DRAFT INSPECTION REPORT FORM

1. Name and Address of Licensee

Veterans Admin. Hospital Center
Wilshire & Sawtelle Blvds.
Los Angeles, California 90073

2. Date of Inspection Sept. 29, 1976

3. Type of Inspection Announced

4. License Number(s), Docket Number(s), Number and Date of Last Amendment for Each License - Category and Priority of Each Licensee

04-00181-04, Amendment 67, Aug. 6, 1975, Category ____, Priority 2
SNM 1440, Amendment 1, May 27, 1976, Category ____, Priority 4

5. Date of Previous Inspection Dec. 3, 1974 (-04 license); Initial inspection for SNM-1440

6. Proprietary Information None

7. Scope of Inspection if Other than Routine Routine

8. Participants (Licensee Representatives & Titles, State Representatives, etc.)

1. L. W. Wettereau, RSO, Physicist
2. W. H. Blahd, M.D., Chief, Nuclear Medicine Service
3. Peggy Joe, Ph.D, Radiopharmacist

9. Management Interview (Information Required for N/C Cases)

The management interview was held with the first two persons listed in paragraph 8.

10. Action and Date - Letter to Licensee _____

NRC-591 Clear X (for both licenses)

NRC-591 N/C _____

11. Recommend Reinspection Date September 1978

12. P. R. Zurakowski
Inspector(s)

Date of Report

H. E. Book
Reviewer

12/21/76
Date of Review

IE:V Form 605

13. Inspection Summary

The inspection of September 29, 1976 disclosed no items of noncompliance or health and safety significance. A clear form AEC-591 was issued for both licenses at the conclusion of the inspection to reflect these findings. The last previous inspection also resulted in the issuance of a clear form AEC-591 for the -04 license. This was an initial inspectin for the SNM license.

14. Summary of Licensed Program

The licensee continues to operate a rather large diversified program in Nuclear Medicine and Research under a broad license. This involves substantial programs in diagnosis, therapy, research and education. The Hospital now also employs a full time Nuclear Pharmacist. During fiscal year 1976 there were 9246 patient visits, an increase of 17%; 39,387 images made, an increase of 56% and 18,106 tests, an increase of 43%. There were only 15 therapy patients in this same time period, a decrease of 20%. The Nuclear Medicine Radioimmunoassay Program has continued to expand performing more than 4,200 procedures quarterly.

A brief description of some of the major research activities are included in the following listing. Protocals & informed consent forms from patients were examined.

Detection of Myocardial Infarction (Blahd)

Technetium-99m pyrophosphate has been used in more than 100 patients with suspected coronary artery occlusions to identify the presence or absence of myocardial infarction. The diagnostic implication of this technique in patient management is being evaluated.

Compton Scatter Tomographic Imaging (Blahd)

Compton scatter tomography is an imaging technique in which photons scattered out of a primary radiation beam are detected. The system incorporates a conventional scintillation camera and its dedicated computer together with a specially designed gamma radiation source. Phantom studies have demonstrated that the spatial resolution of this system is essentially equivalent to the inherent scintillation camera resolution, and its precise tomographic capabilities have been demonstrated. The device was designed for brain imaging. Human studies are now in progress.

Bone Imaging in Parathyroid Disease (Krishnamurthy)

Fifty-three patients with parathyroid disease have been studied by means of Tc-99m-pyrophosphate imaging procedures. The results have been compared with skeletal x-ray studies and indicate that bone lesions are detected in these patients by the imaging technique despite normal x-ray studies. These studies are continuing.

Tc-99m and I-131-Labeled Metronidazole for Liver Scanning (Tubis)

These agents were designed to differentiate amebic hepatic abscesses from other space-occupying lesions of the liver. One of the collaborators in Brazil has reported successful imaging of liver abscesses using I-131-labeled bromometronidazole in cases where the abscesses appeared as "cold" lesions using In-113m colloid. Additional clinical studies are now in progress.

Radioiodinated Chlorpropamide for Pancreas Studies (Tubis)

Chlorpropamide, an oral antidiabetic, has been trace-labeled with I-131 and its distribution studied in mice and rats. The method of labeling has been much improved and the final compound resembles the original drug. Distribution studies showed a ratio of concentration in pancreas to liver of 1:2 to 1:3 but may be higher in larger animals. Labeled chlorpropamide showed an insulin and glucagon release in an isolated rat pancreas preparation. Further animal and later human studies will be carried out.

