Community Hospitals Indianapolis

Community Hospital South

1402 East County Line Road South
P.O. Box 47010
Indianapolis, Indiana 46247-0010
Telephone (317) 887-7000
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April 5, 1993

Docket No. 030-12231
License No. 13-17124-01
EA 93-022

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

Reply to a Notice of Violation

Dear Sir:

Pursuant to the provisions of 10 CFR 2.201, this document is in response to the report of inspection No. 030-12231/92001, dated March 10, 1993. We have addressed each of the nineteen (19) violations separately. Our intent is to request mitigation of the level of fine and documentation in support of this was prepared by hospital counsel and is attached.

If there are any questions regarding the corrective actions we have taken, or suggestions for improvement, please contact us so we may take appropriate action.

Sincerely,

Kathy A. Clark

Kathy A. Clark
Administrator
Community Hospital South

Kathy A. Clark personally appeared before me this 5th day of April, 1993.

Barbara Scheib

Barbara Scheib

My Commission Expires 8/20/94 County of Residence: Marion

sec/radio2

Docket No. 030-12231
License No. 13-17124-01
EA 93-022

Reply to a Notice of Violation

VIOLATION A: Contrary to 10 CFR 35.13 (e), on or about April 1, 1992, the licensee changed the area where byproduct material is used for lung ventilation studies from Imaging Room No. 1 to an adjacent room, and, as of that date, the licensee had not applied for a license amendment authorizing the change.

Plea: Violation Admitted.

Reason for the Violation: This was an oversight on our part which was the result of providing service to our patients.

Corrective Action: When the oversight was pointed out to us, we immediately stopped using Xe-133 for Lung Ventilation Studies.

Corrective steps taken to prevent reoccurrence: We have no intention of using this room for Xe-133 ventilation studies until we can prove that a negative air flow has been established.

Date When in Full Compliance: We have been in full compliance since November 17, 1992.

VIOLATION B: Contrary to 10 CFR 35.205 (b), from April 1 to November 17, 1992, the licensee administered radioactive xenon-133 gas in the new "Raytheon Room," which was not at negative pressure compared to surrounding rooms.

Plea: Violation Admitted.

Reason for the Violation: As mentioned above, this was an oversight on our part.

Corrective Action Taken: We ceased to use this room for Xe-133 ventilation studies when we were informed by the inspector on November 17, 1992.

When in Full Compliance: We were in full compliance on November 17, 1992.

VIOLATION C: Contrary to 10 CFR 35.205 (c), from about April 1, to November 17, 1992, the licensee used Xenon-133 gas in the new "Raytheon Room" and the licensee did not calculate the amount of time needed after a spill to reduce the concentration therein to the occupational limit listed in 10 CFR Part 10, Appendix B.

Plea: Violation Admitted.

Reason for the Violation: As mentioned above, this was an oversight on our part.

Corrective Action Taken: We ceased to use this from for Xe-133 ventilation studies when we were informed by the inspector on November 17, 1992.

When In Full Compliance: We were in full compliance as of November 17, 1992.

VIOLATION D: Contrary to 10 CFR 35.205 (d), from April 1, to November 17, 1992, the licensee used radioactive Xenon-133 gas in the new "Raytheon Room," and the licensee did not post the safety measures to be instituted in case of a spill of Xenon-133 gas and the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 10, Appendix B.

Plea: Violation Admitted.

Reason for the Violation: As mentioned above, this was an oversight on our part.

Corrective Action Taken: We ceased to use this room for Xe-133 ventilation studies when we were informed by the inspector on November 17, 1992.

When in Full Compliance: We were in full compliance as of November 17, 1992.

VIOLATION E: Contrary to 10 CFR 35-205 (e):
1. The licensee used radioactive Xenon-133 gas in Room No. 1 and did not measure the ventilation rates therein each six months from July 31, 1991 to November 17, 1992.
2. The licensee used radioactive Xenon-133 gas in the new "Raytheon Room" and did not measure the ventilation rates therein each six months from about April 1, to November 17, 1992.

