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August 6, 1970

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Region V, Division of Compliance

INSPECTOR'S EVALUATION AS PER MM900/15
VETERANS ADMINISTRATION CENTER - WADSWORTH HOSPITAL
WILSHIRE & SAWTELLE BOULEVARDS - LOS ANGELES, CALIF.
LICENSE NO. 4-181-4

There appeared to be no health or safety problems associated with activities under the license. Facilities at the clinic (Building 114) had not changed since the previous inspection; however, additional facilities have been added at Wadsworth Hospital for routine diagnostic and scanning procedures. Additional rooms at Wadsworth were being modified for radioisotope work at the time of this inspection. Since the previous inspection there has been a moderate reduction in the area of research at the center due to a cutback in government spending. Clinical uses of radioisotopes remains about the same.

It was found during the course of the inspection that the licensee has held no formal radioisotope committee meetings since the previous inspection. Approvals for new protocols had been done on an informal basis, through telephone discussions and individual review of protocols. During an inspection of another license (-10 Teletherapy) at Wadsworth Hospital, the day following the present inspection, it was learned that the principle user under the -10 license had not been contacted for any approvals although he is a member of the Radioisotopes Committee under the subject license. For these reasons the next inspection should include an in depth review of the Isotope Committee functions and review policies. It may be that Dr. Bland, Chief of Nuclear Medicine, is assuming the greater share of the Radioisotopes Committee responsibilities while other members give only token approvals of new uses of radioisotopes.

Notwithstanding, the licensee appears to maintain an adequate program to insure health and safety with sufficient authority invested in the Radiation Safety Officer. The RSO appeared to have a complete understanding of all

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activities for which he has health and safety responsibilities; records appeared to be well maintained and adequate surveys performed.

At the conclusion of the inspection the licensee was issued a Form AEC-591 showing no items of noncompliance.


J. R. Metzger
Radiation Specialist

591 Notes
Metzger:ejn
8-4-70

Inspector 8-6-70

Reviewer 8/1/70

Veterans Administration Center
Wadsworth Hospital
Wilshire and Sawtelle Boulevards
Los Angeles, California 90073

License No. 4-181-4

General Information

1. On July 23, 1970, an announced reinspection of the subject broad medical license was conducted at the above address. There were no representatives from the State of California present. The last inspection was conducted on August 11, 1969, at which time no items of noncompliance were found. The present inspection revealed no items of noncompliance and a Form AEC-591 reflecting these findings was issued at the conclusion of the inspection.

Exit Interview

2. At the conclusion of the inspection a summary of the inspection findings was held in the presence of Dr. W. J. Bland, Chief of Nuclear Medicine and Mr. L. W. Wetterau, Radiation Safety Officer for the Hospital. At that time those present were told that there appeared to be no items of noncompliance or any apparent health or safety problems. Due to the cutback in research activities there followed some reduction in the frequency of bioassays on employees and in wipe surveys for hydrogen-3 and carbon 14 compounds in the laboratories. It was emphasized to those present to consider carefully reviewing the research activities and determine whether or not the bioassay and survey frequencies were adequate for the activities being performed. It was emphasized that there appeared to be no problems in these areas but due to the infrequencies of bioassays

and surveys in recent months a reevaluation may be in order.

3. It was also brought out that the procedures referenced by the license had been revised as of April 1970, and that the Division of Materials Licensing should be notified of the revision. Again it was brought out that there was no significant difference between the old and new procedures but that the AEC wished to be kept current on the procedures used.

Organization and Persons Contacted

4. An organizational diagram as it relates to licensed activities is attached as exhibit A. The organization is essentially the same as found during the previous inspection with the exception that now Dr. W. Bland is Chief of Nuclear Medicine reporting directly to the Center Director, whereas before he reported to the Hospital Medical Director. Also there is a new Head of Principle Research, Dr. N. Baker who reports to Dr. Bland and conducts in vitro procedures and animal research with radioactive materials. Dr. Bland is head of all activities involving human research, however. Also, the use of radioisotopes has been divided into three categories under Dr. Bland, which includes the Radioisotope Research group, the Nuclear Medicine Training group and the Clinical group.
5. Mr. Wetterau stated that he had the authority for insuring the health and safety of personnel using radioisotopes which includes responsibility for the conduct of isotope use, supervising disposal, approvable on procurement of radioactive materials, dosimetry, health physics training,

research activities (health and safety) and protocol approvals for radiation safety considerations. He stated that administratively he reports to Dr. Blahd but for health and safety policy answers to the center director, Dr. C. Modica.

