NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Luke's Hospital
Cleveland, Ohio

Docket No. 030-17512
License No. 34-00398-10
EA 90-128

During an NRC inspection conducted on June 27-29, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990) the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

License Condition No. 13 states that this license is based on the licensee's statements and representations contained in referenced letters including a letter dated July 7, 1987.

The July 7, 1987 letter included, as an attachment, the licensee's Division of Radiation Oncology Quality Assurance and Quality Control Policies. Section 4 of this Policy, "Treatment Planning Process," requires that a patient's treatment planning chart be checked and initialed by the physicist or dosimetrist before the first treatment fraction is administered.

Contrary to the above, during the period February 14, 1990 through April 3, 1990, neither the physicist nor the dosimetrist checked a patient's planning chart prior to the first treatment and did not identify until April 19, 1990 that a therapy misadministration had occurred.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - $1,875.

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.33(a) requires that when a misadministration involves any therapy procedure, the licensee notify by telephone the appropriate NRC Regional Office within 24 hours after discovery of the misadministration.

Contrary to the above, the licensee discovered a therapeutic misadministration involving a cobalt-60 teletherapy treatment about 5:00 p.m. on June 22, 1990 and the NRC was not notified of the event until about 10:00 a.m. on June 25, 1990.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.33(b) requires that when a misadministration involves any therapy procedure, the licensee report, in writing, to the NRC Regional Office and the referring physician within 15 days after an initial report is made to the NRC.

Contrary to the above, the licensee failed to submit a written report to the NRC and to the referring physician within 15 days after initially reporting the therapy misadministration to the NRC. Specifically, the licensee notified the NRC on April 20, 1990 of a therapy misadministration and submitted its written report to the NRC in a letter dated May 7, 1990 and to the referring physician in a letter dated May 8, 1990.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, St. Luke's Hospital is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer may be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition, to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1990) should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provision of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, IL 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, IL
this 14th day of September 1990

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-17512/90001(DRSS)

Docket No. 030-17512

License No. 34-00398-10 Category G(1) Priority I

Licensee: St. Luke's Hospital
Division of Radiation Oncology
Cleveland, Ohio

Inspection At: St. Luke's Hospital
Division of Radiation Oncology
11311 Shaker Boulevard
Cleveland, OH 44104

Site Inspection Conducted: June 27-29, 1990

Inspector: Wayne J. Slawinski
Senior Radiation Specialist
Date: 7-25-90

Reviewed By: G. M. McCann, Chief
Nuclear Materials Safety
Section 1
Date: 7-26-90

Approved By: Bruce Mallett, Ph.D., Chief
Nuclear Materials Safety Branch
Date: 7-26-90

Inspection Summary

Inspection on June 27-29, 1990 (Report No. 030-17512/90001(DRSS))
Areas Inspected: Special, announced safety inspection to review the circumstances surrounding two apparent therapeutic misadministrations reported to the NRC on April 20 and June 25, 1990. The inspection also consisted of a review of selected aspects of the licensee's routine (overall) NRC-licensed teletherapy program including: organization, management controls and staffing; qualifications, experience and training; materials, facilities and equipment; teletherapy unit calibration and spot checks; and posting, labeling and access controls.
Results: The licensee's overall teletherapy program appears generally good. However, an apparent isolated problem was identified with implementation of the licensee's existing teletherapy treatment quality assurance (QA) program and concerns were noted related to its development. Although the Radiation

Oncology staff's dedication to maintaining a quality teletherapy program is evident and staff qualifications are good, staff shortages appear to exist and may be adversely impacting the program. Three apparent violations of regulatory requirements were identified: (1) failure to conduct a quality assurance treatment planning chart check prior to commencement of treatment (Section 6); (2) failure to notify the NRC within 24 hours after discovery of a therapeutic misadministration (Section 6); and (3) failure to submit a timely written report to the NRC and referring physician for a therapeutic misadministration (Section 6).

DETAILS

1. Persons Contacted

*D. Appel, Vice President, Clinical Services
*P. Catanzaro, M.D., Co-Director, Division of Radiation Oncology
*P. Greve, Vice President and General Counsel
J. Jeney, Vice President, Ancillary Services
*J. Mamacos, Medical Physicist/Radiation Safety Officer, Division of Radiation Oncology
*J. Miller, Administrative Director, Division of Radiation Oncology
K. Mullally, Chief Therapy Technologist
K. Sutton, Dosimetrist

*T. Walker, Health Physics Supervisor, Ohio Department of Health

The inspector also contacted other radiation oncology therapy technologists.