Plea: Violation Admitted.

Why Did This Happen: It was the responsibility of the Department Manager to schedule these air flow checks. Due to a change in personnel and schedules, it was not completed in a timely fashion.

Corrective Action Taken:
1. A ventilation check has been conducted in Imaging Room No. 1 (Elscint Room). A copy of the certified air flow analysis is included with this report.
2. We are not using radioactive gas in Imaging Room No. 2, (Raytheon Room).

How Will we Avoid This Problem in the Future: We have contracted with Apex Ventilating Company to put us on their schedule for every six months. This will serve as an additional check step. Additional verification of ventilation will be a bi-annual agenda item for the Radiation Safety Committee.

When in Full Compliance: We are in full compliance as of February 11, 1993 when the air flow check was made in the Elscint Room.

VIOLATION F: Contrary to 10 CFR 35.22 (a) (2), the licensee's Radiation Safety Committee did not meet at least quarterly. Specifically, the Radiation Safety Committee did not meet between January 17, 1991 and July 31, 1991, between July 31, 1991 and January 31, 1992, and between January 31, 1992 and July 23, 1992, periods in excess of one calendar quarter.

Plea: Violation Admitted.

Reason for this Violation: Radiation Safety Committee meetings were scheduled. However, because of various commitments, it became very difficult to obtain a quorum.

Corrective Action Taken: We have scheduled Radiation Safety Committee meetings for the remainder of this calendar year. The responsibility for notifying the members of these meetings is now the responsibility of the Administrative Secretary. The members of the Committee have been notified of the importance of these meetings and instructed to send a replacement if they find it impossible to attend themselves. In addition, we will use a conference call to include those members who are off site and unable to attend.

How will this be avoided in the future: This meeting will be part of our annual scheduling process for standing meetings and will be an item on the Vice President's quarterly report to the Administrator.

When in full compliance: We are currently in corpliance. Our last Radiation Safety Committee meeting was held February 5, 1993 with the next meeting scheduled for May 4, 1993.

VIOLATION G: Contrary to 10 CFR 35.22 (a) (3), on July 23, 1992 and November 12, 1992, the licensee's Radiation Safety Committee met, conducted business, and the Radiation Safety Officer was not present.

Plea: Violation Admitted.

Why did this happen: Like the previous violation, it was so difficult to get everyone together, we felt that we must have a meeting with those who could make the meeting. Our intent was to meet the meeting requirement, but we failed to meet the quorum requirement.

Corrective Action Taken: We have instructed each member of the Committee of the importance of these meetings and if they are unable to attend, they should send a substitute.

How will we assure this won't happen again: We will not have a meeting unless we have a quorum. The Vice President of Operations will contact the absent members to reschedule.

When in Full Compliance: We are now in compliance. Our next Radiation Safety Committee meeting is scheduled for May 4, 1993.

VIOLATION H: Contrary to 10 CFR 35.22 (a) and 10 CFR 35.20 (c), from January 17, 1991 to November 12, 1992, the Radiation Safety Committee did not review and the minutes of the Radiation Safety Committee meetings did not include a review of the ALARA program described in 10 CFR 35.20 (c). Specifically, the summaries of the types and quantities of byproduct material used were not reviewed.

Plea: Violation Admitted.

How Did This Happen: The ALARA program was reviewed as required, however, a specific line item of the types and quantities was not included.

Corrective Action Taken: Our annual ALARA review will dedicate a section of the report to a summary of the types and quantities of byproduct material used.

When in Full Compliance: A written summary was distributed on February 5, 1993 by Dr. Lowe to the members of the Radiation Safety Committee. It will also be an agenda item on the May 4, 1993 Radiation Safety Committee meeting.