6. Persons contacted during the course of the inspection were as follows:

<u>NAME</u>	<u>FUNCTION</u>
L. W. Wetterau	Radiation Safety Officer for the Hospital
W. Blahd	M. D., Chief, Nuclear Medicine, Head, Human Research and Chairman, Radioisotope Committee
M. Tubis	M. D., Chief, Research Biochemistry and Radiopharmacology
Dr. Erwiler	M. D., Neurobiochemist
T. Braun	Research Biologist
L. Wilson	Research Chemist
J. J. Gambino	PhD., Head Nuclear Medicine Training Department
C. Walsh	Nuclear X-Ray Technologist (Registered)
B. J. Kinney	Radioisotope Technician
Panchita Thomas	Radioisotope Technician & Biologist

Radioisotope Committee

7. Although the radioisotopes committee in the past has met once or twice a year on a formal basis there have been no formal meetings since the previous inspection. Mr. Wetterau explained that the meetings between concerned individuals have been informal involving telephone conversations

and individual review of protocols and papers submitted. The committee membership consists of the following people:

W. Bland, M.D., Chairman

C. Modica, M.D., Ex-officio member (Center Director)

J. F. Rouse, M.D., Chief, Hematology

L. Fred, M.D., Special Assistant Director for Outside Affiliations

L. Guze, M.D., Chief of Staff for Research and Education

S. Dayton, M.D., Chief Medical Services, Wadsworth Hospital

E. G. Fishkin, M.D., Chief Laboratory Services, Wadsworth Hospital

J. E. Thornhill, M.D., Chief Radiation Therapy, Wadsworth Hospital

L. W. Wetterau, Physicist and Radiation Safety Officer

8. Since the previous inspection seven new protocols for the use of radioactive materials have been submitted and approved by the Isotopes Committee.
9. The new protocols were examined and contained essentially the following information.
 - a. Approval was granted for the use of Chromium-51 as labelled CrCl_3 in 40 human subjects to be used as a dilution marker for acid in gastric ulcers (work not yet begun).
 - b. Ytterbium-169 in DTPA to be used in the measurement of Glomerular filtration rate (work not yet begun).
 - c. Calcium-45 in CaCl_2 to be used in animals in studies of calcium deprivation depending on vitamin deficiency in conjunction with Hydrogen-3 in vitamin D3.
 - d. Selenium-75 as selenomethionine for brain uptake studies involving amino acid uptake from the blood system.
 - e. Technetium 99m in sulfur colloid for studies in patients suspected of pulmonary ailments.

- f. Technetium 99m as pertechnetate with iron and ascorbic acid complexes for application in kidney scans.
- g. Iodine-131 as labeled fibrogen for the detection for venous thrombosis.

Instruction of Personnel

10. Written procedures are required by the license. The procedures attached to the application for the license are entitled "Radiation Safety Program Manual, Veterans Administration Center, Los Angeles, Calif. Revised December 1964." Mr. Wetterau stated that the procedures had been revised in a revision dated April 19, 1970, a copy of which is attached as exhibit B. A comparison of the two revisions show that the only change in the new procedures is the disposal of animal carcasses quarterly rather than monthly as stated in the old procedures. All other procedures remain the same.
11. Mr. Wetterau stated that all investigators have received copies of the new revised procedures and that the procedures were being followed.
12. A rotational training program for physicians is in effect at the Center. At the time of this inspection Mr. Wetterau stated that 4 physicians were currently undergoing nuclear medicine training with lectures provided by himself and Dr. Blahd and other members of the staff. During the facility tour the lecture room for training of physicians was observed *used in the training program. Mr. Wetterau stated that most of the new equipment* to have desks and various types of equipment that they had procured for use in clinical programs had been purchased with funds allocated for training. Mr. Wetterau also stated that the procedures used in both clinical and research activities were strictly enforced by himself with backing from his superiors.

Procurement - Records of Receipt, Transfer and Export

13. Radioactive material procurement has been described in previous inspection notes. The RSO stated that standing orders included only two radionuclides which were 200 millicuries of Technetium-99m in generators biweekly and 50 millicuries of I-131 per week. He said that all other materials were ordered on a demand basis.

14. Several log books were maintained for the various radioisotopes received which showed the labels removed from the shipping containers together with the isotope, chemical form, volume, date of assay, quantity in millicuries, total activity, and from whom received. Also included in the same books were the name of the patient to whom doses were administered, the physician prescribing the dose, the total activity given to the patient, and the date of assay at the time of the dose administration.

