector Bermudez NRC
Dr. Jeanne Ubinas

Records Reviewed: (General Description)

Incident report from Licensee

NRC Records

Calculated Dose to Individual: 2270 cGy to Vagina

Prescribed Dose (Medical Misadministration Only): 30000 cGy to vagina

Method Used to Calculate Dose: No calculation done-doses stated in licensee's document were reviewed and appear to be correct

Description of Incident:

On 12-9-93 a patient with adenocarcinoma of the endometrium treated with hysterectomy and external beam irradiation received a gynecologic insertion with a 2 cm diameter vaginal cylinder. This was loaded with three 10 mg-eq Cesium-137 sources (30 milli8curies). The labia were sutured following the insertion. Localization films and dosimetery were performed. A dose of 3000 cGy to a specified point was prescribed.

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Medical Consequence of Exposure:

The normal tissues that received unplanned dose was the soft tissue of the thigh. The calculated dose received by this region was 572 cGy. No acute or late effects would be expected to ensue from this radiation dose.

The patient received pelvic irradiation with 5,000 cGy external beam therapy with 2270 cGy to the vaginal cuff from the brachytherapy insertion. This dose is sufficient to treat endometrial carcinoma following surgery. Therefore, the treatment goals were achieved, although the brachytherapy dose was lower than originally planned.

1-19-94 I spoke with the radiation oncologist, Dr Joanne Ubinas regarding the mis-administration. The patient continues to be followed by her gynecologist and by Dr. Ubinas. She has a normal pelvic examination and no evidence of acute or late sequelae. I confirmed that a letter of this event was sent to the patient.

Was individual or individual's physician informed of DOE Long-Term Medical Study Program?	Y+	N
Would individual like to be included in the Program?	Y	N +

COMPLETE FOR MEDICAL MISADMINISTRATION

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to NRC pursuant to 10 CFR 35.33 in the following areas:

a.	Why the event occurred	Y+	N
b.	Effect on the patient	Y+	N
c.	Licensee's immediate actions upon discovery	Y+	N
d.	Improvements needed to prevent recurrence	Y+	N
e.	Licensee's plan for followup of patient	Y+	N
f.	Report submitted to patient or patients responsible relative or guardian	Y+	N

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33), provide the basis for your opinion:

No areas of disagreement.

3. If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with medical ethics?
Y N

If not, comment on why the reason was not valid.

Records indicate that the patient was to be notified of the incident

4. Briefly describe the medical condition of the exposed individual and the cause of the short-term medical care being provided to the individual.

The patient's medical condition will be followed by her attending physician at regular intervals consistent usual management of her endometrial cancer. No changes in the follow-up schedule need to be made as a result of her brachytherapy treatment.

Enclosure 2

PROPOSED ENFORCEMENT CONFERENCE AGENDA

Hospital Metropolitano

Rio Piedras, Puerto Rico

May 20, 1994 9:00 a.m.

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II.	NRC Enforcement Policy and Procedure	NRC
III.	Discussion of NRC Concerns	NRC
IV.	Inspection Findings and Apparent Violations	NRC
V.	Causes of Apparent Violations and Corrective Actions	Licensee
VI.	NRC Followup Questions	NRC
VII.	Closing Comments	NRC and Licensee

Appendix C -- General Statement of Policy and Procedure for NRC Enforcement Actions

Table of Contents

58 FR 14308

B. Procedural Framework

Subpart B of 10 CFR part 2 of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the civil penalty process is initiated by issuing a Notice of Violation and Proposed Imposition of a Civil Penalty. The licensee or other person is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the response, the civil penalty may be mitigated, remitted, or imposed. An opportunity is provided for a hearing if a civil penalty is imposed. If a civil penalty is not paid following a hearing or if a hearing is not requested, the matter may be referred to the U.S. Department of Justice to institute a civil action in District Court.

