

COMPLIANCE INSPECTION REPORT

1. Name and address of licensee UNITED STATES NAVY, DEPT. OF United States Naval Hospital St. Albans 25, New York	2. Date of inspection April 2, 1959 (L.R. Adams) and Sept. 14, 1959 (R.S. Cleveland)
	3. Type of inspection Initial
	4. 10 CFR Part(s) applicable 20 - 30

5. License number(s), issue and expiration dates, scope and conditions (including amendments)

License No. Date Exp. Date

31-76-4
amend. 7 12/17/58 12/31/60

- SCOPE: A. 315 mc of I-131 as iodide for diagnosis of thyroid function. Treatment of hyperthyroidism, cardiac conditions, and thyroid carcinoma.
- B. 20 mc of I-131 as Iodinated human serum albumin for determination of blood volumes and plasma volumes. Circulation rate studies. Localization of brain tumors and liver tumors.
- C. 5 mc of I-131 as rose bengal for liver function studies.
- D. 2 mc of I-131 as triolein and/or oleic acid for fat metabolism studies.
- E. 2 mc of I-131 as urokon for kidney function studies.
- F. 2 mc of I-131 as diodrast for kidney function studies.
- G. 10 mc of I-131 as miokon for laboratory studies in lower animals.
- H. 1 mc of I-131 as triiodothyronine for in vitro studies of thyroid function.
- I. 350 mc of P-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and carcinoma of the bladder. Localization of eye tumors. (CONT'D)

6. Inspection findings (and items of noncompliance)

The Radioisotope Laboratory of this Hospital uses byproduct material in diagnostic and therapeutic medicine. Commander J. S. Burkle is the Clinical Head of the Radioisotope Laboratory, while Captain H. C. Dudley is the Technical Head. Dudley acts as RSO. All radioisotope therapies must be reviewed and approved by either the Hospital's Tumor Board or the Head and Neck Board, as well as by a five-member Radioisotope Committee. About ten personnel are associated with use of the licensed materials. Separate facilities are employed for handling and storage of radioisotopes. Numerous survey instruments are available. Safety instructions are given orally as appropriate; no written procedures have been formulated. Surveys of handling operations are conducted, but records have not been kept of measurements and evaluations. Film badges supplied and processed by the licensee are employed and results recorded. Procurements are controlled by Dudley. Wastes are disposed by storage for decay, release to the sewers, incineration, and burial. Areas were posted. Containers were labeled, though not all as required by Part 20. Records were also maintained of receipts and uses. Leak tests were not conducted. The only items of noncompliance observed or noted during the inspection are as set out below:

License Condition 13

- in that Y-90, procured from BNL for human use, was not independently assayed. (See Item 10 of report details.)

(CONT'D)

7. Date of last previous inspection None.	8. Is "Company Confidential" information contained in this report? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (Specify page(s) and paragraph(s))
---	--

DISTRIBUTION:

Orig. - Div of Ins, Hq.
1 cy - D L & R
2 cys - Ins Div, NYOO

Approved by: **Richard S. Cleveland**
(Inspector)
Robert W. Kirkman
New York
(Operations office)

November 24, 1959
(Date report prepared)

If additional space is required for any numbered item above, the continuation may be extended to the reverse of this form using foot to head format, leaving sufficient margin at top for binding, identifying each item by number and noting "Continued" on the face of form under appropriate item.

C/8

ITEM 5 (CONT'D)