All receipts for compounds of carbon-14 and hydrogen-3 were maintained ^{compounds} in a second log book and all other isotopes in a third log book. Several transfers of radioactive material in labeled ^{material in labeled} in one log book (research), iodine 125, 131 compounds had been made

since the previous inspection - all ^{to} UCLA. The records of transfer showed that 14 transfers involving a total of 345 microcuries of carbon-14, calcium 45, 47 had taken place. Mr. Wetterau explained that prior to any transfers he telephonically confirmed with the UCLA RSO, whether or not the institution was licensed to receive the material. The records of transfer also showed the date of transfer, the user to whom transferred at UCLA and the appropriate UCLA license number together with the amount in microcuries.

16. Mr. Wetterau stated that there had been no exports of radioactive material

Inventory of Licensed Material

Attached as Exhibit C is a recent inventory of materials held under the license as of June 21, 1970. Mr. Wetterau stated that such inventories

are conducted quarterly or semi-annually and usually prior to the AEC annual inspection visit. An examination of the inventory sheet showed that the institution possessed amounts within those authorized by the license.

Use of Licensed Material

18. Some of the nonroutine uses of licensed material were described under the heading "Radioisotopes Committee." Other uses of radioactive material involved routine clinical work and areas of research involving small animals and in vitro systems. Of particular interest was the production of various new compounds used in human research as indicated earlier. Dr. Tubis, Head of Pharmacology, is in charge of proper preparation of the materials with respect to purity and Pyrogen testing. Dr. Tubis is also responsible for a quality assurance program with respect to the production of various isotopic compounds.
19. The VA Center publishes for internal distribution a yearly summary of clinical procedures performed on patients. An examination of the report for fiscal year 1970 was examined. The report showed that a total of 5,457 diagnoses were performed on 4,982 patient for the year. The report showed that more than 2,000 of the diagnoses involved iodine-131 125, for routine uses such as thyroid function studies and scans, determination of blood and blood plasma volume, liver function studies and scans, lung scans, fat absorbtion studies, kidney functions studies and scans and cardiacs scans. Iodine-131 was also used in 33 patients for treatment of hyperthyroidism.

20. Technetium-99m was used for more than 1,000 brain scans during the period but was also used in kidney transplants, cerebral blood flow studies, liver and heart scans. Other radioactive materials used included Xenon-133 for pulmonary studies, selenium-75 for pancreas scans, chromium-51 for spleen scans, iron-59 in iron turnover studies, hydrogen-3 as tritiated water for water turnover studies, bromine-82 for extracellular water studies, sodium 24 for exchangeable sodium studies and fluorine-18 for bone scans. Phosphorous-32 was used in therapy for polycythemia vera. Also used was mercury 203 in brain scans and strontium-95 in bone scans.

Facilities and Equipment

21. The facilities at the clinic (building 114) were found to be the same as described in previous inspection notes. Therefore, only new equipment and facilities will be described. New equipment for the clinic included two Nuclear Chicago Mediac assay analyzers and dose calibrators, a Packard TriCarb Scintillation device which was used in training and for bioassay analysis, and a Nuclear Supplies single channel analyzer. Also new was a Nuclear Chicago portable ionization instrument, Cutie Pie Model 2588, which had low range and high range ionization chambers with ranges of respectively, 2.5 r/hr and 250 r/hr. A tour of the laboratory areas and hot storage room (room 212) revealed that they were properly posted in accordance with the regulations and the containers in storage were properly labeled as required.
22. Room 228 which is used for iodine-131 uptake studies and brain scans contained an adjacent room used for education and training of physicians in nuclear medicine. Noted in the room were various pieces of equipment used in training such as projectors, X ray readers, desks and the usual

class room materials.