The procedure for issuing an order to institute a proceeding to modify, suspend, or revoke a license or to take other action against a licensee or other person subject to the jurisdiction of the Commission is set forth in 10 CFR 2.202. The licensee or any other person adversely affected by the order may request a hearing. The NRC is authorized to make orders immediately effective if required to protect the public health, safety, or interest, or if the violation is willful. Section 2.204 sets out the procedures for issuing a Demand for Information (Demand) to a licensee or other person subject to the Commissioner's jurisdiction for the purpose of determining whether an order or other enforcement action should be issued. The Demand does not provide hearing rights, as only information is being sought. A licensee must answer a Demand. An unlicensed person may answer a Demand by either providing the requested information or explaining why the Demand should not have been issued.

57 FR 5791

III. Responsibilities

The Executive Director for Operations (EDO) and the principal enforcement officers of the NRC, the Deputy Executive Director for Nuclear Material Safety Safeguards and Operations Support (DEDS) and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research (DEDR), have been delegated the authority to approve or issue all escalated enforcement actions.[4] The DEDS is responsible to the EDO for the NRC enforcement programs. The Office of Enforcement (OE) exercises oversight of and implements the NRC enforcement programs. The Director, OE, acts for the Deputy Executive Directors in enforcement matters in their absence or as delegated. Subject to the oversight and direction of OE, and with the approval of the appropriate Deputy Executive Director, where necessary, the regional offices normally issue Notices of Violation and proposed civil penalties. However, subject to the same oversight as the regional offices, the Office of Nuclear Reactor Regulation (NRR) issues Notices of Violation and proposed civil penalties to vendors and suppliers and the Office of Nuclear Material Safety and Safeguards (NMSS) issues Notices of Violation and proposed civil penalties to certificate holders and to fuel cycle facilities for violations involving material control and accounting. Escalated enforcement actions are normally coordinated with the appropriate offices by the OE. Enforcement orders are normally issued by a Deputy Executive Director or the Director, OE. However, orders may also be issued by the EDO, especially those involving the more significant matters. The Directors of NRR and NMSS have also been delegated authority to issue orders, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions not associated with compliance issues. The Director, Office of the Controller, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license and inspection fees.

57 FR 5791

In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion m be exercised in determining the severi levels of the violations and the appropriate enforcement sanctions, including the decision to issue a Notic of Violation, or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of policy a the technical significance of the violations and the surrounding circumstances.

Unless Commission consultation or notification is required by this policy, the staff may depart, where warranted in the public's interest, from this polic with the approval of the appropriate Deputy Executive Director and consultation with the EDO as warranted. (See also Section VII, "Exercise of Discretion.")

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will also be provided notice in those cases where discretion is exercised and discussed Section VII.B.6. In addition, the Commission will be consulted prior to taking action in the following situatior (unless the urgency of the situation dictates immediate action):

(1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of n operating with the potential radiologic or other hazards associated with continued operation;

(2) Proposals to impose civil penalti in amounts greater than 3 times the Severity Level I values shown in Tabl 1A;

(3) Any proposed enforcement actio that involves a Severity Level I violation;

(4) Any enforcement action that involves a finding of a material false statement;

(5) Exercising discretion for matters meeting the criteria of Section VII.A.1 for Commission consultation;

(6) Refraining from taking enforcement action for matters meetin the criteria of Section VII.B.3;

(7) Any proposed enforcement actio that involves the issuance of a civil penalty or order to an unlicensed individual or a civil penalty to a licensed reactor operator;

[4] The term "escalated enforcement action" as used in this policy means a Notice of Violation for any Severity Level I, II, or III violation; a civil penalty for any Severity Level I, II, III, or IV violation and any order based upon a violation.

Therefore, the severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the NRC. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official [7] or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, the severity level of a willful severity level V violation will be increased to at least 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. Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the NRC will normally provide an opportunity for an enforcement conference with the licensee, vendor, or other person prior to taking enforcement action. Although enforcement conferences are not normally held for Severity Level IV violations, they may be scheduled if increased management attention is warranted e.g., if the violations are repetitive. The purpose of the enforcement conference is to (1) discuss the violations or nonconformances, their significance, the reason for their occurrence, including the apparent root causes, and the licensee's or vendor's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information that will help the NRC determine the appropriate enforcement action.