*Denotes those present at the site exit meeting on June 29, 1990.

2. Purpose of Inspection

This was a special inspection to review the circumstances surrounding two apparent therapeutic misadministrations involving patients undergoing cobalt-60 teletherapy treatments. One misadministration occurred during a series of thirty-four treatments beginning February 14, 1990 and ending April 3, 1990. The licensee initially discovered the error during a post treatment chart review on April 18, 1990, and reported a misadministration to the NRC Region III office by telephone on April 20, 1990. The licensee's followup written report to Region III was dated May 7, 1990, and is provided as Attachment 1 to this report. The second misadministration occurred on June 22, 1990, and was discovered when the patient being treated questioned the appropriateness of the treatment fraction that was just administered. The licensee notified the NRC of the second misadministration by telecon on June 25, 1990. The licensee's followup written report to Region III was dated July 3, 1990, and is provided as Attachment 2.

This inspection also included a review of selected aspects of the licensee's routine teletherapy program for compliance with applicable requirements delineated in 10 CFR Parts 35 and 20.

3. Program Scope and Inspection History

On August 11, 1980, St. Luke's Hospital was issued NRC License No. 34-00398-10 for possession and use of up to 14,000 curies of cobalt-60 as two sealed sources, for use in an AECL Theratron 780 teletherapy unit for the treatment of humans. The material was authorized for use only at St. Luke's Hospital, Cleveland, Ohio. The license was last amended in its entirety on October 29, 1987, and was essentially unchanged from the initial 1980 license. On October 11, 1989, the license was amended to

authorize four cobalt-60 sources not to exceed 7000 curies each, housed in two AECL Theratron 780 teletherapy units for use at St. Luke's Hospital, Cleveland, Ohio, and at St. Luke's Medical Center, Solon, Ohio.

As background information and as previously described (Inspection Report No. 030-18977/87001(DRSS)), St. Luke's Radiologist, Inc., was previously licensed under NRC License No. 34-19616-01 (from February 27, 1981 - October 11, 1989) to operate St. Luke's Hospital's satellite facility at St. Luke's Medical Center in Solon, Ohio. While St. Luke's Hospital and St. Luke's Radiologists previously operated under separate NRC licenses, the two licensees were actually a single corporate entity. St. Luke's Hospital owned the teletherapy equipment at St. Luke's Medical Center, performed all treatment planning and related calculations, and also maintained administrative/management control for both licenses, and the two facilities shared common therapy technologists and a common dosimetrist, RSO and oncologist staff. This operational structure remains unchanged to date.

At the time St. Luke's Radiologists, Inc.'s, license was issued in February 1981, it was envisioned that the radiology group would purchase their own teletherapy unit and conduct private practice services out of the offices rented from St. Luke's Hospital at St. Luke's Medical Center in Solon, Ohio. However, the private practice did not materialize and St. Luke's Medical Center has been and continues to be St. Luke's Hospital's satellite teletherapy facility.

From 1987-1989, St. Luke's Hospital averaged about 20-30 cobalt-60 teletherapy treatments per day and the Solon, Ohio medical center about 15-20 treatments per day. According to the licensee, this was an increase in treatment load of about 20% compared to 1985/1986; however, patient load could fluctuate significantly from day to day. In 1990 to date, the combined facilities reportedly averaged a consistent 55-60 treatments per day. The current treatment load represents an approximate 25% increase over the last six months.

Activities conducted under License No. 34-00398-10 were inspected twice by the NRC since 1985. No violations were identified during April 1989 or January 1985 inspections of St. Luke's Hospital's teletherapy (34-00398-10) or nuclear medicine (34-00398-08) licenses. However, a civil penalty was issued to St. Luke's Radiologists, Inc. (34-19616-01) in 1987 for a teletherapy misadministration related reporting violation. The 1987 inspection was the last inspection of activities officially conducted under License No. 34-19616-01, before this license was terminated in October 1989.

4. Organization, Management Controls and Staffing

The inspector reviewed the licensee's organization and management controls for activities conducted under License No. 34-00398-10 (i.e., Division of Radiation Oncology teletherapy program), including the organizational

structure and staffing, effectiveness of management techniques used to implement the program and ability to self-identify and correct program weaknesses.

