

UNITED STATES
ATOMIC ENERGY COMMISSION

In Reply Refer To:
IR:SAL

ACH1.000005.011bc

Oak Ridge, Tennessee
July 19, 1949

Dr. Hymer L. Friedell
Dr. G. Failla
Dr. Joseph G. Hamilton
Dr. A. H. Holland

Subject: REVISED TENTATIVE MINUTES OF MARCH 13, 1949 MEETING OF
SUBCOMMITTEE ON HUMAN APPLICATIONS OF COMMITTEE ON
ISOTOPE DISTRIBUTION OF U. S. ATOMIC ENERGY COMMISSION,
AEC BUILDING, WASHINGTON, D. C.

Gentlemen:

Enclosed is a copy of revised draft of the Tentative Minutes of
March 13, 1949 Meeting of Subcommittee on Human Applications of
Committee on Isotope Distribution of U. S. Atomic Energy Commission,
AEC Building, Washington, D. C. This revision is based upon
written comments received from Dr. Joseph G. Hamilton, Dr. G. Failla,
and upon oral comments received from Dr. Hymer L. Friedell. No
comments on the Tentative Minutes submitted April 29, 1949, were
received from Dr. A. H. Holland.

You are requested to submit a letter of approval of this revised
draft as quickly as possible so that the Isotopes Division can:

1. Prepare the circulars described in letter of April 29,
1949, from S. Allan Lough to the members of the Subcommittee.
2. Send a letter to the Atomic Energy Commission recommending:
 - a. Acceptance of Dr. Hamilton's resignation and the appoint-
ment of Dr. Dr. Harold Copp as his successor.
 - b. Appointment of a chairman of the Subcommittee on Human
Applications to serve from July 1, 1949, to July 1, 1950.

Very truly yours,

S. Allan Lough
S. Allan Lough, Chief
Radioisotopes Branch
Isotopes Division
Oak Ridge Operations

Encl.:
Minutes

ORGANIZATION & MANAGEMENT
Human Applications

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6 Meetings & Conferences - Human Applications

Subcommittee Members
April 29, 1949

This circular may be issued as a revision of Isotopes Division Circular E-35, a copy of which is enclosed.

A third circular will embrace the following items in the minutes:

III.A. Policy regarding field and industrial uses of long-lived radioisotopes.

III.D. Policy on level of activity that might be permitted in products and items sold to the public.

1. Emitters of beta particles.

2. Gamma emitters.

We shall welcome your comments on the tentative minutes.

Very truly yours,

S. Allan Lough, Chief
Radioisotopes Branch
Isotopes Division
Oak Ridge Operations

Encls.:

1. Cir. E-35
2. Minutes

REVISED

TENTATIVE MINUTES OF MARCH 13, 1949, MEETING OF

SUBCOMMITTEE ON HUMAN APPLICATION OF

COMMITTEE ON ISOTOPE DISTRIBUTION OF

U. S. ATOMIC ENERGY COMMISSION

AEC BUILDING, WASHINGTON, D. C.

The Subcommittee on Human Applications of the Atomic Energy Commission Committee on Isotope Distribution convened at 9:30 a.m., March 13, 1949, in Room 213 of the Atomic Energy Commission Building, Washington, D. C.

Those present were Drs. Hymer L. Friedell, Chairman, G. Pailla, and A. H. Holland. Dr. Joseph G. Hamilton was absent. Drs. Nathan H. Woodruff and S. Allan Lough were present as representatives of the Isotopes Division.

The Subcommittee established the following agenda:

- I. Review of the minutes of the last meeting, March 22, 23, 1948.
- II. Distribution of isotopes for cancer research.
- III. Discussion of specific items pointed out by Dr. Woodruff in his letter of February 5, 1949.

- A. Policy regarding field and industrial uses of long-lived materials.
- B. Review of policy relative to allocations on supplementary requests.
 1. Cases in which the quantities requested have been materially increased for the same purpose.
 2. Cases in which the original allocation does not conform with the latest revised policies.

C. Review of action taken on application for human use of radionuclides and formulation of a policy for future guidance.

D. Discussion of policy on level of activity that might be permitted in products and items sold to the public.

E. Clarification of policy on hospitalization and supervision of patients receiving radionuclides through Atomic Energy Commission facilities. Attention was focused on this item by a statement occurring in "Experience with Radioactive Iodine in the Treatment of Hyperthyroidism" by George Crile, E. Perry McCullagh and Otto Glasser in Cleveland Clinic Quarterly 18: 1-7, 1949. The statement read:

"5. Neither hospitalization nor supervision of the patient is required and the cost of treatment is less than that of thyroidectomy or prolonged medical treatment."