During the enforcement conference, the licensee, vendor, or other person 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 an enforcement conference. Enforcement conferences will not normally be open to the public.

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 modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In these cases, an enforcement 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 sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative mechanisms 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 to be applied, 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 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 enforcement action.

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[7] The term "licensee official" as used in this policy statement means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license. Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

(b) *Corrective action.* The purposes of this factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of similar violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be either mitigated or escalated by as much as 50% depending on the promptness and extensiveness of the licensee's corrective action. In assessing this factor, consideration will be given to, among other things, the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the degree of licensee initiative (i.e., whether NRC involvement was required before acceptable action was taken), the adequacy of the licensee's root cause analysis for the violation, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). Notwithstanding good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, mitigation of the civil penalty based on this factor will not normally be considered and escalation may be considered to address the licensee's failure.

(c) *Licensee performance.* The purpose of this factor is to recognize and encourage good or improving licensee performance and to recognize and deter poor or declining performance. Therefore, the base civil penalty shown in Tables 1A and 1B may be mitigated by as much as 100% if the current violation is an isolated failure that is inconsistent with a licensee's outstandingly good prior performance. The base civil penalty may also be escalated by as much as 100% if the current violation is reflective of the licensee's poor or declining prior performance. Neither mitigation nor escalation may be appropriate based on this factor where a licensee's poor prior performance appears to clearly be improving. Prior performance, as used in this policy statement, refers to the licensee's performance normally (1) within the last two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer. In assessing the licensee's prior performance, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as Systematic Assessment of Licensee Performance (SALP) evaluations for power reactors, and the licensee's prior enforcement history overall and in the area of concern, including escalated and non-escalated enforcement actions and any enforcement actions that the NRC exercised discretion and refrained from issuing in accordance with Section VII.B. Notwithstanding good prior performance, mitigation of the civil penalty based on this factor is not normally warranted where the current violation reflects a substantial decline in performance that has occurred over the time since the last NRC inspection. In addition, this factor should not be applied for those cases where the licensee has not been in existence long enough to establish a prior performance or inspection history. Similarly, mitigation based on this factor is not normally appropriate where the area of concern has not been previously inspected, unless overall performance is good.

(d) *Prior opportunity to identify.* The purpose of this factor is to encourage licensees to take effective action in response to opportunities to identify or prevent problems or violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% for cases where the licensee should have identified the violation sooner as a result of prior opportunities, such as (1) through normal surveillances, audits, or quality assurance (QA) activities; (2) through prior notice (i.e., specific NRC or industry notification; or (3) through other reasonable indication of a potential problem or violation, such as observations of employees and contractors, and had failed to take effective corrective steps. Prior notification may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, consideration will be given to, among other things, the opportunities available to discover the violation, the ease of discovery, the similarity between the violation and the notification, the period of time between when the violation occurred and when the notification was issued, the action taken (or planned) by the licensee in response to the notification, and the level of management review that the notification received (or should have received). Escalation of the civil penalty based solely on prior notification is normally not warranted where the licensee appropriately reviewed the notification for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

(e) *Multiple occurrences.* The purpose of this factor is to reflect the added significance resulting from multiple occurrences of the violation. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% where multiple examples of a particular violation are identified during the inspection period. Escalation of the civil penalty based on this factor will normally be considered only when there are multiple examples of Severity Level I, II, or III violations with the same root causes. Alternatively, separate civil penalties may be imposed for each violation.

(f) *Duration.* The purpose of this factor is to recognize the added significance associated with those violations (or the impact of those violations) that continue

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C. Orders

An order is a written NRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper (see 10 CFR 2.202). Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate for Severity Level I, II, or III violations. Orders may be issued as follows:

(1) License Modification orders are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.