The technical staff of the Division of Radiation Oncology for St. Luke's Hospital/St. Luke's Medical Center generally consists of radiation oncologists, medical physicists and a dosimetrist, and therapy technologists. The therapy technologists report to both the oncologists and Administrative Director of the Division of Radiation Oncology who, in turn, reports to the Director of the Department of Radiology. The Radiology Department Director ultimately reports to Mr. J. Jeney, Vice President of Ancillary Services. The current technical staff is comprised of two oncologists, both listed as authorized users in the NRC license; one medical/ teletherapy physicist; one dosimetrist; and five therapy technologists (four full time equivalent (FTE) technologists) including the chief technologist. Another individual was employed full time as a therapy technologist from September 1989 to mid-June 1990, before returning as a technologist to the hospital's diagnostic x-ray department. This recently vacated therapy technologist position is anticipated to be filled by a new hire starting July 9, 1990.

In 1985-1987, the hospital's budget reportedly allocated three (FTE) therapy technologist positions. The current budget allocates five FTE positions; however, this staffing level may be insufficient for the current scope and breadth of the treatment program. These issues are discussed further below.

In 1985/1986, the combined St. Luke's Hospital/St. Luke's Medical Center facilities performed about 25-35 cobalt-60 teletherapy treatments daily, and employed three full time technologists, a dosimetrist and a physicist. Experienced radiation oncology staff members indicated that the previous technologist staffing level was insufficient, despite a consultant's evaluation in 1985 or 1986 which concluded that three technologists were adequate at that time. The licensee currently conducts about 50-60 treatments daily, and in the last year expanded the technologist staff to its full complement of five FTEs. During the inspection, the inspector interviewed several members of the radiation oncology technical staff including an oncologist, the dosimetrist and physicist, and selected technologists. Those interviewed expressed concern that the current therapy technologist staff level continues to be insufficient for the size/scope of the treatment program and that overwork and stress related errors are more likely to occur. The inspector noted that therapy technologist responsibilities routinely include duties not typically assigned to technologists at other similar NRC-licensed facilities. These additional responsibilities include patient simulations, fabrication of custom blocks/wedges, etc., and completing initial phases of patient treatment planning.

Three therapeutic misadministrations resulted from technologist errors since 1986; however, these errors cannot be directly attributed to inadequate training, understaffing or overwork fatigue. In 1990 through June 6, technologists averaged about five hours/week overtime and the chief technologist about eleven hours. While this overtime is not excessive, the pace and critical nature of the work could effect technologist performance. Based on inspector interviews with the technical staff, the increasing size/scope of the program and considering the technologists' responsibilities, it appears desirable to expand the therapy technologist staff. Therefore, licensee management should review therapy technologist staffing levels and evaluate its adequacy Although the current physicist and dosimetrist staff appears sufficient, the licensee should also consider expanding this staff to compensate for changing technologist staffing levels and responsibilities, and to effectively implement future program demands. These concerns were discussed during the inspection and at the site exit meeting on June 29, 1990.

While no violations were identified with respect to management controls and staffing, concerns were noted that warrant the licensee's attention. The NRC will continue to monitor staffing and related issues during future inspections.

5. Qualifications, Experience and Training

The inspector reviewed the qualifications and experience of the licensee's physicist, dosimetrist and technologist staffs and discussed the training/instruction provided to them.

The licensee's principal physicist is an authorized Teletherapy Physicist and meets the qualification criteria specified in 10 CFR 35.961. This individual is listed as an authorized Teletherapy Physicist and as the licensee's Radiation Safety Officer in Condition 11 of the license. This individual has been employed as the physicist at St. Luke's Hospital for over ten years. A second teletherapy physicist is listed in Condition 11 and assists the licensee, as necessary, during absences of the principal physicist. The second physicist normally works at another hospital in the Cleveland, Ohio, area and does not visit the licensee's facility routinely.

The licensee's current dosimetrist was promoted to the position in September 1989, permanently filling an open position that existed since early 1988. The licensee's previous dosimetrist from 1980 - early 1988 assumed a Systems Analyst position within the institution. Although the current dosimetrist has less than one year experience as a dosimetrist, the individual's dedication and knowledge are noteworthy. Training provided to the dosimetrist has been primarily on-the-job, under the supervision of the physicist. Additional formal didactic training is encouraged for this individual.

The overall experience and qualifications of the current technologist staff is good. Four of the licensee's five technologists are registered therapy technologists. Two technologists each have approximately ten years experience as a therapy technologist at the licensee's institution, another has about six years therapy technologist experience at another institution. The other two technologists have about three years and one year experience as therapy technologists, respectively. Although technologist training/instruction was not extensively reviewed during this inspection, the inspector verified that technologists are instructed in the licensee's QA program, teletherapy unit operating and emergency procedures and applicable requirements of 10 CFR 19.12. No problems were noted with respect to this training/instruction; however, the licensee has not instructed all technologists in pertinent 10 CFR 35.33 misadministration requirements, and actions to be taken if a treatment related error is discovered. This inspector concern was expressed during the inspection and at the exit meeting.