F. Use of radionuclides in pregnancy and in normal children.

IV. Review of Violation of "Acceptance Terms".

V. Review of specific applications not yet acted upon by this Subcommittee.

VI. Revision of Form AEC-313. ✓

VII. Development of method for replacement on some regular basis of members of the Subcommittee on Human Applications.

I. Review of the minutes of the last meeting, March 22, 23, 1948.

A. Consideration of use of radioisotopes in tracer studies in normal adult humans. The following remarks apply to beta and gamma emitters with a biological half-life of 20 days or less. These remarks are for general guidance but the Subcommittee on Human Applications will examine each case on its own merits.

Applicants who desire to use radioisotopes in normal adults should submit the results of animal experiments, or adequate references to the literature, concerning the following points.

1. Metabolism and distribution of the radiomaterial in the form administered.
2. The tissue of highest concentration and the relative concentration therein.
3. The relative concentrations in the tissue of interest and particularly radiosensitive tissues such as the gonads and hematopoietic system.
4. The biological half-life of the radioisotope in the tissue of highest concentration, the tissue of interest and the particularly radiosensitive tissues.

All tracer studies in normal humans must be approved by the local Radioisotopes Committee before consideration of the Application will be made by the Subcommittee on Human Applications.

The above statements apply to both Atomic Energy Commission and other installations.

B. Applications for use of radioisotopes in normal children will be given special scrutiny by the Subcommittee on Human Applications.

C. Review of Policy with regard to long-lived radioisotopes.

1. In general, for isotopes with a biological half-life greater than 20 days, the dosage in the critical tissues should be such as to conform to the limitations stated by the National Committee on Radiation Protection. In special cases, however, the Subcommittee on Human Applications may permit the use of radioisotopes in higher dosages.
2. The Subcommittee on Human Applications feels that each request for use of a long-lived radioisotope in human subjects must be reviewed separately.
3. In the minutes of the initial meeting of the Interim Advisory Committee on Isotope Distribution Policy, held June 28, 1946, at Oak Ridge, the following statement appears on page 9.

"Carbon 14. The Opinion was generally expressed that, even though the scarcity of C 14 is a major factor to be considered, the use of this material in a human being should not be sanctioned until its absorption and elimination properties is clearly demonstrated in animals. The very long half-life of the material makes caution desirable."

The Subcommittee on Human Applications feels that, in view of recently accumulated information, it is prepared to consider applications for use of certain C 14 compounds in humans. In arriving at this conclusion, the following papers were considered:

July 1945
C-14 use ok

a. "The Fate of C 14 in the Tissues of Mice after Administration of C 14 Methyl-Labeled Glycine" By George L. Nardi, M. D., Radiation Laboratory and Division of Medical Physics, University of California, Berkeley, California. January 6, 1949.

b. Letter from John E. Lawrence, Donner Laboratory, University of California, February 18, 1949, which accompanied Nardi's paper, listed as "a", above.

c. "Report on Estimated Doses Delivered to Organs of Man by C 14 in Methyl-Labeled Glycine". By William Siri. This report is based on Nardi's paper, listed as "a", above.

d. "Studies on the Hazard Involved in Use of Carbon 14. I. Retention of Carbon from Labeled Sodium Bicarbonate". TECHNICAL REPORT NO. 1 to Office of Naval Research (Biophysics Branch, Medical Sciences Division) and Atomic Energy Commission, Division of Biology and Medicine. Contract N7conr-385, Task Order II, NR 171642. By Southern Research Institute, Birmingham, Alabama, March 28, 1949. 457-121-TI.

4. The Subcommittee asked that the Isotopes Division send to the members a complete re-statement of Allocation No. 2283 of tritium to Dr. John Lawrence. This statement will be prepared and sent out under separate cover. (Dispatched to the Subcommittee on Human Applications on March 25, 1949.)

D. It is recognized that there may be instances in which the disease from which a patient is suffering permits the administration of larger doses for investigative purposes. Applications for such uses of radioisotopes will be given special consideration by the Subcommittee providing:

1. Full responsibility for conduct of the work is assumed by a special committee of at least three competent physicians in the institution in which the work is to be done. This will not necessarily be the local Radioisotope Committee.

2. The subject has given his consent to the procedure.
3. There is no reasonable likelihood of producing manifest injury by the radioisotope to be employed.