Clinical Measurement of Bowel Perfusion (Winston)

Studies of Xe-133 washout rates from bowel wall have been obtained in patients with mesenteric artery occlusion, both before and immediately after bypass of obstructed segment by means of surface radioactivity counting. Comparison in patients without this disease indicates only a partial restoration of washout rates right after bypass. Further clinical studies are in progress.

Treatment of Thyrotoxicosis in Graves' Disease (Blahd)

This is a prospective study to evaluate the therapeutic efficacy of a I-131 treatment protocol that attempts to deliver 5,000 rads to the thyroid gland of patients with Graves' disease. A precise dosimetric technique is employed. To date, 58 patients have been studied.

Radiolabeled Anti-CEA for External Detection of GI Tumors (Blahd)

In this study, a technique has been developed for labeing CEA with indium 111 by means of a conjugation method that employs transferrin. The primary objective of the study is the use of the labeled antibody for the detection by means of radioisotope scanning of gastro-intestinal cancer. Clinical studies are now in progress.

Body Composition Changes in Radiation Therapy of Malignancy (Blahd)

Body water and electrolyte studies are being carried out in patients undergoing radiation therapy for bronchogenic and ENT cancer. In addition, blood from these patients is being examined for evidence of DNA repair by means of a tritiated thymidine labeling technique.

Detection of Multiple Sclerosis by Labeled Leukocytes (Winston)

Work on isolation and labeling of leukocytes has continued, largely in tumor bearing experimental animals. Labels such as Cr-57 and Tc-99m have been tried in an attempt to study migration of leukocytes into a malignant tumor. When techniques are perfected, it is planned to study human subjects to determine if such migration can be detected in tumors.

Only one use of the SNM license has been made. One patient has had a pacemaker implanted containing 160 mg of Pu-238. Dr. R. A. Williams, Asst. Chief of the Cardiology Section has been named the Physician responsible for the care of this patient. The patient is seen routinely every six months for a physical examination. On the basis of records examined, discussions with personnel and observations by the inspector, uses of licensed materials by both licensees appeared to be as authorized under the subject licenses.

15. Organization and Administration

(An organizational chart has been included as Enclosure II)

There have been no changes in basic organizational structure since the last inspection. There have been only a few personnel changes and research programs added. Dr. J. Coburn has been named Head of the Renal Lab and has incorporated Na-22 and H-3 into his research program.

A new tumor lipid lab under Dr. W. Baker has been formed. The isotopes used by Dr. Baker are H-3 and C-14. The Cerebral Circulation Lab under Dr. Aldendorf has shut down. The last previous inspection report under the -04 license should be consulted for more detail. Under the SNM license, Dr. R. A. Williams has been named to replace Dr. J. S. Carey as the person responsible for the one patient using a pacemaker containing Pu-238.

16. Facilities

The facilities used by both licensees have not changed since the last inspection. The last previous -04 inspection report should be consulted for more detail. However, the entire Nuclear Medicine Program will be moved into the new Hospital Building (which has not been given a number yet) in the next few months.

17. Equipment

Because of the impending move to the new building, a detailed inventory of equipment was available to the inspector. It is listed below:

a. Imaging Equipment - Cameras

Searle, Pho/Gamma Scintillation Camera System, Model HP, 1972

Searle, Pho/Gamma IV Model 7407A Scintillation Camera, 1975

Searle, Pho/Gamma III Scintillation Camera System, Model 6403, 1969 - upgraded to HP Model, 1974

MDS, Basic Modumed Clinical Computer, 1975

Nuclear-Chicago M-09009 Dual Isotope Display, 1974

Riverside Bio-Engineering Camera (70 mm), Model 801, 1974

b. Imaging Equipment - Scanners

Picker Nuclear, Magnascanner II, 3" crystal, Model 6184-D, 1964

Picker Nuclear, Magnascanner 500, 3" crystal, Model 2806-K, 1970

Picker Nuclear Magnascanner III, 5" crystal, Model 500, 1969

Picker Nuclear Magnascanner 500, 5" crystal, Model 500, 1969

Nuclear-Chicago, Pho/Dot V, 5" crystal, Model 1775, 1973

Picker Nuclear Magnascanner, Dual 5", Model M-1000, 1976

c. Probes

Nuclear-Chicago Probe-Scaler Assembly, Model 820582, 1970

Nuclear-Chicago Probe-Scaler Assembly, Model 8725, 1971

d. Other Equipment

Picker Renogram Assembly Dual Analyzer/Ratemeter, Model 620-085, 1966

Nuclear-Chicago Auto/Gamma Spectrometer, Model 1085, 1971

Packard Tri/Carb Liquid Scintillation Spectrometer, Model 3320, 1971

Kodak X-Omat Dry Film Processor, Model M6A-N, 1970

Kodak X-Omat Dry Film Processor, Model M6A-N, 1972

Technical Associates, Portable Analyzer-Scaler Model FS-7 AP, 1976

Capintec Dose Calibrators, with CXC9 Dose Computers (2), 1975

Picker Nuclear Ultrasonoscope, Model 1020-2, 1972, with Dynamic Range Scan Converter, 1975