No violations or deviations were identified; however, one inspector concern was noted.

6. Review of Apparent Misadministrations

a. Overview

Two apparent therapeutic misadministrations were identified by the licensee and reported to the NRC from late April to late June 1990. An overview of these two misadministrations is provided below.

On April 20, 1990, the licensee's radiation safety officer/physicist notified Region III of an apparent therapy misadministration to a patient undergoing cobalt-60 teletherapy treatments for carcinoma in the neck area. A three part prescription required: (1) a tumor dose to the neck area of 155 rads per treatment, delivered equally over 34 fractions (77.5 rads per treatment each to the right and left lateral neck areas) and a total prescribed treatment dose of 5270 rads; (2) a concurrent tumor dose to the anterior para-clavicular area of 155 rads per treatment, delivered equally over 34 fractions and a total dose of 5270 rads; and followed by (3) a tumor "boost" dose to the right and left lateral neck areas of 155 rads per treatment, delivered equally over 9 fractions and a total dose of 1395 rads. The 34 fraction right and left lateral neck and para-clavicular treatments were administered concurrently from February 14, 1990 through April 3, 1990. However, because of a data entry error into the licensee's computerized treatment planning program, the patient was administered 136 rads per fraction rather than the intended 155 rads. Therefore, the total dose delivered over the 34 fractions to the left/right lateral neck and para-clavicular areas was 4624 rads to each of the two areas instead of the prescribed 5270 rads. This translates to an underdose of about 12% to both the neck and para-clavicular areas. The error was

initially discovered by the licensee during a post treatment chart review on April 18, 1990. The third part of the prescription (boost dose) was delivered as required from April 4, 1990 through April 16, 1990. The licensee's written report of the incident, dated May 7, 1990, is provided as Attachment 1.

On June 25, 1990, the licensee's radiation safety officer notified Region III of an apparent therapy misadministration to a patient undergoing cobalt-60 teletherapy treatments for carcinoma of the lung. A prescription required a total tumor dose to the mediastinum (chest area) of 2000 rads, to be delivered equally over 10 fractions (100 rads per fraction each to the anterior and posterior mediastinum). The patient was administered eight treatment fractions as prescribed from June 11-20, 1990; however, on June 22, 1990, the patient's ninth treatment was erroneously administered to one side of the head instead of the chest area. The error occurred because the treating technologists assumed the area to be treated was the brain and failed to verify that assumption by reviewing the set-up page of the patient's treatment chart. The error was discovered after the left side of the head was treated and the patient questioned if the chest area would also be treated. The patient received an entry dose to the left side of the brain of 178 rads. The licensee's written report of the incident, dated July 3, 1990, is provided as Attachment 2.

b. Details of February - April, 1990 Misadministration

In February - April 1990, a sixty-one year old female patient diagnosed with carcinoma of the oropharynx, hypopharynx, soft palate and pyriform sinus, was being treated using cobalt-60 external beam teletherapy concurrent with chemotherapy. The treating oncologist prescribed a three part treatment as described in Section (a) above to the right and left lateral neck areas (fields 1 and 2), the anterior para-clavicular area (field 3), and followed by a "boost" dose to the right and left lateral neck areas (fields 4 and 5). The right and left lateral neck areas were each prescribed a tumor dose of 77.5 rads per fraction at a depth of 7.5 cm, and the para-clavicular area a tumor dose of 155 rads per fraction at a depth of 3.0 cm. Thirty-four treatment fractions were planned for each area for the original treatment of Fields 1-3.

The physician's prescription was written in November 1989 and initial phases of the treatment plan were developed by one of the licensee's therapy technologists, based on an 80.0 cm source-to-skin distance (SSD) technique. Technologists are normally responsible for developing treatment plans for SSD technique treatments, and employ the licensee's Central Axis Dose (CAD) Computation computer program to calculate treatment times. The

CAD program generates a treatment plan based on the treatment set-up data entered by the technologist and pre-prints a record of the patient's treatment regimen. A source-to-axis distance (SAD) technique is used for patients requiring more extensive or complex treatment plans and employs the licensee's Theraplan computer program. The Theraplan program produces three dimensional plots of isodose levels and contours and is normally executed by the licensee's dosimetrist or physicist and not technologists. The apparent misadministrations detailed in this report involved SSD techniques.