II. Distribution of isotopes for cancer research.

A. Cancer research is interpreted to include the following:

1. Investigation of the basic aspects of normal and abnormal cellular growth.
2. The development and evaluation of therapeutic and diagnostic procedures for cancer and allied diseases.

B. The Subcommittee on Human Applications expresses confidence in the way the Isotopes Division is handling the allocation of Iodine 131, Phosphorus 32 and Sodium 24 for use in diagnosis, therapy and research in cancer and allied diseases.

C. Cobalt 60 needles.

The use of Cobalt 60 needles is not considered research by the Subcommittee on Human Applications unless the needles are of some unusual design or incorporate some unusual feature.

The National Cancer Institute has standards for determining those to whom radium needles might be lent. The Isotopes Division was asked to obtain these standards and to send them to the Subcommittee. The Subcommittee will then recommend a way to control the distribution of Cobalt 60 needles.

III. Discussion of specific items pointed out by Dr. Woodruff in his letter of February 9, 1949.

A. Policy regarding field and industrial uses of long-lived materials.

The Subcommittee's opinion is that consideration of requests for field and industrial uses of radioisotopes is primarily one of safety control accountability. Illustrative situations were reviewed as follows:

1. Cobalt 60 in nails to be used in wooden survey stakes. (Request No. 2330, U. S. Dept. of Interior, Bureau of Reclamation, Great Falls, Montana. Also Request No. 2373, Tracerlab, Inc.). In the use as proposed, the hazard was considered nil, but this application was rejected because of inadequate long-term control of the activity.
2. S 35 in the underground firing of coal mines. (Request No. 2895, cancelled). This proposal by the Southern Research Institute was considered safe under the conditions outlined.
3. Yttrium 90 in simulated plane crashes. (Request No. 2863). The National Advisory Committee on Aeronautics' proposal to use Y 90 stearate in labeling gasoline in simulated plane crashes was considered acceptable, providing the work would be done in an area sufficiently remote from human habitation. The proposal to conduct this work on the Cleveland Airport was disapproved.
4. The use of Cobalt 60 for standards (100 mc each) to calibrate field instruments of the Armed Services was briefly discussed. The Subcommittee on Human Applications felt that the use of Cobalt 60 in amounts of the order of 100 mc for standardization of instruments is reasonable. If and when the Armed Services

make such requests, a way should be found to provide the standards but without relaxation of safety rules.

B. Review of policy relative to allocations on supplementary requests for use in human subjects.

1. When greatly increased amounts are requested for the same purpose, as indicated on an earlier request, the decision as to whether the application can be approved will be left to the Isotopes Division. Such applications should be justified by:

- a) A commensurate increase in patient load.
- b) An expanded research program.
- c) Provision of adequate storage and handling facilities.
- d) Assurance that personnel protection and supervision are adequate for the larger amounts requested.

2. If the supplementary application includes a proposal which was formerly acceptable, but now conflicts with revised policies, it will not be approved. The applicant will be asked to revise his application to make it conform with current policies. This application will then be submitted to the Subcommittee on Human Applications for review and recommendation.

C. Review of action taken on applications for human use of radioiron and formulation of a policy for future guidance.

Dr. Holland was requested to work up data on the distribution of iron in the organism and to send a statement on this matter to the members of the Subcommittee on Human Applications for their use in

ing calculations. The Subcommittee would then formulate a policy with regard to allocation of iron for human use.

D. Discussion of policy on level of activity that might be permitted in products and items sold to the public.

1. Emitters of beta particles.

Proposals to incorporate beta emitting radioisotopes in products offered for sale can be approved if (1) the activity is in insoluble form and incorporated permanently in inert material, and (2) the product produces no more radiation than 0.3 rep/wk at the surface. Dr. Holland suggested that a survey be made in the field to determine the actual background of radioactivity in industrial materials.

2. Gamma emitters.

Products containing gamma emitters must meet the conditions outlined above for beta emitters. In addition, when products are stored in warehouses, monitoring must be done to show that the radiation level is in accord with the regulations stated in the handbook on Safe Handling of Radioisotopes issued by the National Committee on Radiation Protection.

(See Section 1, (c), (2), p. 5).

E. Clarification of policy on hospitalization and supervision patients receiving radioisotopes through Atomic Energy Commission facilities.