Olivetti Desk Programmer, Model 101, 1969

Whole-body Counter (constructed in 1959)

5" steel chamber
4" x 8" crystal
Nuclear Data 512-channel Analyzer System, Series 2200, 1971

e. Computerized System

(1) Dedicated scintilation camera computer
Medical Data Systems (MDS)
Unicam model, 1975
Purchase Cost: $65,000

(2) The MDS Unicam computer is a software based system. As such, the software is an integral part of the unit and is included in the purchase cost.

(3) Software capabilities:

Acquisition in 64 x 64, or 128 matrices
Light pen region of interest selection
Curve generator programs
Math analyzer programs
Image enhancement
Quality control

(4) Software is upgraded every six months by MDS and is an integral part of the contract cost.

18. Radiological Safety Procedures

The licensee has developed a Procedures Manual, May 1974 (Appendix D) and QC procedures for counting instruments (Appendix E) both of which are considered Proprietary and are not to be released. These procedures were developed in response to an AMA requirement for hospital certification. These procedures are available to all authorized users of licensed materials. For the SNM license, the procedures used are those submitted with the application for the current license. No changes have been made to any of the procedures without Licensing Review. All Part 19 requirements were being met by both licensees (L. W. Wetterau is the RSO for both licenses.)

A very significant training program is conducted for both professional and technical staff and for residents, interns and trainees.

a. Description of Residency Training

The Nuclear Medicine Service has an AMA-approved residency program. Physicians seeking eligibility for certification by the American Board of Nuclear Medicine take two years of residency training. Formal instructional activities include regularly scheduled lectures, laboratories, seminars, and conferences. Residents receive instruction in the theoretical and practical aspects of diagnostic and therapeutic nuclear medicine. Instruction includes lectures in relevant basic sciences such as nuclear physics, radiation biology, radiopharmaceuticals, statistics, radiation protection, and instrumentation. Residents spend about two-thirds of their time participating in the Nuclear Medicine Service clinic activities which provides the opportunity for direct patient care.

During FY 1976 three physicians were trained in nuclear medicine. One of the three is now board eligible in Nuclear Medicine. One resident who received training during FY 1975 took and passed the ABNM examination in September of 1975.

b. Basic Scientists

Nuclear Medicine scientific personnel offer the following courses:

Radioisotope Handling and Safety - 13 hr/qrtr
Physical Aspects of Nuclear Medicine - 12 hr (1 qtr/yr)
Radiopharmacy - 12 hr (1 qtr/yr)
Radiobiology - 12 hr (1 qtr/yr)
Radioimmunoassay - 12 hr (1 qtr/yr)

c. Nuclear Medicine Technologist Training

The Nuclear Medicine Service conducts a one-year AMA-approved training program in Nuclear Medicine Technology. Training includes didactics covering clinical applications of radionuclides, in vitro testing, radiation safety, radiopharmacy, radiobiology, nuclear physics, and nuclear instrumentation. In addition, trainees receive laboratory and clinic experiences. Upon completion of the program, trainees are eligible for the examination in Nuclear Medicine offered by the ARRT.

During each of the past two years, 4 trainees were in the program. Four trainees are currently enrolled.

d. Radiopharmacy Training

During the past six years the Nuclear Medicine Service and the University of Southern California School of Pharmacy have co-sponsored Radiopharmacy training. The program culminates in a Master's degree in Radiopharmacy from the University of Southern California. The training year has been divided into an academic portion (9 months) and internship (3 months). Internship is provided within the Nuclear Medicine Service. Beginning in FY 1977, a stipend will be paid for the internship period only. Three trainees are funded each year.

The RSO takes a very active part in the training which takes place in a college type atmosphere. The fall schedule shows Mr. Wetterau as one of the principle instructors.