SSD technique treatment prescriptions are reviewed by the technologist and oncologist, and a target volume is outlined on an x-ray simulation film. At this time, the oncologist determines whether treatment aids such as wax compensation, blocks or wedges are required. If deemed necessary, the blocks and wedges are fabricated by the technologist. The treatment parameters determined above are then entered by the technologist into the CAD program and include the dose prescription information, fractionation schedule and treatment plan date. The treatment plan date is usually chosen to coincide with the chronological midpoint date of the treatment program. The plan date is used by the computer for teletherapy source output decay correction and therefore treatment time computation. In this particular case, the CAD treatment plan was generated by the technologist on February 12, 1990, and the treatment plan date entered into the computer program for the initial neck and para-clavicular area treatments (field 1-3) was erroneously specified as March 9, 1989, rather than March 9, 1990. This data entry error translated to a higher teletherapy source output and hence resulted in a reduced treatment time calculated by the computer.

The erroneous treatment time yielded an actual dose per fraction of 136 rads rather than the intended 155 rads. (The treatment plan date entered for the subsequent neck boost treatments was correct and these treatments were administered as prescribed.) The complete 34 fraction treatment program was administered at the incorrect lower dose from February 14, 1990 through April 3, 1990, and resulted in a total delivered treatment dose of 4624 rads to the neck and para-clavicular areas rather than the intended 5270 rads to each area. The error was discovered by the licensee's physicist during a routine post treatment chart review on April 18, 1990. After further evaluation on April 19, 1990, the licensee determined that the error resulted in a misadministration and reported the incident to the NRC on April 20, 1990. The patient was subsequently administered five treatments to the neck area at 160 rads per fraction to compensate for the underdose.

A letter dated July 7, 1987, referenced in License Condition 13, transmitted to the NRC, the licensee's Division of Radiation Oncology quality assurance and quality control policy and procedures (QA program). The QA program was submitted in response to a May 29,

1987 Confirmatory Action Letter, issued as a result of a 1986 cobalt-60 teletherapy misadministration at St. Luke's Medical Center and reported to the NRC on May 27, 1987. Section 4.2.A of the licensee's policy and procedure entitled "Treatment Planning per CAD Systems" outlines the treatment planning process and requires that a patient's treatment planning chart (i.e., preprinted record of patient's treatment regimen including the treatment set-up page) be checked by the physicist or dosimetrist before the first treatment fraction is administered. Contrary to this requirement, a patient was administered cobalt-60 teletherapy treatments and a treatment planning chart check was not performed by the physicist or dosimetrist before treatments commenced. Specifically, from February 14, 1990 - April 3, 1990, a patient was administered a cumulative dose of 4624 rads over 34 fractions to the right/left lateral neck and para-clavicular areas before a physicist or dosimetrist check of the treatment planning chart was conducted. An April 18, 1990 post treatment chart check by the licensee's physicist revealed that the aforementioned data entry error (i.e., treatment plan date) occurred and that a misadministration resulted from the error. The failure to perform a physicist or dosimetrist treatment planning chart check prior to treatment initiation appears to be a violation of License Condition 13, which references the licensee's July 7, 1987 letter and attached QA program. According to the licensee, the patient's treatment planning chart had not been referred to "physics" for an independent review and calculation prior to the commencement of treatments, as required by their internal protocol.

The error continued undetected through the 34 fraction treatment program, despite numerous opportunities for the treating technologists to identify the planning date error printed on the treatment set-up pages and treatment record, or realize that a physicist/dosimetrist had not initialed the treatment record or set-up pages, indicating that a treatment planning chart check was performed. The licensee's internal (unwritten) protocol requires that technologists not administer treatments unless the physicist/dosimetrist and oncologist initial the treatment chart sheets before the first treatment (except for an emergency palliative treatment). The initials indicate that an independent dose calculation and treatment parameter (set-up) check was performed by the physicist or dosimetrist and that the treating physician authorized treatments to commence and has reviewed certain treatment planning and set-up information.

Corrective actions taken by the licensee for this apparent misadministration are described in the licensee's May 7, 1990 report (Attachment 2). The corrective actions consisted of: (1) inservice retraining of staff regarding QA procedures pertaining to independent verification of treatment planning charts, and (2) instituting an additional QA (physics) check prior to administration of 20% of the prescribed total dose.