Dr. Crile's statement in the article referred to was discussed. The Subcommittee objected to the phrase "no supervision". It was felt that patients could appropriately be treated with radioactive iodine without hospitalization but that it was an overstatement to say that they did not require supervision. There was some objection to Dr. Crile's statement that the cost of treatment with radiiodine is low. Dr. Friedall felt that the present price is artificial and is lower than it should be, if cost of production were included. It was pointed out that the cost has been established by considering the radiiodine as a byproduct of pile operation and that on this basis the price may not be out of line. Dr. Failla remarked that, after all, the price considered by Dr. Crile is the price now.

F. Use of radioisotopes in pregnancy and in normal children.

1. Pregnancy.

The Subcommittee on Human Applications feels that the use of radioactive materials in all normal pregnancies should be strongly discouraged where no therapeutic benefit is to be derived.

2. Normal children.

In general the use of radioisotopes in normal children should be discouraged. However, the Subcommittee will consider proposals for use in important researches, provided the problem cannot be studied properly by other methods and provided the radiation dosage level in any tissue is low enough to be considered harmless. It

should be noted that in general the amount of radioactive material per kilogram of body weight must be smaller in children than that required for similar studies in the adult.

IV. Review of violation of "Acceptance Terms."

The Subcommittee reviewed the violation of the "Acceptance Terms" by Dr. F. C. Henriques of Tracerlab, Incorporated. Specifically, Dr. Henriques used Iodine 131 on human subjects in studying the behavior of Krim-Ko Gel. After study of the situation, the Subcommittee recommended that a strong letter be sent to Tracerlab, Incorporated. The letter should state that a recurrence of this type of violation will result in stopping shipments of radioactive materials to Tracerlab, Incorporated, and a thorough review of the entire situation by the highest authority in the Atomic Energy Commission. Such a letter was sent to Tracerlab, Inc. on April 11, 1949. Attached to these minutes are (1) a copy of letter dated April 11, 1949, from Paul C. Aebersold to William E. Barbour, Jr., (2) a copy of letter dated April 14, 1949, from William E. Barbour, Jr., to Paul C. Aebersold, and (3) a copy of memorandum dated April 14, 1949, from William E. Barbour, Jr., to selected members of the staff of Tracerlab, Inc.

V. Review of specific applications not yet acted upon by this Subcommittee.

No. 2431 - Southwestern Medical College - Allen F. Reid, J. B. Howell, P 32 in applicators for treatment of basal cell carcinoma. This application had been approved earlier on favorable

decision by three members of the Subcommittee, despite Dr. Friedell's objection. Dr. Friedell was concerned because of fear that P 32 might be too widely disseminated if used on filter paper plaques.

No. 2661 - Southwestern Medical College - Allen F. Reid, Gladys J. Fashena, for use in blood volume study in children. Dosage proposed is from one-fourth to one microcurie Phosphorus 32 per kilogram. This application was approved on February 14, 1949, after the Isotopes Division had received unqualified approvals from Dr. Hamilton, Dr. Holland and Dr. Quimby. No response had been received from Dr. Friedell. In response to a letter from S. A. Lough, dated January 26, 1949, to the members of the Subcommittee on Human Applications, Dr. Quimby sent the letter which is quoted, herewith:

"In Dr. Failla's absence I am acting on the applications for isotope allotment.

This morning your letter arrived concerning application 2661 for the use of P 32 in blood volume studies. I had approved this application and sent it back to you yesterday. The levels which they propose using, 1/4 to 1 microcurie of P 32 per kilogram of human host, are considerably below the levels calculated by Karinelli, Quimby and Hine, as that which will deliver .1 r in the first 24 hours. This is 2.4 microcuries per kilogram. If in children they keep to 1/4 microcuries per kilogram they have an extra factor of safety of 10.

On this basis I still feel it reasonable to approve the application. They should, however, understand that repeats are not to be done on the same patient until after a considerable interval of time -- several months -- has elapsed."

On the basis of the three unqualified approvals and the statements in Dr. Quimby's letter, the allocation was made. Despite this previous action and the submitted opinions of three members of the Subcommittee, when Dr. Friedell opened the issue again,

Dr. Holland and Dr. Failla thought that this application should be turned down. It was suggested that Dr. Reid should be asked to state the importance of making the study in children and that the dosage should be no larger than one-half microcurie per kilogram. Finally, the Subcommittee, assembled, decided that the Isotopes Division should make the allocation with the proviso that the Phosphorus 32 should not be used in children and with the statement that the Subcommittee on Human Applications will reconsider this decision if the significance of making the study in children is established. Since allocation has already been made, and in view of the careful analysis of the proposal which was made by Dr. Quimby, the Isotopes Division prefers to take no further action on this case at this time. When a request for a supplementary amount is received, the expressed desire of the Subcommittee will be applied to the situation.