(2) Suspension Orders may be used:

(a) To remove a threat to the public health and safety, common defense and security, or the environment;

(b) To stop facility construction when:

(i) Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component; or

(ii) The licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

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(3) Revocation Orders may be used:

(a) When a licensee is unable or unwilling to comply with NRC requirements;

(b) When a licensee refuses to correct a violation;

(c) When licensee does not respond to a Notice of Violation where a response was required;

(d) When a licensee refuses to pay an applicable fee under the Commission's regulations; or

(e) For any other reason for which revocation is authorized under section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.

(5) Orders to unlicensed persons, including vendors and contractors, and employees of any of them, are used when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities.

Unless a separate response is warranted pursuant to 10 CFR 2.201, a Notice of Violation need not be issued where an order is based on violations described in the order. The violations described in an order need not be categorized by severity level.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the NRC believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show why the order should not be issued in the proposed manner by way of a Demand for Information. (See 10 CFR 2.204)

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D. Related Administrative Actions

In addition to the formal enforcement mechanisms of Notices of Violation, civil penalties, and orders, the NRC also uses administrative mechanisms, such as Notices of Deviation, Notices of Nonconformance, Confirmatory Action Letters, letters of reprimand, and Demands for Information to supplement its enforcement program. The NRC expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met.

(1) Notices of Deviation are written notices describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A Notice of Deviation requests a licensee to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

(2) Notices of Nonconformance are written notices describing vendor's failures to meet commitments which have not been made legally binding requirements by NRC. An example is a commitment made in a procurement contract with a licensee as required by 10 CFR part 50, appendix B. Notices of Nonconformances request non-licensees to provide written explanations or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.

(3) Confirmatory Action Letters (CALs) are letters confirming a licensee's or vendor's agreement to take

(3) *Daily civil penalties.* In order to recognize the added technical safety significance or regulatory significance for those cases where a very strong message is warranted for a significant violation that continues for more than one day, the NRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of $100,000 for each day the violation continues. The NRC may exercise this discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

B. Mitigation of Enforcement Sanctions

Because the NRC wants to encourage and support licensee initiative for self identification and correction of problems, the NRC may exercise discretion and refrain from issuing a civil penalty and/or issuing a Notice of Violation under certain circumstances. In addition, while the NRC may exercise this discretion for violations meeting the required criteria where the licensee failed to make a required report to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make a required report. The circumstances under which this discretion may be exercised are as follows:

(1) Severity Level V Violations. The NRC may refrain from issuing a Notice of Violation for a Severity Level V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(b) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(c) It was not a willful violation.

(2) Licensee Identified Severity Level IV and V Violations. The NRC may refrain from issuing a Notice of Violation for a Severity Level IV or V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was identified by the licensee, including as a result of a self-disclosing event;

(b) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(c) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(d) It was not a willful violation or if it was a willful violation:

(i) The information concerning the violation, if not required to be reported, was promptly provided to appropriate NRC personnel, such as a resident inspector or regional section or branch chief;

(ii) The violation involved the acts of a low level individual (and not a licensee official as defined in section IV.C);

(iii) The violation appears to be the isolated action of the employee without management involvement and the violation was not caused by lack of management oversight as evidenced by either a history of isolated willful violations or a lack of adequate audits or supervision of employees; and

(iv) Significant remedial action commensurate with the circumstances was taken by the licensee such that it demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's organization. While removal of the employee from licensed activities is not necessarily required, substantial disciplinary action is expected.

(3) Violations Identified During Extended Shutdowns or Work Stoppages. The NRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after (i) the NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee (or a work stoppage at a construction site), or (ii) the licensee enters an extended shutdown or work stoppage related to generally poor performance over a long period of time, provided that the violation is documented in an inspection report (or official field notes for some material cases) and that it meets all of the following criteria:

(a) It was either licensee identified as a result of a comprehensive program for problem identification and correction that was developed in response to the shutdown or identified as a result of an employee allegation to the licensee; (If the NRC identifies the violation and all of the other criteria are met, the NRC should determine whether enforcement action is necessary to achieve remedial action, or if discretion may still be appropriate.)

(b) It is based upon activities of the licensee prior to the events leading to the shutdown;

(c) It would not be categorized at a severity level higher than Severity Level II;

(d) It was not willful; and

(e) The licensee's decision to restart the plant requires NRC concurrence.