10 CFR 35.33(b) requires that when a misadministration involves any therapy procedure, the licensee shall report, in writing, to the NRC Regional Office and the referring physician within 15 days after the initial telephone notification is made to the NRC. Contrary to this requirement, the licensee failed to submit a written report to the NRC and to the referring physician within 15 days after the NRC was initially notified of the therapeutic misadministration described above. Specifically, the licensee initially notified the NRC of the therapeutic misadministration April 20, 1990, and submitted their written report to the NRC Region III in a letter dated May 7, 1990 (received May 14, 1990) and to the referring physician dated May 8, 1990. Therefore, the written report was submitted to the NRC 17 days (received 24 days) and to the referring physician 18 days after the initial telephone notification to the NRC. This constitutes an apparent violation of 10 CFR 35.33(b).

c. Details of June 22, 1990 Misadministration

In June 1990, a fifty-seven year old female patient diagnosed with large cell carcinoma of the lung and occluding right mainstem bronchus, was undergoing cobalt-60 external beam teletherapy treatments. The treating oncologist prescribed a first series total tumor dose to the mediastinum (chest area) of 2000 rads, to be delivered equally over ten fractions at 100 rads per fraction each to the anterior and posterior mediastinum. The dose was to be delivered over a field size of 14 x 13 cm at 80 cm SSD, and at a tissue depth of 10.5 cm. A second series was also prescribed at a reduced dose per fraction to the same volume, to be administered following the first series. (The second series treatments had not initiated prior to this inspection and are not discussed further in this report.)

The prescription was written on June 5, 1990, and treatment planning was conducted by a technologist as described in Section (b) above, using the licensee's CAD computer program. No problems with treatment planning or physics and physician checks were identified. The patient was administered eight treatments to the mediastinum as prescribed from June 11-20, 1990. However, on June 22, 1990, the patient's ninth treatment was erroneously administered to the left side of the patient's brain at a standard brain irradiation field size of 15 x 18 cm. The left side of the patient's head received an entry dose of 178 rads; no treatments were prescribed for this area. The apparent misadministration occurred because the two therapy technologists involved in administering the ninth treatment assumed the area to be treated was the brain and did not verify this assumption by reviewing the patient's treatment set-up page or view the treatment field polaroid photograph which shows the patient's tattooed and marked treatment field. The failure of the technologists to review the patient's treatment set-up page prior to administering a treatment is contrary to the licensee's internal (unwritten) protocol. No regulatory requirements were violated as

a result of this failure. The error was discovered while the technologist proceeded to position the patient for a right side brain irradiation and the patient questioned if the chest would also be treated. The patient's chart was then reviewed by the technologists and the error discovered.

The treating radiation oncologist was working in the teletherapy unit control area at the time of the error and was immediately informed of the event and, in turn, immediately informed and counselled the patient. The patient's mediastinum (correct area) was then treated as prescribed. According to the licensee, an ad hoc review was conducted shortly after the event at about 6:00 p.m. on Friday, June 22, 1990, involving the licensee's two oncologists, the physicist/radation safety officer and treating technologists. Uncertainty existed, at that time, whether the event was an NRC reportable incident. The licensee was also unaware that the NRC provides continuous telephone coverage and assumed that a telephone call to the NRC would not be answered after about 5:00 p.m. Upon further licensee investigation, they concluded that the event constituted a misadministration and the NRC Region III office was notified on Monday morning, June 25, 1990.

10 CFR 35.33(a) requires that when a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office within 24 hours after discovery of the misadministration. Contrary to this requirement, the licensee failed to notify the NRC within 24 hours after discovery of a therapeutic misadministration. Specifically, the licensee was aware of an event that constituted a therapeutic misadministration shortly after it occurred at about 5:30 p.m. on June 22, 1990, and the NRC was not notified of the event until about 10:00 a.m. on June 25, 1990. This appears to constitute a violation of 10 CFR 35.33(a). (As previously described in Section 3, a civil penalty was imposed in 1987 on St. Luke's Radiologists, Inc., for failure to timely notify the NRC of a therapeutic misadministration that was discovered by the licensee in 1986.)

The licensee attributed the root cause of the error to therapy technician understaffing, overwork and related stresses. The apparent misadminstration occurred at about 5:30 p.m. on Friday, at the end of a busy treatment week. Additionally, one of the licensee's therapy technolgists terminated her position in the department the week prior to this event and the vacated position remained unfilled through June 1990. (Staffing issues are discussed in Section 4.)