23. The tour was made of the Neurobiochemistry laboratory (Building T-85) which had been used in carbon-14 and hydrogen-3 research studies involving about 3 millicuries per month of the compounds, total. The building and equipment had not changed since the previous inspection. Also, the building was posted and most containers labelled in accordance with the regulations. For those containers which were not labeled there was a readily available log book showing the amounts, date, and the isotope in the containers which had been made up from stock solutions for research.
24. A new waste handling facility has been added and was located adjacent to Building 114. The building was observed to be built with concrete blocks with a 9-inch thick concrete roof. Mr. Wetterau stated that since the on-site burial had created some problems with respect to disposing of the real estate that they had decided that all of their waste would be transferred it to a licensed waste handling firm. As a result, Mr. Wetterau stated that they were allocated funds to construct the waste storage building. The door to the building was observed to be locked and posted "Caution Radiactive Materials" with the words "Restricted Area" with the usual symbol and colors. Two freezers were stored in the room, one for carbon-14 and hydrogen-3 compounds in animal carcasses, and the second freezer for all other isotopes in animal carcasses. There were sign sheets located on each freezer for the investigators to show the amount of isotope and date that the animal carcass was put in to the freezer. Near the entrance door there was a Nuclear Chicago count rate

meter used for surveying personnel after loading waste. The room was divided up into two sections, one used for low level storage of radioactive materials and another used for high level materials and liquid waste. Several waste drums were stored near the freezers for beta emitters which also contained sign sheets to indicate the amounts put in the barrels on a given day. The second half of the room contained three liquid waste jugs and two concrete caves, one used for gamma emitters with dose rates less than 5 mr/hr and the second highly shielded cave for gamma emitters with dose rates of greater than 5 mr/hr. Mr. Wetterau stated that these were called decay pits where higher level wastes were left for decay for ease in handling later on.

25. Other rooms visited in Building 114 included room 118 used in carbon-14 research which contained a Barbara Colman Gas chromatography unit with two H-3 100 millicurie detector cells which were noted to be properly labeled. There was also a temperature indicating device which was set at 160° centigrade on the Barbara Coleman unit. Room 135 also contained another Barbara Coleman unit which had a temperature control mechanism.
26. Room 317 contained a Varian Aerograph gas chromatography unit with 250 millicuries of hydrogen 3 which had not been used.
27. Since the previous inspection new rooms have been modified in the Wadsworth Hospital for additional radiosotope clinic space. Room B-1 on the main floor was being used as a thyroid uptake and thyroid scanning room and contained a new nuclear Chicago thyroid scanner. There was also a new Picker Renogram scanner in the room. In Room B-48 there was a Picker

Magna Scanner-500 with a 5-inch sodium iodide crystal and two lead caves for storage of compounds of iodine-131 ~~and~~ (uptake capsules), The caves were posted in accordance with the regulations.

28. Room B-47 contained two new Picker Magna Scanners, Models II and 500, respectively, and space was allocated for radiopharmaceutical preparations. Mr. Wetterau stated that part of the hot lab in building 114 would be relocated to Wadsworth Hospital. Room B-47 was not quite completed and a new fume hood was being installed. In room B-245 there was new Nuclear Chicago Pho/Gamma III scanner and a new Picker scanner.
29. One more area used in research was a laboratory in a quonset hut near Wadsworth (Building T-22) which had been used in carbon-14 and hydrogen-3 studies in animals. At the time of the inspection there was no work being performed in the building and the compounds were stored in a freezer which was properly posted and the containers properly labelled. There was also an Indium generator stored in the room. The principle user in laboratory T-22 was Mr. T. Braun who stated that at any one time no more than $\frac{1}{2}$ microcuries of carbon-14 or hydrogen-3 labeled amino acids were ever used. ^ROther new instrumentation purchased since the previous inspection included a Picker Magna Scanner III with a 3-inch sodium iodide crystal and a Nuclear Chicago model 8725 uptake scanner with a two inch and a three inch sodium iodide crystal.
30. Restricted areas are defined to be those laboratories in all the buildings where radioactive materials are used or stored, according to Mr. Wetterau. He stated that in addition to the VA Center being patrolled

at night that all rooms and building where radioisotopes were stored were kept locked during nonworking hours.

31. All other facilities and equipment have been fully described in previous inspection notes.
32. A number of AEC Form 3's were posted in each facility where radioactive materials were either being used or stored.