VIOLATION I: Contrary to 10 CFR 35.22 (b) (6), from about February 15, 1990 to November 17, 1992, the licensee, through its Radiation Safety Committee, did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program annually.

Plea: Violation Denied.

The annual review of the operations was performed. The personnel exposure assays and the consulting physicist/lab review were reviewed at every meeting. The construction of the report was delegated by the Radiation Safety Officer to the Consultant.

VIOLATION J: Contrary to 10 CFR 35.21 (a), from January 2 to November 17, 1992, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were performed in accordance with the approved procedure.

Plea: Violation Admitted.

VIOLATION J - 1: No annual training for ancillary personnel.

Why did this happen: Other demands on the Radiation Safety Officer and Department Manager's time caused these annual reviews to be delayed.

Corrective Action Taken: We have since obtained an educational review program and have inserviced all Maintenance and Environmental Services personnel for the calendar year 1993.

What have we done to make sure this will not happen again: This review has been scheduled as part of their annual inservice schedule. The Nuclear Medicine Department will be notified of the schedule and will again present this program.

Item J - 2: The Radiation Safety Officer not reviewing and signing records for area contamination surveys on a monthly basis.

Why did this happen: This was being done by our consulting physicist in the past but not the Radiation Safety Officer. We were unaware of the monthly requirement to sign these documents.

Corrective Action Taken: We have established a department policy so that the Radiation Safety Officer will review and sign the prior month's area surveys at the beginning of the subsequent month.

How to keep from happening again: The department policy and records are reviewed by the Radiation Safety Committee on a periodic basis.

When in full compliance: We consider this to be in full compliance as of January 1, 1993.

VIOLATION K: Contrary to 10 CFR 35.7 (a), as of November 17, 1992, the licensee did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

Plea: Violation Denied.

The survey instruments possessed did not meet the intent of 10 CFR 35.22. The instruments, Victoreen CDV-700 and Victoreen 740F, have been identified in various communications with the NRC. Because the range was covered and the NRC had approved amendments listing these instruments, we thought we were in full compliance.

We did, however, immediately following the November 17 inspection, obtain a survey meter from Community Hospital East that covered the range up to 100 millirem per hour. We purchased a Ludlum Model 14-C that also covers the required range. This instrument had been budgeted for prior to the site survey and was received, calibrated and placed into service on December 12, 1992.

VIOLATION L: Contrary to 10 CFR 35.70 (a), on numerous occasions from about January 2, to November 17, 1992, the licensee did not survey with a radiation detection instrument at the end of the day, the nuclear medicine "hot" lab and imaging room, areas where radiopharmaceuticals are routinely prepared for use or administered.

Plea: Violation Admitted.

How did this happen: The technologist admits to doing these at the beginning of the work day to avoid forgetting to do them at the end of the day.

Corrective Action Taken: The technologists have been instructed in the proper procedure. They know the purpose for doing area surveys at the end of the day and assure us this will be done.

When in full compliance: November 19, 1992.

VIOLATION M: Contrary to 10 CFR 35.59 (b) (2), the licensee did not test a sealed source containing nominally 224 microcuries of cesium-137 for leakage between January 17, 1991 and November 17, 1992, an interval in excess of six months, and no other interval was approved by the commission or an Agreement State.

Plea: Violation Admitted.

How did this happen: At the time of the last NRC inspection, the inspector advised us to discontinue doing leak test on this source because the activity level was below the requirement. This was questioned by our physicist and documented in our Radiation Safety Committee meeting minutes. However, we stopped doing leak tests on this source based upon this advice.

Corrective Action Taken: Wipe test performed as soon as deficiency identified. We will continue to perform a leak test every six months.

How will we avoid this in the future: The leak test will be added to the operation review.

When in full compliance: February 22, 1993.

VIOLATION N: Contrary to 10 CFR 35.50 (e), from about February 17, 1989, to November 17, 1992, the licensee's records of dose calibrator tests for accuracy, linearity and geometrical dependence did not include the signature of the Radiation Safety Officer.