Corrective actions taken by the licensee for this apparent misadministration are described in the licensee's July 3, 1990 report (Attachment 2). The corrective actions include requiring a second technologist to verify that treatment set-up is correct by reviewing the treatment chart set-up page and polaroid photograph of the field location prior to administering the treatment. This action, however, is contingent upon staff availability.

d. Treatment Quality Assurance (QA) Program

The licensee's radiation oncology quality assurance and quality control policies and procedures were submitted to the NRC in letter dated July 7, 1987, initially incorporated by reference in License Condition 13, Amendment No. 3, dated October 29, 1987. The QA program, although pre-existing for several years, was not incorporated into St. Luke's Hospital's license until October 29, 1987. The QA program was submitted to the NRC in response to concerns raised in an NRC Confirmatory Action Letter dated May 29, 1987, issued as a result of a 1986 cobalt-60 teletherapy misadministration involving a patient undergoing treatments at St. Luke's Radiologists, Inc., Solon, Ohio. The 1986 misadministration was reported to the NRC on May 27, 1987. An inspection to review the 1986 misadministration was conducted in June 1987 and findings are documented in Inspection Report No. 030-18979/87001(DRSS).

The referenced QA program consists of a description of the licensee's treatment planning process and clinical quality assurance program. The clinical quality assurance program is comprised of patient quality assurance monitors (e.g., patient clinical reactions to treatments) which are assessed and evaluated by oncologists. Although clinically important, the clinical quality assurance program does not provide a system of checks and independent verification to ensure that the prescribed dose will be administered to the patient prior to commencement of treatments. The QA program's treatment planning process outlines the steps taken during various treatment planning phases. Portions of this process were previously described above in Section 6(b). The treatment planning process specifies that the CAD program computes treatment times and the patient's treatment planning chart "goes to the physicist or dosimetrist for checking and initialing and also to the radiation oncologist," before the first fraction is administered. The clinical quality assurance program further states that "all patients' charts are also reviewed at weekly intervals."

The inspector reviewed the overall implementation of the licensee's referenced QA program including an independent review of twenty randomly selected patient charts for treatments administered in 1990 to date. The inspector's independent review disclosed that written prescriptions were completed, physics checks were performed by the physicist or dosimetrist, weekly chart checks were conducted by the oncologists, and the administered dose appeared to correspond to the prescribed dose; no problems were noted.

Although the licensee's referenced QA program contains certain general information and elements necessary in any QA program, the existing program lacks the specificity and clarity necessary to ensure proper verification and independency of checks by different

personnel and uniformity/consistency in its implementation. Based upon inspector concerns with respect to the licensee's QA program and the misadministrations that have occurred, it appears desirable that the licensee's existing QA program be modified to require and formally address or specify the following:

(1) Prescriptions

- Specify that only clearly written prescriptions signed by the treating physician are acceptable.
- Specify that confusion or questions regarding interpretation or clarity of the prescription will be discussed with the physician and documented.

(2) Physics Checks

- Address what constitutes an acceptable physics check including which parameters and information will be checked.
- Specify that treatment planning chart checks (physics checks) and computer data entry information will be reviewed for accuracy by the physicist/dosimetrist prior to treatment initiation or before 25% of the total prescribed dose is administered.
- Specify that physics checks will be performed by the physicist or dosimetrist other than the one who was primarily responsible for developing the treatment plan. Evidence of check completion will include the individual's signature or initials and the date of the check. (Independent verification)

(3) Treatment Chart Reviews

- Address what constitutes an acceptable chart review, its documentation and who is authorized to perform them.
- Specify that initial treatment chart review will be performed prior to administering the fifth treatment. Subsequent chart reviews will be conducted at intervals not to exceed seven days or five treatments.

(4) Technologist Responsibilities

- Describe technologist responsibilities with respect to treatment administration and treatment planning. Specify that technologists not administer treatments unless documentation shows that physics checks and chart reviews have been performed and require that a second technologist independently verify that the patient and treatment set-up are correct.

In addition to the above, the licensee should consider expanding their QA program to include all applicable elements contained in the NRC Draft Regulatory Guide "Basic Quality Assurance Program for Medical Use" dated January 1990. Specifically, the licensee should consider enhancing their QA program to specify (1) annual program audits by qualified personnel not involved with the activity being audited, as described in Item 1.2 of the draft guide and (2) physical measurement of unit output if the patient's treatment includes unique field sizes, treatment distances or beam modifying devices, as described in Item 5.9 of the draft guide.

These matters were discussed with the licensee during the inspection and summarized at the site exit meeting on June 29, 1990.