License No. Date Exp. Date

31-764
amend. 7

- SCOPE: J. 35 mc of P-32 as colloidal chromic phosphate for intracavitary treatment of malignant pleural and peritoneal effusions and ascites. Interstitial treatment of tumor masses.
- K. 900 mc of Y-90 as oxide and/or chloride for intracavitary treatment of malignant serous effusions. Treatment of carcinoma of the bladder. Preparation of soluble filaments and implantation of the filaments in tumors. Tissue distribution and excretion studies on terminal cancer patients. Treatment of polycythemia vera and leukemia.
- L. 100 mc of K-42 as carbonate for determination of total exchangeable body potassium.
- M. 10 mc of Na-24 as carbonate for determination of sodium space, circulation times, and cardiac output.
- N. 10 mc of Cr-51 as chromate and/or chloride for determination of red cell mass and red cell survival times.
- O. 100 mc of Ga-72 as oxide for tracer studies to determine chronic osteomyelitis, healing of fractures, and bone lesions.
- P. 50 mc of Co-60 as Vitamin B-12 for diagnosis of pernicious anemia.
- Q. 15 mc of As-74 as chloride for localization of brain tumors.
- R. 5 mc of C-14 as carbonate for metabolism studies.
- S. 5 mc of H-3 as gas for metabolism studies.
- T. 5 mc of Fe-59 as chloride for diagnosis of hematologic disorders.
- U. 5 mc of S-35 as sulfate for determination of body water.
- V. 2 mc of Ca-45, any form, for laboratory studies in lower animals.
- W. 3 mc of Hg-203 in any form for laboratory studies in lower animals.
- X. 3 mc of Zn-65 in any form for laboratory studies in lower animals.
- Y. 850 mc of Au-198 as colloidal for intracavitary treatment of pleural and peritoneal effusions and ascites. Liver blood flow studies.
- Z. 40 mc of Sr-90 as Tracerlab Model RA-1A sealed medical applicator for treatment of tumors of the eyelids, conjunctive, corneal vascularization, vernal catarrh, and chronic infection of the lids and conjunctive.

CONDITIONS: #11-Compliance with Part 20. #12-The use of byproduct material in humans shall be by, or under the direct supervision of, Commander J. S. Burkle, MC, USN, or Captain C. Cartenlaub, MC, USN. Byproduct material may also be used, not in humans, by or under the direct supervision of, Captain H. C. Dudley, MSC, USN. #13-Byproduct material acquired from an Atomic Energy Commission facility shall not be used in humans until its pharmaceutical quality and assay have been independently established. #14-Byproduct material as sealed source shall not be opened. #15-The sealed source containing Strontium 90 shall be tested for leakage and contamination at intervals of not more than six (6) months and records of test results shall be maintained by the licensee. The leak test shall be performed by Captain H. C. Dudley. #16-Total amount of Hydrogen 3 (tritium) acquired under this license shall not exceed 100 mc.

ITEM 6 (CONT'D)

License Condition 15

- in that leak tests have not been performed and records of results maintained. (See Item 13 of report details.)

20.203 (f)(1) and (4)

- in that storage containers were not all labeled with radiation symbol, radioactive materials warning, and information as to type, amount, and date of assay of contents. (See Items 13 and 16 of report details.)

20.305

- in that carcasses of animals used for radioisotope experiments are routinely disposed by incineration without specific Commission approval. (See Item 15 of report details.)

20.401 (e)

- in that records of surveys and records of disposals by incineration and release to the sewers have not been maintained. (See Items 18 and 15 of report details.)

30.3

- in that the licensee possessed Tm-170 and H-3 as thymidine without holding a valid license authorizing such possession. (See Item 11 of report details.)

PART 30 INSPECTION

UNITED STATES NAVY, DEPT. OF
United States Naval Hospital
St. Albans 25, New York

Dates of Inspection: April 2, 1959 (L.R. Adams) and September 14,
1959 (R.S. Cleveland) Both pre-announced.

Persons Accompanying Inspector:

None.

Persons Contacted (April 2, 1959):

Captain H. C. Dudley, PhD, MSC, USN

Persons Contacted (September 14, 1959):

Captain H. C. Dudley, PhD, MSC, USN
Commander J. S. Burkle, Clinical Head, Radioisotope Lab.
Charles L. Bransford, Hospitalman First Class, USN, Senior Technician

DETAILS

9. Organization and Administration

The St. Albans Naval Hospital uses byproduct materials in a number of diagnostic and therapeutic medical applications and in research studies. Materials are used in the Hospital's Radioisotope Laboratory. Commander J. S. Burkle, M.D. is the Clinical Head of this Laboratory, while Captain Dudley is the Technical Director of the Laboratory. These two officers are the principal users of byproduct materials at the Hospital. They are assisted in this work by six enlisted Navy personnel. C. L. Bransford is the Laboratory's Senior Technician, and he acts in a direct supervisory capacity over the actual handling of the radioactive materials in preparing doses. Captain C. Gartenlaub, MD, MC, USN, the Hospital's Chief of Radiology, occasionally uses byproduct material for patient treatment under the direction of Commander Burkle. Captain George Stocker, Assistant Chief of Radiology, also occasionally works with Gartenlaub in using byproduct materials.