Plea: Violation admitted with mitigating circumstances.

How did this happen: The tests were performed and the results were reviewed by the Radiation Safety Committee. The consulting physicist was authorized by the Radiation Safety Officer to perform the review.

Corrective Action Taken: These records are now also being signed by the Radiation Safety Officer of record.

How to prevent this in the future: The signature requirement is documented as part of the departmental operational policy.

When in full compliance: January 1, 1993.

VIOLATION O: Contrary to 10 CFR 35.59 (d), from about February 17, 1989 to November 17, 1992, the licensee's records of the leak test of its sealed source did not included the signature of the Radiation Safety Officer.

Plea: Violation admitted.

How did this happen: Same as Violation M.

Corrective Action Taken: The leak test was performed. The Radiation Safety Officer reviewed and signed the results.

How to prevent in the future: The Radiation Safety Officer will sign the reports.

When in full compliance: February 22, 1993.

VIOLATION P: Contrary to 10 CFR 35.59 (g), from about February 17, 1989 to November 17, 1992, the licensee's records of physical inventories of its sealed source did not include the signature of the Radiation Safety Officer.

Plea: Violation Admitted.

How did this happen: Believed source was below activity requiring inventory per Violation M.

Corrective Action Taken: The inventory has been re-established as part of the departmental operations review.

When in full compliance: February 22, 1993.

VIOLATION Q: Contrary to 10 CFR 35.22 (a) (4), the minutes for the meetings of the Radiation Safety Committee held from January 17, 1991 to November 17, 1992 did not include members absent from the meeting.

Plea: Violation Admitted.

How did this happen: We were not aware of this requirement.

Corrective Action Taken: The members who are absent as well as those present will be documented in the Radiation Safety Committee minutes.

How to prevent from happening in future: Now that we are aware of this requirement, we do not expect this to be an issue in the future.

When in full compliance: February 5, 1993.

VIOLATION R: Contrary to 10 CFR 35.92 (b), from January 2, 1992 to November 17, 1992, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92 (a) did not include the date on which the byproduct material was placed in storage and the background dose rate.

Plea: Violation Admitted.

How did this happen: There wasn't a category in the waste disposal log.

Corrective Action Taken: We have created a new form with the required information heading the columns. A copy of the new form is included with this report.

How to prevent form happening again: We believe the new form will prevent this from happening again.

When in full compliance: November 23, 1992.

VIOLATION S: Contrary to 10 CFR 35.70 (h), from January 2, 1992 to November 17, 1992, the licensee failed to retain records of surveys required by 10 CFR 35.70 that included the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. Specifically, removable contamination was expressed in counts per minute.

Plea: Violation Admitted with mitigating circumstances.

How did this happen: The counting efficiency of our well counter had been determined and trigger levels established. The data from the well counter was stored as cpm on the well counter tape.

Corrective Action Taken: We have designed a new form with conversion calculations for the technologists to record their readings in dpm/100 cm2.

How to prevent in the future: The technologist will use this method of recording their removable contamination survey information and will not have the option of recording it in cpm.

When in full compliance: November 19, 1992.

Answer to a Notice of Violation

Community Hospital South requests that there be remission of the civil penalty proposed to be imposed in the Notice of Violation dated March 10, 1993 from the U. S. Nuclear Regulatory Commission to Community Hospital. The reasons for remission of the proposed penalty are that the asserted bases for the increase of the base penalty are factually incorrect and that extenuating circumstances exist.

Community Hospital's Reply to Notice of Violation accompanies this Answer. We request that you read that Reply prior to reading this Answer as the information in the Reply forms much of the basis for our Answer.

The central point that we would like to make is that Community Hospital has taken its duties seriously and acted responsibly. It has made mistakes--having the wrong person review and sign reports, using report forms that did not fully reflect what was done, doing tests at the wrong time of day--but throughout the time period in which these violations occurred, it was acting to perform, in substance, the duties expected of it. Furthermore, it has acted promptly to correct the violations.