(4) Violations Involving Old Design Issues. The NRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as in engineering, design, or installation, provided that the violation is documented in an inspection report (or official field notes for some material cases) that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee identified as a result of a licensee's voluntary formal initiative, such as a Safety System Functional Inspection, Design Reconstitution Program, or other program that has a defined scope and timetable and is being aggressively implemented;

(b) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

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VIII. Enforcement Actions Involving Individuals

Enforcement actions involving individuals, including licensed operators, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action involving an individual will normally be taken only when the NRC is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew, or should have known, the required actions; and knowingly, or with careless d' regard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV, or V violations will be handled by citing only the facility licensee.

More serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as against the facility licensee. Action against the individual, however, will not be taken if the improper action by the individual was caused by management failures. The following examples of situations illustrate this concept:

- Inadvertant individual mistakes resulting from inadequate training or guidance provided by the facility licensee.

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- Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.
- Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.
- Individual error directly resulting from following the technical advice of an expert unless the advise was clearly unreasonable and the licensed individual should have recognized it as such.
- Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Listed below are examples of situations which could result in enforcement actions involving individuals, licensed or unlicensed. If the actions described in these examples are taken by a licensed operator or taken deliberately by an unlicensed individual, enforcement action may be taken directly against the individual. However, violations involving willful conduct not amounting to deliberate action by an unlicensed individual in these situations may result in enforcement action against a licensee that may impact an individual. The situations include, but are not limited to, violations that involve:

- Willfully causing a licensee to be in violation of NRC requirements.
- Willfully taking action that would have caused a licensee to be in violation of NRC requirements but the action did not do so because it was detected and corrective action was taken.
- Recognizing a violation of procedural requirements and willfully not taking corrective action.
- Willfully defeating alarms which have safety significance.
- Unauthorized abandoning of reactor controls.

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- Dereliction of duty.
- Falsifying records required by NRC regulations or by the facility license.
- Willfully providing, or causing a licensee to provide, an NRC inspector o investigator with inaccurate or incomplete information on a matter material to the NRC.
- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization.
- Submitting false information and as a result gaining unescorted access to a nuclear power plant.
- Willfully providing false data to a licensee by a contractor or other person who provides test or other services, when the data affects the licensee's compliance with 10 CFR part 50, appendix B, or other regulatory requirement.
- Willfully providing false certification that components meet the requirements of their intended use, such as ASME Code.
- Willfully supplying, by vendors of equipment for transportation of radioactive material, casks that do not comply with their certificates of compliance.
- Willfully performing unauthorized bypassing of required reactor or other facility safety systems.

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- Willfully taking actions that violate Technical Specification Limiting Conditions for Operation or other license conditions (enforcement action for a willful violation will not be taken if that violation is the resul of action taken following the NRC's decision to forego enforcement of the Technical Specification or other license condition or if the operator meets the requirements of 10 CFR 50.54 (x), i.e., unless the operator acted unreasonably considering all the relevant circumstances surrounding the emergency.)

who is involved in the sale, use, or possession of an illegal drug is also subject to license suspension, revocation, or denial.

In addition, the NRC may take enforcement action against a licensee that may impact an individual, where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted. The NRC may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence, fitness for duty, or other matters that may not necessarily be a violation of specific Commission requirements.

In the case of an unlicensed person, whether a firm or an individual, an order modifying the facility license may be issued to require (1) the removal of the person from all licensed activities for a specified period of time or indefinitely, (2) prior notice to the NRC before utilizing the person in licensed activities, or (3) the licensee to provide notice of the issuance of such an order to other persons involved in licensed activities making reference inquiries. In addition, orders to employers might require retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities.

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IX. Inaccurate and Incomplete Information

A violation of the regulations involving submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee normally will be categorized based on the guidance herein, in Section IV "Severity of Violations," and in Supplement VII.

