

WSS
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REPLY REFER TO:
MC:HL

UNITED STATES
ATOMIC ENERGY COMMISSION

C. E. Center - 3
J. A. Swartout - 4

cc: F. R. Bruce
W. H. Jordan
K. Z. Morgan
A. Hollaender
9-6

Oak Ridge, Tennessee
August 30, 1963

Forwarded By
C. E. Larson

SEP 9 1963

Union Carbide Nuclear Company
Post Office Box P
Oak Ridge, Tennessee

Attention: Dr. C. E. Larson
Vice President

Gentlemen:

Reference is made to your letter of August 7, 1963, regarding the experimental ingestion of Iodine 131 by personnel of ORNL.

We note the low levels of radiation involved and agree that in terms of actual hazard to the individuals there is little cause for concern.

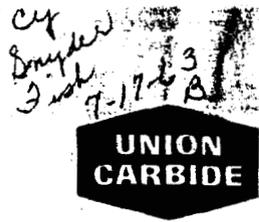
However, in view of the possible legal consequences flowing from such an experiment, and the fact that any experiment involving human beings is sensitive and may have implications beyond the immediate area of radiation effects on the participants, it is requested that no further activities involving the voluntary intake of radioisotopes by human beings be undertaken except with the prior approval of AEC.

Very truly yours,

S. R. Sapirie
S. R. Sapirie
Manager
Oak Ridge Operations

REPOSITORY MMES-ORNL
COLLECTION 4500S, ATIC
BOX No. K. Z. Morgan
FOLDER E-9

A-00535
Human Studies Project



JUL 17 1963
E-9 (Godine)

INTERNAL CORRESPONDENCE

UNION CARBIDE NUCLEAR COMPANY

POST OFFICE BOX X, OAK RIDGE, TENNESSEE

To (Name) **D. G. Schultz**
Company **ORGDP; Bldg. K-1001**
Location

Date **July 16, 1963**

Originating Dept.

Answering letter date

Copy to **K. Z. Morgan**

Subject

I believe the two enclosed memoranda adequately answer the recent planned exposure of some Laboratory personnel to I-131. Since some people are reluctant to sign waivers in the case of such experiments, may we have your views on the necessity for same?

Signed - F. R. Bruce

F. R. Bruce

FRB:mb

Enclosures

1168180

BUSINESS - CONFIDENTIAL

E-9 (Snyder)

July 15, 1963

To: F. R. Bruce

From: K. Z. Morgan

Enclosed is a copy of a memorandum from Fish to Snyder and me dated June 21, 1963, and a copy of my letter to Fish dated June 24, 1963. In view of the fact that some questions were raised relative to the safety of this program, I am sending you this correspondence. I believe the letter from Fish answers most of the questions relative to the nature of this study and why it was conducted. I think such studies should be continued because they provide some of our most valuable data. If there is any further information desired relative to this program or if you wish us to take any further specific action, please let me know.

Original Signed By
K. Z. MORGAN

Karl Z. Morgan

KZM:jc

Enclosures

cc: B. R. Fish
W. S. Snyder

1168181

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BUSINESS - CONFIDENTIAL

E.9 (Iodine)

June 24, 1963

To: B. R. Fish

From: K. Z. Morgan

Thank you for sending me your memo of June 21, 1963, relative to your experimental ¹³¹I program. I am quite proud of this study and the results it has produced. It appears to me that this program has already given more definitive answers to certain important questions relative to ¹³¹I than any other and I am confident it was carried out under the best of supervision and that the small exposure received by the participants was negligible and completely justified. I am glad and happy to share with you any responsibility for the need, desirability and authorization of these studies. In view of the sensitivity of legal-minded individuals, however, I agree that in the future, for your protection and for our own, it would be best to discuss plans and document decisions by appropriate written memos. I hope, however, that this will in no wise discourage your plans for other such studies because I consider them of great value and urgently needed.