The NRC letter of March 10 proposes to increase the base civil penalty by 50 percent because all of the violations were identified by the NRC and by 100 percent because our consulting medical physicist had identified violations that were not corrected. We believe that, even before examining the underlying facts, a reasonable person would conclude that it is not fair or desirable to penalize the Hospital both for not identifying violations and for identifying violations. The Civil Penalty Adjustment Factors in 10 CFR Part 2, Appendix C demonstrate the intention to encourage activities by the licensee to identify violations. If a licensee is penalized because of the fact that the consulting medical physicist has diligently reviewed and reported on compliance matters, it would discourage the behavior that Appendix C seeks to encourage.

We would also ask the NRC to look at the facts which underlie the violations. In a few instances there was ignorance of the requirement, but in most circumstances you will see a genuine effort to comply. Of the 19 claimed violations, we believe that two (Violations I and K) were in compliance. Of the remaining 17, in four instances, the form of reporting did not comply with the NRC requirements, but the required actions that were the subject of the reporting requirements were being performed. These instances were Violations H (ALARA review occurred but summary of byproduct material not put in report of that review),

Q (meetings held and those present listed, but not those absent), R (disposal of byproduct material logged, but form did not include date and background dose rate), and S (removable contamination measured and recorded, but conversion calculations not done to change data from cpm to dpm/100 cm2).

In three of the 17 violations (Violations J-2, N, and P), the only violation was that the review and/or signature of documents was delegated by the Radiation Safety Officer to the consulting physicist. In all instances, the review and signature of documents was occurring by a qualified individual. In Violation L, the area survey was being done at the beginning of the work day instead of at the end of the work day, but it was being done.

Two of the violations (Violations M and O) occurred because of the Hospital's reliance on advice that it was given by an NRC inspector at the time of the prior inspection. We would also like to point out that these violations were not identified by the NRC inspectors in the course of their inspection and were not in the NRC Inspection Report. These were identified by the Hospital's consulting physicist in a telephone conversation with NRC personnel on February 22, 1993, and were corrected within one day.

Lastly, with regard to the three violations relating to meetings or training that was not held or was held without the presence of the Radiation Safety Officer (Violations F, G, and J-1), we know that the Hospital's conduct was not acceptable, but we hope that the NRC will take into account that the Hospital was trying to achieve compliance. The Hospital did schedule meetings and training sessions, but ran into problems when participants became unavailable. The Hospital's motivation in holding meetings that the Radiation Safety Officer could not attend was to try to accomplish some of the purposes of having a Radiation Safety Committee even if legal compliance was not being achieved.

We believe that these facts show positive licensee performance. The Hospital and its employees, especially the consulting physicist, have acted responsibly. In most instances, the goals of the NRC's regulations have been accomplished. When these facts are considered along with the speed with which the Hospital has corrected the violations (discussed below), we believe that mitigation of the base civil penalty should occur. Section VI.B.2.(c) of 10 CFR Part 2, Appendix C permits mitigation by as much as 100 percent. We believe that the efforts of Community Hospital should result in mitigation under that section by at least 50 percent.

As indicated in the prior sentence, we believe that another important factor is the rapidity with which the Hospital has

addressed the violations. The NRC letter of March 10 identifies 19 claimed violations. Our Reply shows that for two of these, Violation I and Violation K, Community Hospital was in continuous compliance. Of the remaining 17 claimed violations, two (Violation M and Violation O) were not identified until a February 22, 1993 telephone conversation with the NRC. Those violations were corrected within one day of being identified.

Of the remaining 15 violations, seven were corrected immediately following the NRC inspection, including all of the violations that related to the use of radioactive materials. The remaining eight violations were all corrected prior to Community Hospital's receipt of the NRC Inspection Report.