The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as (1) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience, (2) the opportunity and time available prior to the communication to assure the accuracy or completeness of the information, (3) the degree of intent or negligence, if any, involved, (4) the formality of the communication, (5) the reasonableness of NRC reliance on the information, (6) the importance of the information which was wrong or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

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Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee thereby permitting an opportunity to correct the oral information, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue a Notice of Violation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the NRC or the licensee identified the problem with the communication, and whether the NRC relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee prior to reliance by the NRC, or before the NRC raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after the NRC relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information became available or the advancement in technology was made, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplet submission may be treated as a more severe matter if the licensee later determines that the initial submittal wa in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions in not correcting or providing information raise questions about its commitment to safety or its fundamenta trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes tha enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section

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pressure safety injection pump inoperable for a period in excess of that allowed by the action statement: or

(b) In a boiling water reactor, one primary containment isolation valve inoperable for a period in excess of that allowed by the action statement.

2. A system designed to prevent or mitigate a serious safety event:

(a) Not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available: materials or components not environmentally qualified); or

(b) Being degraded to the extent that a detailed evaluation would be required to determine its operability (e.g., component parameters outside approved limits such as pump flow rates, heat exchanger transfer characteristics, safety valve lift setpoints, or valve stroke times);

3. Inattentiveness to duty on the part of licensed personnel;

4. Changes in reactor parameters that cause unanticipated reductions in margins of safety;

5. A significant failure to meet the requirements of 10 CFR 50.59, including a failure such that a required license amendment was not sought;

6. A licensee failure to conduct adequate oversight of vendors resulting in the use of products or services that are of defective or indeterminate quality and that have safety significance;

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities; or

8. A licensed operator's confirmed positive test for drugs or alcohol that does not result in a Severity Level I or II violation.

9. Equipment failures caused by inadequate or improper maintenance that substantially complicates recovery from a plant transient.

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D. Severity Level IV—Violations involving for example:

1. A less significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In a pressurized water reactor, a 5% deficiency in the required volume of the condensate storage tank; or

(b) In a boiling water reactor, one subsystem of the two independent MSIV leakage control subsystems inoperable;

2. A failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation;

3. A failure to meet regulatory requirements that have more than minor safety or environmental significance; or

4. A failure to make a required Licensee Event Report.

E. Severity Level V—Violations that have minor safety or environmental significance.

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Supplement II—Part 50 Facility Construction

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of part 50 facility construction.

A. Severity Level I—Violations involving structures or systems that are completed [1] in such a manner that they would not have satisfied their intended safety related purpose.

B. Severity Level II—Violations involving for example:

1. A breakdown in the Quality Assurance (QA) program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). These deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

C. Severity Level III—Violations involving for example:

1. A deficiency in a licensee QA program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). This significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. A failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

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[1] The term "completed" as used in this supplement means completion of construction including review and acceptance by the construction QA organization.

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Supplement IV—Health Physics (10 CFR Part 20)

≫ This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of health physics. 10 CFR part 20[1] ≪

Paragraphs A.–E.

≫ [Reserved 58 FR 67657.] ≪

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Sections 20.1001—20.2401

F. Severity Level I—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;

3. A radiation exposure during any year of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. An annual exposure of a member of the public in excess of 1.0 rem total effective dose equivalent;

5. A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public as described in 10 CFR 20.1302(b)(2)(i); or

6. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of 10 CFR 20.2003.

G. Severity Level II—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 1.0 rem total effective dose equivalent;

[1] Personnel overexposures and associated violations incurred during a life-saving or other emergency response effort will be treated on a case-by-case basis.

[2] [Reserved 58 FR 67657.]