Survey Program

33. Surveys of the laboratories are performed monthly and include a direct survey of equipment, room bkgd. radiation, and wipes of surfaces as needed. Records of surveys were examined and showed the date the surveys were made, the highest dose rates on the containers or areas surveyed, and the highest contamination found on wipes. Results of the surveys indicated radiation levels equivalent to background in the rooms and up to 2 mr/hr on storage caves; all wipes taken showed less than 100 d/m per 100 cm². Mr. Wetterau stated that although routine surveys of the labs are done monthly that surveys are made by informal request as well.
34. Air sampling is performed as needed during iodine-125 iodination and samples are taken of stack air exhaust when synthesizing ACTN with iodine-125 or iodine-131. Results of the air samples recorded in a log-book showed that the average concentration during iodination was 10⁻⁹ μ Bi/cc and for stack air the maximum concentration was shown to be 5 x 10⁻⁹ μ Bi/cc. Iodination lasts about 3 hours at any one time. Mr. Wetterau explained that air sampling is not routine but done each time these *radioactive compounds since these present the greatest potential for airborne* activities are performed, principally for radioactivity problems.
35. Bioassays on personnel and whole body counting are performed as needed in accordance with the levels of radioactivity used. Mr. Wetterau explained that bioassays are performed for personnel using greater than 10 milli-

curies of H-3 per week by internal procedure and he stated that there had been only one case where anyone used greater than 100 millicuries in one week. He stated that due to the cutback in research there was no bioassays performed for hydrogen-3 at the present since very little was being used. Some urine samples were provided by personnel who used calcium-45 and carbon-14 compounds. It was noted that urine samples have not been provided for the past several months because of the reduction in the use of these compounds. For those samples submitted within the last year there had been no significant internal exposure from the radioisotopes used.

36. The results of the whole body counting which was last performed in December of 1969 were examined. These records showed that 12 people were given whole body counts with only one showing 1/100th of a microcurie of iodine-131 and no detectable activity in other personnel or for calcium-45 and technetium 99m. The limit for iodine-131 is 0.7 microcuries with the thyroid taken as the principle organ.

Personnel Monitoring

37. Film badges are provided for the employees and exchanged monthly. The film badges are supplied and analyzed by the Radiation Detection Company of Mt. View, California. The records supplied by the Radiation Detection Co. of 1969 were 140 mr; for the 4th quarter 1969 270 mr; for 1970 first quarter were examined and showed that the highest exposure for the third quarter the maximum exposure was 165 mr and for the second quarter 195 mr.
38. The Radiation Detection Company reports showed no unusually high doses received as reported to this office by the Radiation Detection Company on May 28, 1970 (Memo Route Slip - H. E. Book to File 5/28/70). Mr.

Wetterau was asked if there had been any unexplainable or unusually high exposures to badges in the past year; he said there had not been any.

39. Pocket dosimeters are available but generally not used according to Mr. Wetterau. The types available are self reading Landauer model No. L-49 with the range of 0 - 200 mr.

Waste Disposal

40. Prior to the last inspection of August 11, 1969 the licensee had buried low level waste on VA Center land and at that time had considered releasing the land to the City of Los Angeles for a park. (Referenced Memo to File December 22, 1969 signed by H. S. North). Mr. Wetterau stated that there had been nothing new with respect to the land disposal but that at present he felt that it was not going to be released. He stated that in any event they had not buried any additional waste on the land in question and had decided to make it a policy to transfer all wastes to a disposal firm.
41. According to Mr. Wetterau there have been no disposals by sanitary sewage and this had been discouraged as a policy. He stated that all wastes were being saved, both liquids and solids and transferred once per quarter to California Salvage Company waste disposal firm. As a result of the new changes in waste handling policy a new waste building was constructed which has been described earlier in these notes. Records of waste transfer to California Salvage were maintained. An examination of these records showed that four transfers had taken place since the previous inspection as follows:

<u>Date</u>	<u>Quantity</u>	<u>Principle Isotopes</u>
8-18-69	59.6 millicuries	Iodine 131, Carbon-14, Hydrogen-3, Iodine-12

<u>Date</u>	<u>Quantity</u>	<u>Principle Isotopes</u>
11-5-69	35 millicuries	Iodine-131, Iodine-125, Hydrogen-3
2-20-70	1,847.6 millicuries	Iodine-131, Iodine-125, Carbon-14, hydrogen-3, Radium-226. (included 1 hydrogen-3 gas chromatography foil)
6-25-70	30 millicuries	Iodine-131, Iodine-125, Carbon-14, Hydrogen-3, rubidium-86, and Molybdenum 99