Each use of byproduct material for therapy must first be thoroughly reviewed and approved by either the Hospital's Tumor Board or the Head and Neck Board. After this, the therapy treatment must also be reviewed and approved by the Hospital's Radioisotope Committee. The Radioisotope Committee is composed of the Chiefs of Radiology, Surgery, and Laboratories, plus the Technical and Clinical Heads of the Radioisotope Laboratory. The personnel presently holding these positions are, respectively, Captain Gartenlaub, Captain Timmes, Captain Sarkisian, Commander Burkle, and Captain Dudley.

Work with X-ray units and radium sources is separate from that involving byproduct materials, and the two radiologists mentioned above who occasionally use byproduct materials are the only personnel reported to participate in both activities. Dudley acts as RSO for the work with licensed materials in the Radioisotope Laboratory and is responsible for placing orders and ensuring that license limits are not exceeded. Burkle and Dudley have had a number of years experience in working with radioactive materials and other radiation sources. Bransford has had about seven years full-time on-the-job experience in isotope work. He took courses and later taught at the Naval Hospital in Bethesda on uses of radioisotopes and radiation safety. All of the Radioisotope Laboratory technicians were reported to have taken an eight months training course at the Bethesda Naval Hospital.

10. Facilities and Uses of Byproduct Material

Facilities of the Radioisotope Laboratory at the St. Albans Hospital include several rooms used for administration of diagnostic doses and performance of up-take studies, plus a combined counting room and hot laboratory, which is equipped with isotope handling fume hoods and a shielded storage closet. Remote handling tongs, plastic shielding for strong beta emitters, lead shielding, absorbent paper, and spill-catch trays were noted to be available and reported to be routinely used in handling procedures in the hot laboratory.

Materials on hand at the time of the 9/14/59 inspection visit included 165 μ c I-131 as triolein, 5 μ c I-131 as diodrast, 5 mc I-131 as RISA, 8.3 mc Au-198, 250 μ c Cr-51, 9.5 μ c Co-60 as Vitamin B12, 720 μ c H-3 as thymidine, 5 mc I-131 as iodide, and 40 mc Sr-90 in an eye applicator. In 1958, radioisotope diagnosis was reportedly performed on 3,192 patients, with 52 patients receiving therapeutic doses of byproduct materials. Current usage was described as involving about 250 diagnostic studies and one therapeutic application per month. Animal studies were also performed involving several dozen rabbits and dogs during the past year. The animal work has been performed by Commander Burkle and has mainly involved studies with Y-90 and Au-198. Most of the animal work was conducted with a maximum of 10 μ c Y-90 or Au-198 given per animal. One experiment was reported to have involved application of 10 mc Au-198 per week for 14 weeks to a dog.

Iodine-131 as iodide has been routinely procured at a rate of 5 mc per week for the diagnostic studies. Therapy doses are procured individually as needed. RISA is used less frequently. Iodine-131 as rose bengal has been used at a rate of about 5 mc per year, with none currently in use. Iodine-131 as triolein and/or oleic acid is procured and used at the rate of two shipments of 2 mc each per month. Iodine-131 as diodrast has been used occasionally, with only four shipments of one to two mc, each having been procured. Occasional use is also made of I-131 as mickon. P-32 as a soluble phosphate has been procured and used at the rate of five shipments of 10 mc each in the past two years. Y-90 is being procured and used at the rate of 100 mc per two weeks. Only one shipment of about 100 mc K-42 has been procured and used in 1959. Na-24 has been procured and used to the extent of three shipments of 3 to 7 mc each in

the past two years. Nine shipments of 2 to 5 mc each of Cr-51 have been procured and used in the past two years. Four shipments of 10 uc each of Co-60 as Vitamin B₁₂ have been procured and used in the past two years. Two shipments of 250 uc each of H-3 as a gas have been procured and used in the past two years. Five shipments of 250 uc each of Fe-59 have been obtained and used in the past two years. Occasional shipments no more than a few hundred millicuries Au-198 have been obtained and used.