4. A failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity Level III—Violations involving for example:

1. Surface contamination in excess of five but not more than 10 times the NRC limit:

2. External radiation in excess of one but not more than five times the NRC limit:

3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

(a) A significant failure to identify the type, quantity, or form of material:

(b) A failure of the carrier or recipient to exercise adequate controls: or

(c) A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material:

4. A failure to make required initial notification associated with Severity Level III violations: or

5. A breakdown in the licensee's program for the transportation of licensed material involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

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D. Severity Level IV—Violations involving for example:

1. A breach of package integrity without external radiation levels exceeding the NRC limit or without contamination levels exceeding five times the NRC limits:

2. Surface contamination in excess of but not more than five times the NRC limit:

3. A failure to register as an authorized user of an NRC-Certified Transport package:

4. A noncompliance with shipping papers, marking, labeling, placarding packaging or loading not amounting to a Severity Level I, II, or III violation:

5. A failure to demonstrate that packages for special form radioactive material meets applicable regulatory requirements:

6. A failure to demonstrate that packages meet DOT Specifications for 7A Type A packages: or

7. Other violations that have more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement VI—Fuel Cycle and Materials Operations

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations.

A. Severity Level I—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license:

2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function:

3. A nuclear criticality accident: or

4. A failure to follow the procedures of the quality management program, required by § 35.32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient.

57 FR 5791

B. Severity Level II—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license:

2. A system designed to prevent or mitigate a serious safety event being inoperable: or

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3. A substantial programmatic failure in the implementation of the quality management program required by 10 CFR 35.32 that results in a misadministration.

C. Severity Level III—Violations involving for example:

1. A failure to control access to licensed materials for radiation purposes as specified by NRC requirements:

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety:

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3. Use of radioactive material on humans where such use is not authorized:

4. Conduct of licensed activities by a technically unqualified person:

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license:

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6. Substantial failure to implement the quality management program as required by § 35.32 that does not result in a misadministration: failure to report a misadministration; or programmatic weakness in the implementation of the quality management program that results in a misadministration.

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities:

8. A failure, during radiographic operations, to have present or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by 10 CFR part 34:

9. A failure to submit an NRC Form 241 in accordance with the requirements in § 150.20 of 10 CFR part 150: or

10. A failure to receive required NRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership: lack of an RSO or replacement of an RSO with an unqualified individual: a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines: or a change in the quantity or type of radioactive material being processed or used that has radiological significance.

57 FR 5791

D. Severity Level IV—Violations involving for example:

1. A failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment:

2. Other violations that have more than minor safety or environmental significance: or

3. Failure to follow the quality management program, including procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by § 35.32; or

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4. A failure to keep the records required by §§ 35.32 or 35.33.

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E. Severity Level V—Violations that have minor safety or environmental significance.

D. Severity Level IV—Violations involving for example:

1. Incomplete or inaccurate information of more than minor significance that is provided to the NRC but not amounting to a Severity Level I, II, or III violation;

2. Information that the NRC requires be kept by a licensee and that is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation;

3. An inadequate review or failure to review under 10 CFR part 21 or other procedural violations associated with 10 CFR part 21 with more than minor safety significance;

4. Isolated failures to meet basic elements of the fitness-for-duty program not involving a Severity Level I, II, or III violation; or

5. A failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.73.

E. Severity Level V—Violations involving for example:

1. Incomplete or inaccurate information that is provided to the Commission and the incompleteness or inaccuracy is of minor significance;

2. Information that the NRC requires be kept by a licensee that is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance;

3. Minor procedural requirements of 10 CFR part 21; or

4. Minor violations of fitness-for-duty requirements.

Supplement VIII—Emergency Preparedness

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of emergency preparedness. It should be noted that citations are not normally made for violations involving emergency preparedness occurring during emergency exercises. However, where exercises reveal (i) training, procedural, or repetitive failures for which corrective actions have not been taken, (ii) an overall concern regarding the licensee's ability to implement its plan in a manner that adequately protects public health and safety, or (iii) poor self critiques of the licensee's exercises, enforcement action may be appropriate.

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A. Severity Level I—Violations involving for example:

In a general emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff.)

B. Severity Level II—Violations involving for example:

In a site emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

2. A licensee failure to meet or implement one emergency planning standard involving assessment or notification; or

C. Severity Level III—Violations involving for example:

In an alert, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);

2. A licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

A licensee failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.

E. Severity Level V—Violations that have minor safety or environmental significance.