SCHEDULE 1976 FALL COURSE

Oct	7	History & Review Radiation Safety	Dr. Mirell
	14	Atomic Structure - Terminology	Dr. Mirell
	21	Radioactivity - Units - Decay Schemes	Dr. Mirell
	28	Interaction of Radiation with Matter	Dr. Mirell
Nov	4	Detection of Radiation - Units of Measurement	Mr. Wetterau
	11	Biological Effects of Radiation, I	Dr. Gambino
	18	Principles of Radiation Safety	Mr. Wetterau
Dec	2	Biological Effects of Radiation, II	Dr. Gambino
	9	Control of Contamination, and Waste Disposal	Mr. Wetterau
	16	Liquid Scintillation Counting - Principles	Mr. Wetterau
	23	Gamma Ray Spectrometry	Mr. Wetterau

19. Personnel Monitoring and Exposure to External Radiation

Monthly film badges and TLD finger rings are supplied and evaluated by Radiation Detection Company of Sunnyvale. At the time of the inspection 72 badges and 22 finger rings were being used. Exposures in general were quite low, the high quarterly exposure being about 50 mrem and the high finger ring exposure was approximately 400 mrem. The one patient wearing a pacemaker does not use a film badge or TLD dosimeter.

20. Exposure of Employees to Airborne Radioactive Materials

There is no evidence that employees are exposed to airborne radioactive material. All leak tests have been negative. The health physics log disclosed no major spills where airborne material would be released.

21. Effluents to Unrestricted Areas

The RSO stated that they do not release radioactive materials to unrestricted areas via effluents.

22. Disposals

The services of W. H. Hutchinson and Sons (Cal Salvage) are utilized for waste disposal. Approximately 15-18 55 gallon drums per quarter are picked up by Cal Salvage. Shipments average 10-100 mCi per quarter. Records of disposal are maintained. No disposals of SNM have been made.

23. Miscellaneous Surveys, Evaluations and Records

Routine area surveys are performed on a weekly basis by the RSO and or his assistant Mr. R. Bennett. An examination of the health physics log disclosed no significant spills or related problems. Routine whole body counts and urine assays for tritium or C-14 are also done by the RSO and/or his assistant. An examination of the records disclosed no significant exposures in these areas. Leak tests of a Ni-63 chromatographic source, a Sr-90 eye applicator and a Co-60 sealed source were all negative. These leak tests were performed and evaluated in a timely manner by the RSO.

24. Special License Condition

Condition 18 requires bioassay for H-3 when quantities greater than 100 mCi are handled. The RSO performs and evaluates these bioassays. No problems have occurred in this area.

25. Posting and Labeling

The posting and labeling observed during a tour of the facilities were in conformance with NRC regulations. The pacemaker patient carries identification with him at all times which identifies him as wearing a pacemaker containing Pu-238.

26. Independent Measurements

None

27. Operations Observed

The Radiopharmist was observed making up a diagnostic dose of I-131. She appeared to use good health physics techniques to limit her exposure. Both a shielded syringe and a lead glass barrier were used during the process. The Radiopharmacist also was wearing a film badge and a TLD finger ring. Afterwards she was questioned about the safety aspects of her job. She appeared to be very knowledgeable in this area. Her quarterly exposures have been quite low.

28. Incidents, Overexposures, Theft or Loss, Equipment Malfunction

The RSO stated that no problems of this nature have occurred since the last inspection.

OPTIONAL FORM NO. 10
JULY 1973 EDITION
GSA FPMR (41 CFR) 101-11.6

(ENCLOSURE I

UNITED STATES GOVERNMENT

Memorandum

TO : U. S. Nuclear Regulatory Commission
Region V Office

DATE: Sept. 29, 1976

FROM : L. W. Wetterau, Radiation Safety Officer
VA Wadsworth Hospital Center

SUBJECT: NRC License 04-00181-04, Hospital Radioisotope Inventory as of 9-29-76

Radioisotope		Millicuries
^{3}H - as labeled compounds	-	338.000
^{14}C - as labeled compounds	-	31.200
^{22}Na- as labeled compounds	-	0.500
^{32}P - as labeled compounds	-	22.850
^{36}Cl- as labeled compounds	-	0.200
^{45}Ca- as labeled compounds	-	8.900
^{47}Ca- as labeled compounds	-	0.250
^{51}Cr- as labeled compounds	-	1.000
^{54}Mn- as labeled compounds	-	1.000
^{57}Co- as labeled compounds	-	0.130
^{63}Ni- as labeled compounds	-	0.100
^{99m}Tc- as labeled compounds	-	375.000
^{125}I - as labeled compounds	-	21.305
^{131}I - as labeled compounds	-	20.500
^{137}Cs- as labeled compounds	-	0.362
^{192}Ir- implant seeds	-	443.500
^{125}I - Norland sealed source	-	35.000
^{63}Ni- Hewlett Packard G.C. source	-	15.000

(continued)