We oppose by the NRC's proposed decision to escalate the civil penalty by 25 percent for the Hospital's supposed failure to correct all issues, especially because it states that xenon-133 procedures continued and no room ventilation studies were made. We do not know how the misunderstanding occurred, but that statement is incorrect. As we describe in our Reply to Violations A, B, C,D and E, we immediately stopped using xenon-133 gas in Room No. 2 and have conducted a ventilation check of Room No. 1.

The NRC letter also states that our proposed corrective actions did not include measures to ensure management involvement in radiation safety. In actuality, however, our corrective actions result in active involvement of management at the highest levels. Please review our Reply to Violations G and H. You will see that the Vice President of Operations not only must monitor compliance, but must report to the Administrator, who is the chief operating officer for the Hospital.

We believe that the promptness with which Community Hospital corrected all of the violations, including the immediate correction of all violations that involved use of radioactive materials, should be considered a mitigating factor. We would ask that the base civil penalty be reduced by 50 percent because of these actions. Such a reduction is appropriate under Section VI.B.2(b) of 10 CFR Part 2, Appendix C.

When the mitigation that is justified because of Community Hospital's performance is combined with the mitigation that is justified because of the Hospitals' prompt corrective action, the result is mitigation of 100 percent of the civil penalty. We would request that the NRC grant a remission of the proposed civil penalty.

Thank you for your consideration of this Answer.

In Support of "E"

CERTIFIED TEST, ADJUST, AND BALANCE REPORT

DATE 2-11-93

PROJECT Community Hospital South

ADDRESS Nuclear Medicine
1402 East County Line Road

ARCHITECT NA

ENGINEER NA

HVAC CONTRACTOR NA

NEBB TAB FIRM Apex Ventilating Co., Inc.

ADDRESS 2216 West 60th
Indpls., In 46208

Apex Ventilating Co.
William L. Pavon
Certificate
2495

NEBB

CERTIFICATION

PROJECT Community Hospital South - Nuclear Medicine

ADDRESS 1402 East County Line Road

Indpls., In.

THE DATA PRESENTED IN THIS REPORT IS AN EXACT RECORD OF SYSTEM PERFORMANCE AND WAS OBTAINED IN ACCORDANCE WITH NEBB STANDARD PROCEDURES. ANY VARIANCES FROM DESIGN QUANTITIES WHICH EXCEED NEBB TOLERANCES ARE NOTED THROUGHOUT THIS REPORT.

THE AIR DISTRIBUTION SYSTEMS HAVE BEEN TESTED & BALANCED AND FINAL ADJUSTMENTS HAVE BEEN MADE IN ACCORDANCE WITH NEBB "PROCEDURAL STANDARDS FOR TESTING — ADJUSTING-BALANCING OF ENVIRONMENTAL SYSTEMS" AND THE PROJECT SPECIFICATIONS.

NEBB CONTRACTOR Apex Ventilating Co., Inc

REG. NO. 2495 CERTIFIED BY William L. Knight (Air TAB Supervisor) DATE 2/11/93

THE HYDRONIC DISTRIBUTION SYSTEMS HAVE BEEN TESTED & BALANCED AND FINAL ADJUSTMENTS HAVE BEEN MADE IN ACCORDANCE WITH NEBB "PROCEDURAL STANDARDS FOR TESTING — ADJUSTING-BALANCING OF ENVIRONMENTAL SYSTEMS" AND THE PROJECT SPECIFICATIONS.

NEBB CONTRACTOR _____

REG. NO. _____ CERTIFIED BY _____ (Hydronic TAB Supervisor) DATE _____

SUBMITTED & CERTIFIED BY:

NEBB CONTRACTOR Apex Ventilating Co., Inc.