Sincerely,

Original Signed By
K. Z. MORGAN
Karl Z. Morgan

KZM:jc

cc: W. S. Snyder

1168182

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INTRA-LABORATORY CORRESPONDENCE

OAK RIDGE NATIONAL LABORATORY

June 21, 1963

To: K. Z. Morgan
W. S. Snyder

From: B. R. Fish

Subject: Human Ingestion of Resin-treated Milk.

In order to answer questions posed by the Carbide Legal Department, Mr. Bruce has asked that we give him a brief recounting of the I^{131} milk ingestion studies which we did. The following paragraphs present the story in about as few words as I can muster. If you have any changes or additions, please include them in the final form which you transmit to Mr. Bruce. It is my understanding that Laboratory Management does not imply censure of our actions by this request for information; rather, it appears that our lawyers may have been sensitized to such questions by recent legal action and because of the incompleteness (with regard to dose, etc.) of our statement in the ORNL monthly status report. If you agree, all such studies in the future will be documented in the form of a proposal-memo for your approval before any actual human exposures, however trivial, are undertaken.

BACKGROUND

In anticipation of action by the Federal Radiation Council to lower control criteria for I^{131} contamination in the environment, the Health Physics Technology Section, in 1960, initiated a study to improve the sensitivity and scope of the available environmental monitoring procedures for I^{131} . A correlation was sought between ORNL stack releases, meteorological data, grass contamination, and I^{131} content in cattle thyroids.⁽¹⁾

Following the resumption of weapons tests by the USSR in September 1961, a considerable increase in the amount of I^{131} was observed in cattle thyroids,⁽²⁾ in milk from local dairies⁽²⁾ (including that obtained from ORNL Cafeteria) and in local citizens as measured using the ORNL Whole Body Counter.⁽³⁾ One method used to concentrate I^{131} from large volumes of milk is that of collecting the I^{131} on a relatively small volume of a strong-base anion resin column.⁽⁴⁾ It was shown by Farabee⁽⁴⁾ that, whereas most

(1) B. R. Fish, J. W. Youngblood, et al "A Study of Methods for Monitoring I^{131} Contamination in the Environment" ORNL-3189, pp 232-234 (July 1961).

(2) B. R. Fish, P.E. Brown, et al, " I^{131} in Milk and in Cattle Thyroids" ORNL-3347, pp 148-149, 151 (July 1962).

(3) B. R. Fish, L. B. Farabee, "Radioactivity in Foods", ORNL-CF-62-2-74, pp 23-24, 26 (Feb. 1962).

(4) B. R. Fish and L. B. Farabee "Analysis of Milk for I^{131} by Anion Exchange Resin: The Effect of Protein-Bound I^{131} ", ORNL-3347, pp 149-150, 152 (July 1962).

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of the I^{131} is extracted from liquid milk passed over a resin column, about 3% to 20% of the I^{131} is not extracted. There is evidence that suggests the non-extractable fraction is protein-bound I^{131} . At the time this was noted, it was not known whether and to what extent protein-bound I^{131} in milk is assimilated by man.

A local citizen (██████████, employee of UT-AEC farm) was observed to have an average daily intake of 150 pc/day via milk from a cow grazing on his home farm during October 1961. The I^{131} was deposited on the grass as a result of Soviet weapons tests in early September 1961. After about five (5) weeks of nearly constant exposure at that level of daily intake, the individual had 220 pc, or less than 1.5 times the daily intake, in his thyroid. Using the NCRP-ICRP biological parameters for I^{131} , it would be expected that the thyroid burden should reach about 3.3 times the daily intake. Because of the important social and health problems involved in applying the FRC's criteria for exposure of a population to I^{131} , it was believed desirable to review the bases for the NCRP-ICRP thyroid uptake model. The presently accepted biological parameters used to calculate permissible chronic intakes of I^{131} are based upon extrapolation of single dose human exposures. After consultation with K. Z. Morgan and W. S. Snyder it was decided that, if a second period of significant I^{131} fallout should occur, it would be desirable to follow the chronic uptake of I^{131} by human volunteers drinking milk containing known and constant amounts of I^{131} . Since fallout I^{131} on pastures would be expected to fluctuate, the plan was to select the highest "naturally" occurring level in milk, and dilute with enough clean milk to maintain a nearly constant daily intake for as long as possible, perhaps to about 1 1/2 months. The clean milk was to be obtained by resin treatment as necessary. However, no significant I^{131} fallout occurred until about the end of May 1962, and, even then, the levels were much below those of October 1961.