No uses are being made of I-131 as Urokon, I-131 as triiodothyronine, P-32 as colloidal chromic phosphate, Ga-72, As-74, C-14, S-35, Ca-45, Hg-203, or Zn-65. All uses were confirmed to be as specified in Item 9 of amendment 7 of the license.

The major amounts handled were noted to be of Y-90, I-131, P-32, and Au-198. Patient therapy with I-131 was reported to amount to a maximum of 8 mc per patient; P-32, 5 mc per patient; and Au-198, 50 mc per patient. Considerable work is being done with Y-90 in several treatment applications. A maximum of 30 mc Y-90 per patient has been administered intraperitoneally as a substitute for similar use of Au-198. About four patients per year have been treated this way. A maximum of 20 mc per patient Y-90 has also been administered intravenously to treat blood conditions in place of P-32. Y-90 as an oxide has been obtained from BNL about six times per year in amounts of 100 mc each. This material has been made into tissue soluble filaments for tumor therapy. About 15 mc has been implanted per patient in these filaments. This is the only material which has not been obtained from Abbott or Squibb. Dudley reported that the yttrium oxide was checked by BNL for assay, but that no independent assays of the material had been performed. Dudley further reported that arrangements were being made to obtain this material from Squibb in the future in a pre-assayed form.

11. Thulium Radiography Sources

At the time of the 4/2/59 inspection visit, it was noted that some Tm-170 radiography sources were in storage at the Hospital in a room located behind the million-volt X-ray facility. The sources were stored in a heavy metal cask within a wooden shipping box. The only label on the shipping box was an AEC label which indicated the activity of the sources to be 10 curies. A shipping notice within the shipping box indicated that the sources were shipped from BNL to St. Albans Hospital, attention of Dr. Dudley, on 7/21/55.

Dudley said that the cask contained six Tm-170 sources and that this material was being stored for the Army installation at Ft. Totten in Queens according to special arrangement between the Army and Dudley. Dudley stated during this visit that he was merely storing the material for the Army and that he expected the Army to attend to its disposal shortly. Dudley said that this material was procured under a license issued to the Army naming Dudley as responsible user, but that he thought that this license had since expired. It was noted that License 31-76-1 which was issued to St. Albans Hospital on 3/16/56 and which expired on 3/31/58, authorized the Hospital to receive, store and load six Tm-170 sources of 20 curies each "into specially designed lead shields for use as portable field X-ray units for re-distribution to other AEC licensed Armed Forces installations".

Dudley stated during this first visit that he had recently checked the radiation level on the outside of the cask and found it to be about 20 mr/hr at the surface of the wooden shipping case. This radiation level was confirmed by the inspector during the first visit using a recently calibrated Nuclear Measurements Corporation Model GS-2 GM survey meter, N100 #5588.

During the second inspection visit on 6/14/59, Dudley reported that he had arranged for transfer of these sources to BNL about 7/5/59. He stated that this transfer was made in cooperation with the U.S. Army Experimental Laboratory at Ft. Totten. St. Albans Hospital personnel and truck were used to make the transfer.

12. Instrumentation

The Naval Hospital is a disaster control center and, as such, maintains an inventory of 50 survey instruments of all types. In addition, two Navy-type hand-and-foot laboratory monitors are available. All these instruments are maintained by the Navy and are calibrated and checked each six months. One or two instruments from this pool are kept on hand in the radioisotope facilities. The instruments used by the Radioisotope Laboratory personnel are equipped with end window GM probes and have ranges from 0 - .5 mr/hr up to 0 - 500 mr/hr.