TAB SUPERVISOR William L. Knight

REG. NO. 2495

DATE 2/11/93

Apex Ventilating Co.
William L. Knight
Certified

NEBB

AIR OUTLET TEST REPORT

PROJECT Nuclear Medicine SYSTEM Suppl. / Exhaust

OUTLET MANUFACTURER _____ TEST APPARATUS Al. Balometer

AREA SERVED	OUTLET				DESIGN		PRELIMINARY				FINAL		REMARKS
	NO.	TYPE	SIZE	AK	CFM	VEL	VEL OR CFM	VEL OR CFM			VEL	CFM	
Nuclear Med.	S1	4" Slot	8"Ø		200			185				185	Supply
" "	S2	"	8"Ø		200			180				180	"
Hot Lab	E1	E.G.	6"x6"		100			115				115	Exhaust
Nuclear Med.	E2	"	10"x10"		400			450				450	"

REMARKS:

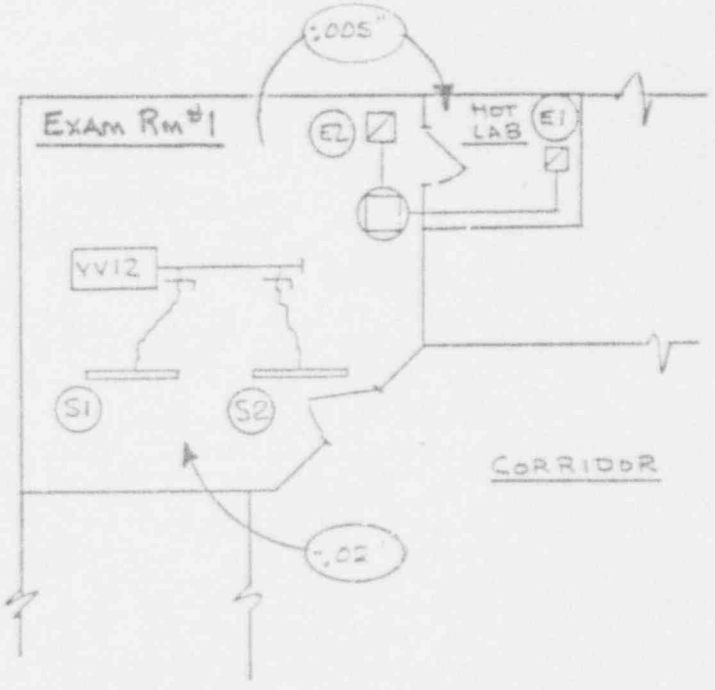
Apex Ventilating Co.
WILLIAM L. KNIGHT
CERTIFICATE
2485

TEST DATE 2/11/93 READINGS BY John R Striby

NEBB

PROJECT Community Hosp. South SYSTEM Nuclear Medicine

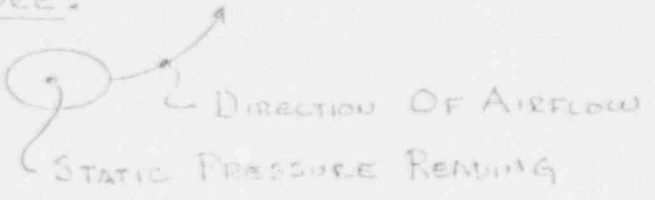
LOCATION Room 41



INDIVIDUAL ROOM STATIC PRESSURE PROFILE

* NUCLEAR MEDICINE ROOM NEGATIVE TO CORRIDOR, HOT LAB NEGATIVE TO NUCLEAR MEDICINE ROOM.

NOMENCLATURE:



In Support of "R"

Community Hospital South
Nuclear Medicine Department
Radiation Waste Disposal Record

Date Waste Placed in Storage	RA Elemente in Waste Container	Surface Reading when placed in storage (cpm)	Calculated Date of discard as non RA trash (10 T-1/2)	Initial of Tech placing in storage	Date actually discarded as non radioactive	Surface Reading when discarding as non RA trash. (cpm)	Initials of Tech discarding (Remove Labels)