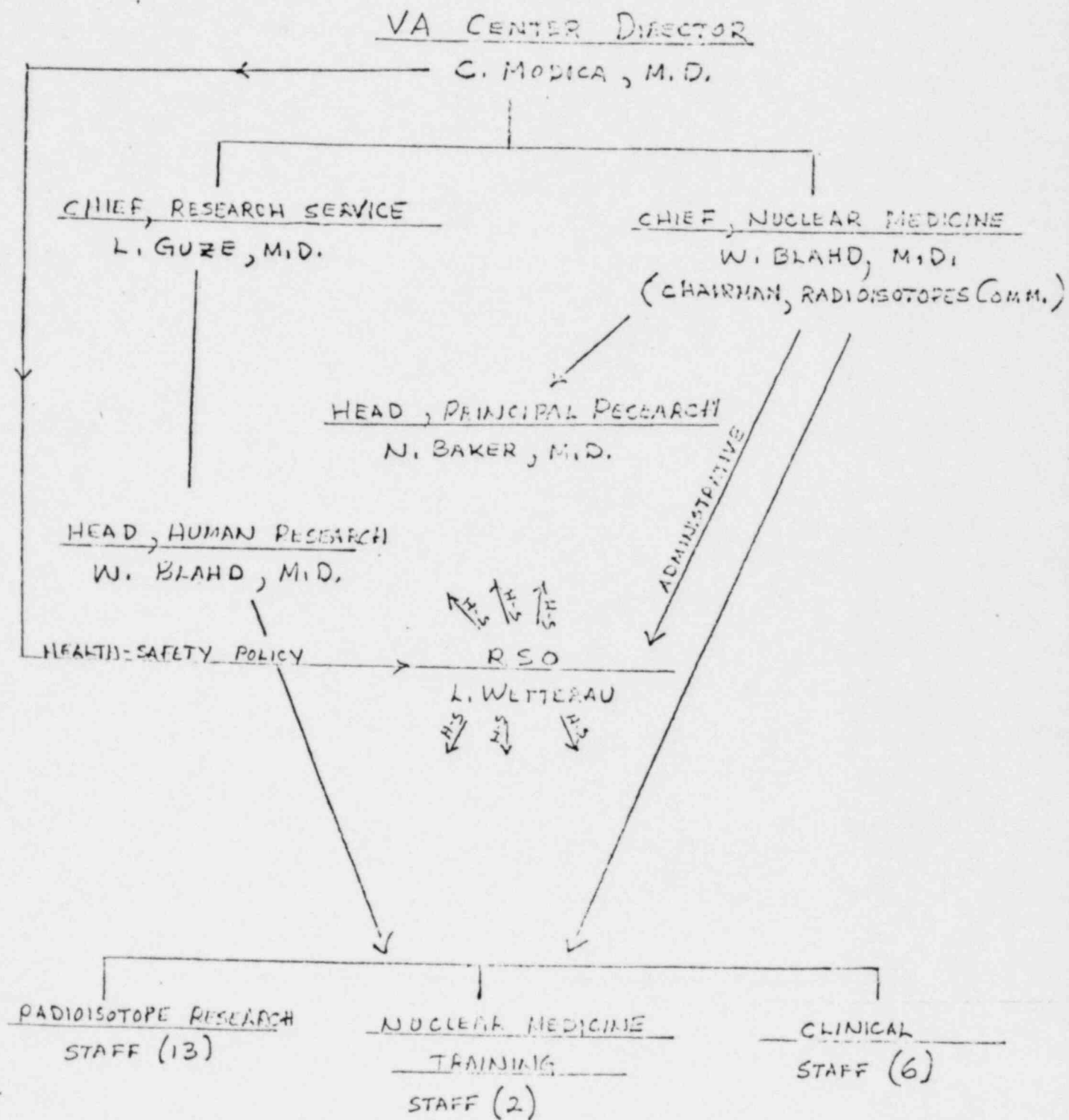
42. As stated earlier both solids and liquids were transferred to California Salvage Company. Such methods of disposal are the only ones currently in use at the VA Center.

Leak Tests

43. Leak tests are required by conditions of the license at 6 months intervals for gamma emitting sources. Currently, the licensee possesses only two sources requiring leak tests, one cobalt-60, 100 microcuries - Tracerlab Model R-30 source and one strontium-90 eye applicator model R-1-A of 50 millicuries. Records showed that both sources were leak tested on October 1, 1969, and again on April 1, 1970 with the results of less than 0.005 microcuries of removable contamination. The leak tests are performed and analyzed by the licensee.

Miscellaneous

44. According to Mr. Wetterau there had been no unusual occurrences or incidents since the previous inspection. Mr. Wetterau maintains a special log book with a summary of occurrences the last of which occurred on October 23, 1968 involving a radioisotope leak inside a shipping container. Mr. Wetterau also stated that they had no AEC contracts.



ORGANIZATION - VA CENTER