No. 2778 - Ohio State University - Dr. Norton, Cobalt 60 needles. Request for 5000 plus pieces of Cobalt 60 wire is considered excessive. The allocation should not be made on a free basis because this is not interpreted as cancer research. The application is to be denied because so many pieces of active wire constitute too great a hazard. The Isotopes Division is to suggest to the applicant that he resubmit an application for a much smaller number of Cobalt 60 wires. This application and the decision of the Subcommittee are to be called to the attention of Dr. Abersold. No communication is to be made to Dr. Norton until Dr. Hamilton's rating sheet has been returned.

The proposal of Tracerlab, Incorporated, to use Cobalt 60 in embalming fluids was disapproved on the basis that there was not adequate provision for long-term control of the radioactivity involved.

VI. Revision of Form AEC-313.

The Subcommittee urged that the application Form AEC-313 be revised so as to include spaces where the following information is specifically requested.

1. Dosage, both tracer and therapeutic.
2. The name of the compound administered.
3. Frequency of administration to the same patient.
4. The training and experience in the field of radioactivity possessed by the user.
5. An item to replace the one where the applicant is asked to check YES or NO regarding publication. The new item should read, "MAY WE RELEASE GENERAL INFORMATION REGARDING PROPOSED USE? IF NOT, PLEASE EXPLAIN."

VII. Development of method for replacement on some regular basis of members of the Subcommittee on Human Applications.

It was decided that a Subcommittee member would have a term of four years and that the terms would be staggered in such a way that one member would retire from the Committee each year. The Subcommittee members present drew lots to determine the order of retirement from the Committee. Dr. Holland drew the four-year term. Dr. Friedell drew the three-year term. Dr. Failla drew the two-year term. This left the one-year term for Dr. Hamilton. On the assumption that this drawing had been made one year ago

this permits Dr. Hamilton to retire at this time. It was felt that the appointment of a chairman of the Subcommittee on Human Applications should be left to the Atomic Energy Commission and that the Chairman should be reappointed each year. The Subcommittee suggested that Dr. D. Harold Cogg be considered as a successor to Dr. Hamilton. The Subcommittee expressed its desire to recommend replacements on the Subcommittee's membership to the Atomic Energy Commission.

Proposed Addition to this section (Section VII)

Dr. Hamilton has expressed his willingness to resign from membership on the Subcommittee on Human Applications to take effect as of July 1, 1949. The present membership of the Subcommittee recommends to the Atomic Energy Commission that this resignation be accepted. The Subcommittee recommends further that D. Harold Cogg, M.D., Assistant Professor of Physiology, University of California Medical School, Berkeley, California, be appointed to succeed Dr. Hamilton for a term of four years from July 1, 1949, to July 1, 1953.

ADDENDUM

Dr. Joseph G. Hamilton has proposed a slight modification of the rules governing approval of a request for a radioisotope to be used in human subjects.

On page 11 of the Tentative Minutes of Initial Meeting of the Committee on Isotope Distribution, U. S. Atomic Energy Commission, AEC Building, Washington, D. C., January 20, 1948, the following appeared under the caption "I. ACTION COMPLETED":

"2. All requests for materials to be used in human subjects will be reviewed and rated by the four members of the Subcommittee on Human Applications. Allocation of materials based upon the recommendation of the Subcommittee will be made in the following manner:

- a. If a request receives four approvals, the Isotopes Division will promptly allocate the requested material.
- b. If the request receives three approvals, the Isotopes Division will allocate the requested material unless the fourth vote is a definite "NO". In the latter case the request will be resubmitted for rating to the Subcommittee along with the views of the dissenting member and a review by the Isotopes Division. If a request receives three approvals after the review, the Isotopes Division will allocate the material.
- c. If a request receives two approvals, the Isotopes Division will attempt to resolve the difficulties causing the two disapprovals and resubmit the request, along with a summary of the modified situation, for a second rating. No allocations will be made in such cases until approved by three members of the Subcommittee."

the letter of June 21, 1949, from Dr. Hamilton to Dr. Abersold,

Hamilton wrote, as follows:

"I am willing to accept the understanding that a request receiving 3 out of 4 votes for approval be allowed. However, whenever there is a dissenting vote, I wish to make the recommendation that the entire matter be reviewed again by the 4 members of the Subcommittee and a second poll be taken, the request being allowed even though one member still casts a negative vote.