Three apparent violations of regulatory requirements were identified. One concern associated with development of the licensee's QA program was noted.

7. Materials, Facilities and Equipment

The inspector toured the licensee's teletherapy facility at St. Luke's Hospital, verified that material possession and use complies with license requirements, discussed inspection and servicing of teletherapy units, and evaluated facility/unit operation and checks pursuant to the requirements of 10 CFR 35.634-35.636 and license referenced documents. Records of teletherapy unit maintenance and servicing were not reviewed during this inspection.

No problems were noted with the following aspects of the licensee's teletherapy program at St. Luke's Hospital:

- Sealed source leak tests (both units).
- Portable survey meter availability and calibration.
- Facility interlocks and patient viewing system operability.
- Facility radiation monitor operability.
- Beam limitation use restriction operability and checks.

No violations or deviations were identified.

8. Teletherapy Unit Calibration and Spot Checks

The inspector evaluated the licensee's methods for conducting teletherapy unit calibrations and output spot checks and reviewed records of test results for both AECL Theratron 780 teletherapy units for 1989 and 1990 to date. No problems were noted with the licensee's testing protocols, frequency of tests, test results, or records. Calibrations and output spot checks were performed pursuant to 10 CFR 35.632 and 35.634(a)-(c), respectively. The tests were conducted by the licensee's principal teletherapy physicist (and radiation safety officer) using a dosimetry

system that met 10 CFR 35.630 requirements. The licensee's dosimetry system was last calibrated in March 1990, by an AAPM accredited laboratory. Both of the licensee's teletherapy units were last calibrated pursuant to 10 CFR 35.632 in November 1989.

No violations or deviations were identified.

9. Posting, Labeling and Access Controls

During radiation oncology department tours, the inspector verified that St. Luke's Hospital facility area posting satisfied applicable 10 CFR 20.203 requirements, teletherapy unit safety and emergency procedures were posted pursuant to 10 CFR 35.610 and that access controls to radiation and high reduction areas were appropriate.

The roof area directly above the isocenter of the teletherapy unit at St. Luke's Hospital is posted as a radiation area, and access to it is controlled by a locked six foot high chain link fence constructed around the perimeter of the area. Maximum surface radiation levels measured by the licensee on this roof area were 8 milliroentgen/hour with the beam directed in a specific atypical orientation. Licensee surveys were performed in November 1987, after a new (5800 curie) cobalt-60 source was installed in the teletherapy unit. The current activity of the cobalt-60 source in the teletherapy unit at St. Luke's Hospital is approximately 4025 curies.

No violations or deviations were identified.

10. Independent Inspection Effort

The inspector performed radiological surveys[1] at the licensee's St. Luke's Hospital facility and verified that teletherapy unit head radiation levels met 10 CFR 35.641 requirements. The inspector also verified that teletherapy room access controls, door interlocks and room radiation monitor met 10 CFR 35.615 requirements and that beam stops for the hospital's teletherapy unit functioned as described in the licensee's referenced letter dated July 25, 1985.

The inspector also surveyed ground level unrestricted areas surrounding the teletherapy facility at St. Luke's Hospital. Surveys were performed for several beam orientations and a field size of 35 by 35 cm. No problems were noted.

No violations or deviations were identified.

11. Exit Meeting

The inspector met with licensee representatives (denoted in Section 1) at the conclusion of the onsite inspection on June 29, 1990, and summarized the scope and findings of the inspection, the NRC Enforcement Policy, and the likely informational content of the inspection report with regard to

[1]Surveys were conducted with an NRC Eberline PIC-6A, last calibrated May 3, 1990.

documents and processes reviewed during the inspection. The licensee did not identify any such documents or processes as proprietary. The following matters were discussed specifically by the inspector.

a. The two apparent therapeutic misadministrations and their causes (Section 6).

b. The apparent violation of License Condition 13, regarding the failure to perform a treatment planning chart check prior to administration of treatments (Section 6(b)).

c. The apparent violation of 10 CFR 35.33(b), regarding the timeliness of a written report to the NRC and referring physician (Section 6(b)).

d. The apparent violation of 10 CFR 35.33(a), regarding timeliness of NRC notification after discovery of a therapeutic misadministration (Section 6(c)).

e. Inspector concerns regarding QA program development and lack of specificity, therapy technologist staffing and technologist instruction. (Sections 6(d), 4 and 5, respectively.)

Attachments:
1. Licensee report to NRC Region III dated May 7, 1990
2. Licensee report to NRC Region III dated July 3, 1990