U. S. Nuclear Regulatory Commission
Region V Office

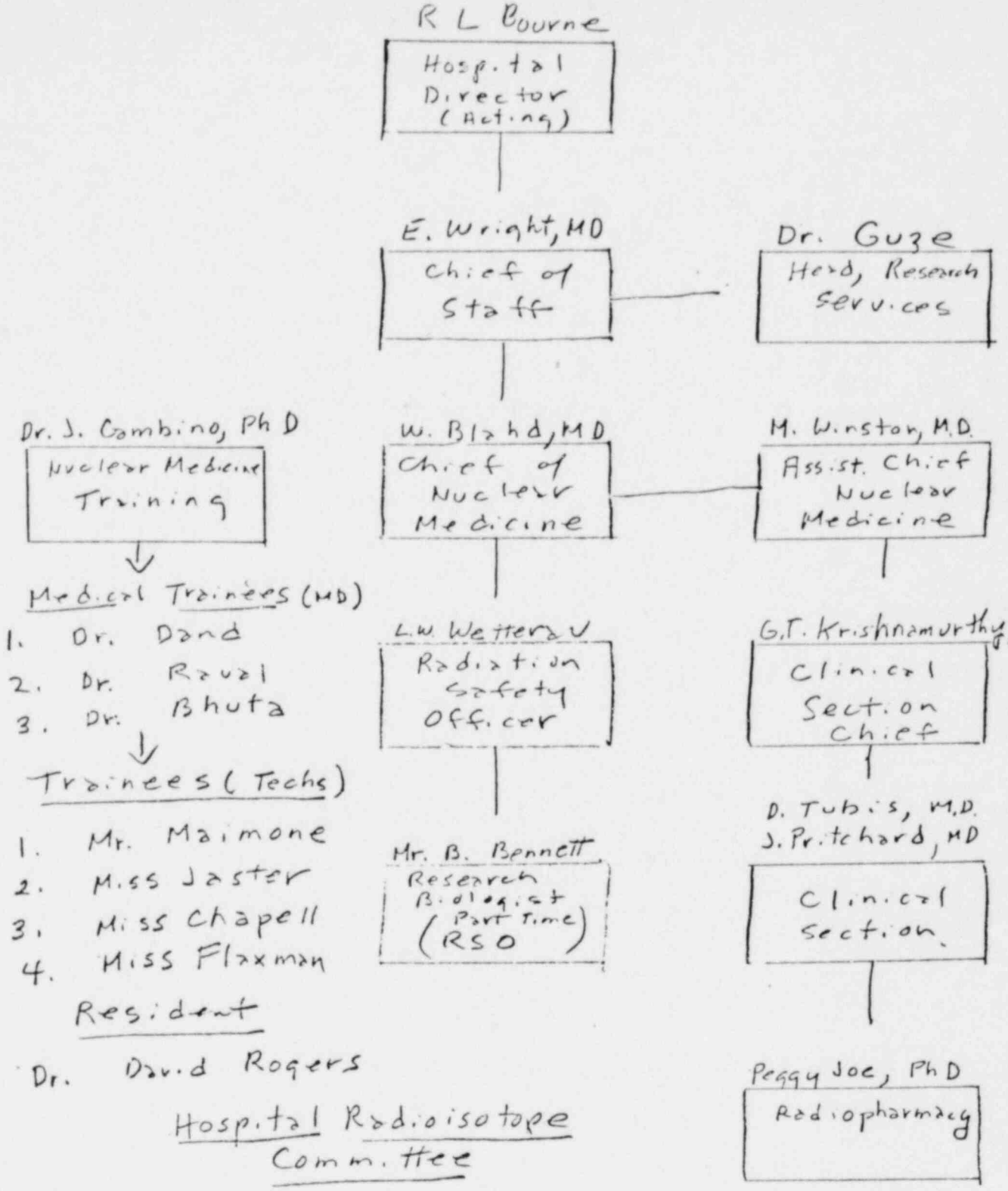
9/29/76

^{3}H - Varian G.C. source	-	166.400
^{90}Sr - Ophthalmic Eye Therapy M-RA-1A	-	24.750
^{60}Co - Calibration source MR-30	-	0.055

L. W. Wetterau

L. W. WETTERAU

((ENCLOSURE 2



Hospital Radioisotope Committee

1. Dr. W. Bland, Chairman
2. Dr. E. Wright, Chief of Staff
3. Dr. Z. Petrovich, Therapy
4. Dr. Daton, Chief of Medicine
5. Dr. Guze, Head, Research Services
6. Dr. Ross,