13. Radiological Safety Precautions and Procedures

All technicians handling radioisotopes have received formal instruction in handling techniques and safety precautions. Additional instructions for specific operations have been issued as considered appropriate. No written general safety procedures have been drawn up.

Rubber gloves and lab coats are routinely worn during preparation and administration of doses. Meter surveys are performed for all handling operations with therapeutic doses. These surveys were described to be of an informal nature, and no records are maintained of the measurements. Isotope handling operations at the Hospital have been evaluated as involving little hazard, but no records have been maintained of these evaluations. Dudley was aware of the very high dose rates associated with unshielded millicurie amounts of Y-90. His described handling techniques indicated that he relied on an air separation of only about one foot between his hands and the open-topped beaker in which up to 100 mc of Y-90 would be incorporated into filaments. Dudley stated that he had also monitored his hands occasionally with wrist film badges, but specific records of these evaluations were not available.

Dudley reported no major spills to have occurred and that minor spills were cleaned up with no difficulty. Sheets and other bed clothing of patients being treated with Au-198, and Y-90 are monitored before laundering. If contamination is found, the sheets are stored in the hot laboratory storage area for at least six half-lives before being sent to the laundry.

The 40 mc Sr-90 eye applicator was stored in a cabinet in one of the treatment rooms in the radioisotope laboratory. This applicator was obtained from Tracerlab in 1952. Neither the applicator's storage box nor the applicator itself had a label bearing a standard radiation symbol or information as to type, amount or date of assay. Both the applicator and its storage box bore labels saying "Caution - Radioactivity". Dudley stated that the eye applicator had not been leak tested for about three years and that it had not been used during 1958, although it was used on one or two occasions early in 1959. During the 4/2/59 inspection visit, the recess in the storage case which accepts the Sr-90 capsule was surveyed for contamination using an end-window GM survey meter, but no contamination was observed. During the 9/14/59 visit, Dudley reported no new leak tests to have been performed or uses made of the unit.

14. Storage and Security

Byproduct material was noted to be stored in a refrigerator in the administration room, on shelves in a closet off the administration room, and in the hot lab, with all these areas located within the Radioisotope Laboratory. Entrances to these storage areas were reported to be kept locked when the department personnel were not present and supervising the areas.

15. Waste Disposal

Radioactive wastes are routinely disposed of by storing for decay. Residual activities in original shipping containers are routinely stored for about six months. Low level solutions are eventually released in soluble form to the sanitary sewerage system. Drain disposals were reported by Dudley to have never exceeded a total of one mc in any one day. Carcasses of animals used in tracer experiments are disposed of by burning in the Hospital's incinerator. No more than a few microcuries are reportedly involved in such disposals. The carcass of a dog which had received 10 mc Au-198 per week for 14 weeks was disposed of by burial.

16. Posting and Labeling

As noted previously in Item 13 of report details, the Sr-90 eye applicator and its storage container were not labeled as required by Part 20. A bottle containing 900 mc Au-198 and stored in the refrigerator in the dose administration room was noted to lack a label saying "Caution - Radioactive Materials" and displaying a standard symbol, although information was included in the container's label as to type, amount and date of assay of the contents. Several other containers were also noted to lack labels which fully complied with the Regulations of Part 20, though most containers noted were observed to be properly labeled. Areas of use and storage were noted to be properly posted with radioactive materials caution signs.

17. Personnel Monitoring

Personnel monitoring is accomplished by use of film badges which the Naval Hospital supplies and processes itself. The Naval Hospital obtains dental-type film from Dupont and provides a personnel monitoring service for Naval facilities and fleet units operating in the Atlantic coastal area. The Hospital processes its own films and uses calibration charts supplied by the manufacturer. Films are developed under standardized conditions along with control badges. One chest badge and one wrist badge are supplied to each radioisotope worker. Exposure records showed a maximum of a few hundred mr/month to the badges for the past several years.

18. Records

Detailed records are maintained of procurements, inventories, and uses. Records are also maintained of film badge results. No records were available for surveys, leak test results, or any disposals other than for the burial of one experimental animal.