In the event of a 3 to 2 vote, the proposal should be reviewed a second time and if a 3 to 1 majority is not obtained, the request should be disapproved."

is considered that these remarks by Dr. Hamilton are a reaffirmation

the Subcommittee's desire that the Histoplasma Division follow the

orders outlined in the quoted minutes presented on page 15, immediately

C O P Y

TRACERLAB, INC.
55 OLIVER STREET
BOSTON, MASS.

April 14, 1949

Dr. Paul C. Aebersold, Chief
Isotopes Branch, Field Operations
U. S. Atomic Energy Commission
Oak Ridge, Tennessee

Dear Dr. Aebersold:

All members of the Management and of the Executive Committee of the Board of Directors of Tracerlab, Inc., have full knowledge of the Krim-Ko situation.

No compromise short of dismissal, as stated in the attached memorandum to the department heads responsible for radiochemicals, will be made in the event of recurrence. A copy of your letter of April 11, 1949, has been transmitted to these department heads with the attached memorandum.

I am very sorry that this violation occurred and has made such time demands on both yourself and the members of the Subcommittee on Human Applications.

Very truly yours,

/s/ Wm. E. Barbour, Jr.
President

WEB/m

C O P Y

April 14, 1949

SUBJECT: VIOLATION OF A.E.C. REGULATIONS

TO: HENRIQUES
ZUMWALT
FIELDS
STEVENS
MARGNETTI

Please note carefully the attached letter. A second violation Tracerlab of unauthorized use of radioactive materials not specifically approved by A.E.C. form 374 would mean cessation of all radiochemical operations of the Company.

In turn this would jeopardize the investments of several thousand new stockholders who have placed great faith in the integrity and ability of the management. A violation of a specific agreement with the A.E.C. would be a breach of that faith and could only result in the automatic dismissal of anyone contributing to such violation.

William E. Barbour, Jr.
President

WEB/m

C O P Y .

UNITED STATES
ATOMIC ENERGY COMMISSION

in Reply Refer To:
R:SAL

Oak Ridge, Tennessee
April 11, 1949

Mr. William E. Barbour, Jr.
President
Tracerlab, Inc.
55 Oliver Street
Boston 10, Massachusetts

Subject: VIOLATION OF "ACCEPTANCE OF TERMS AND CONDITIONS
FOR ORDER AND RECEIPT OF BYPRODUCT MATERIALS
(RADIOISOTOPES)"

Dear Mr. Barbour:

Reference is made to the following:

1. Letter of January 26, 1949, from F. C. Henriques, Jr., to S. Allan Lough, concerning experiments conducted for the Krim-Ko Corporation of New Bedford, Massachusetts. Enclosed with this letter was a copy of a report submitted to the Krim-Ko Corporation.
2. Letter of February 21, 1949, from Paul C. Aebersold to F. C. Henriques, Jr.
3. Letter of February 24, 1949, from F. C. Henriques, Jr., to Paul C. Aebersold.
4. Letter of March 3, 1949, from W. E. Barbour, Jr., to Paul C. Aebersold.

The subject violation was thoroughly discussed by the Subcommittee on Human Applications in their meeting in Washington, D. C., on March 13, 1949.

The Subcommittee looked upon the violation as a serious departure from the procedure established to promote the maintenance of conditions which insure the safe use of radioisotopes in human subjects. It was acknowledged that in this instance the level of activity used and the conditions under which it was used did not

Mr. William E. Harbour, Jr.
April 11, 1949

lead to any unfortunate results from the standpoint of radiation hazard. The willingness of Tracerlab, Inc., to proceed without prior approval, however, was considered extremely unfortunate. The Subcommittee expressed the opinion that a recurrence of this type of violation should result in cessation of all shipment of radioactive materials to Tracerlab, Inc., and that, under these circumstances, a thorough review of the entire situation should be conducted by the highest authority in the Atomic Energy Commission.

The Isotopes Division is of the opinion that Tracerlab, Inc., shares the conviction that the violation has created a very unfortunate situation and is inclined to believe that you will take steps to prevent any such recurrences. The Isotopes Division does not plan to take further action on this violation other than to express concurrence with the opinion of the Subcommittee. However, your letter of March 3 states "that any action necessary will be taken to prevent recurrence of the kind of irregularities outlined in your letter of February 21 referring to the Krim-Ko work". This office would be interested in learning what action has been taken by the management of Tracerlab on this matter.

Very truly yours,

/s/Paul C. Asbersold, Chief
Isotopes Division
Oak Ridge Operations