FIRST SERIES

In the meantime, a sample of milk containing I^{131} was obtained from UT-AEC farm to use in testing the resin column extraction technique. The column effluent milk contained about the same level of I^{131} that had been anticipated for use in connection with our envisioned human study using fallout contaminated milk. After notifying Supervision verbally, but without further detailed consultation, three volunteers began to drink milk containing 150 pc in 250 ml of total milk once daily. This level of intake is the same as the daily intake observed in the case of ██████████ (above). The individuals participating in this study were: ██████████

It should be noted that these daily intakes of I^{131} represent 0.3 per cent of the maximum permissible daily intake in water (ICRP) and are completely negligible in significance. Furthermore, intake was terminated after 11 days when the trend of thyroid buildup could just barely be discerned by using the most sensitive detection methods. Thus, the total individual intake was 1.6 mc which is less than 0.04 per cent of the maximum permissible quarterly intake of I^{131} by water (ICRP). The resultant radiation exposure to the thyroid is estimated to be less than 3 mrem for each person during the calendar quarter. That figure is only about seven (7) per cent of the average dose received by members of the population from natural background radiation during a quarter.

Although the results of the preliminary study were inconclusive because of the low level of intake, the trend of thyroid burden appeared to be definitely lower than the NCRP-ICRP predicted levels by a factor of about 2.

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These data were discussed with Supervision. The concensus was that much more data were needed, including more people, longer observation times and higher intakes to provide a more readily detectable level. Since there was no other comparable data in the literature, it was considered to be especially urgent to extend the chronic ingestion study.

SECOND SERIES

The second study was begun in October 1962. Five human volunteers participated as follows. [redacted] had participated in the previous chronic intake study (above) and, since they were to be away on Company business during part of the study period, they decided to ingest a single intake for direct comparison with NCRP-ICRP parameters and to test the validity of extrapolating single intake data to predict chronic uptake. These two individuals drank resin-treated milk containing 0.092 μc of I^{131} , which is two (2) per cent of the maximum permissible quarterly intake (MPQI = 4.3 μc in water). Total radiation dose to the thyroid of [redacted] was 0.17 REM which is only two (2) per cent of the maximum permissible quarterly exposure (MPQE) to the thyroid (NCRP-ICRP). The next lowest dose was experienced by subject [redacted] who received 0.070 REM, which is less than one (1) per cent of the MPQE.

Three other persons ingested milk containing 1.84 nc of I^{131} per day. [redacted] participated in the study for 63 consecutive days and consumed less than three (3) per cent of the MPQI, resulting in a total radiation dose of 0.056 REM, which is on the order of the average dose from natural background radiation during a quarter. [redacted] ingested 1.84 nc I^{131} in milk per day for eight (8) consecutive days and withdrew because of a mixup in the aliquots of milk which were to be consumed on the 9th and 10th days. [redacted] consumed less than 0.4 % of the MPQI and received a total radiation dose of 10 mrem to the thyroid (less than background). [redacted] (see study above), ingested 1.84 nc I^{131} in milk per day for four days and withdrew when he had to be away from the Laboratory for a number of days on personal business. [redacted] ingested less than 0.2 per cent of the MPQI and received about five (5) mrem to the thyroid (less than background).

SUMMARY

1. The most restrictive specific limitation written in ORNL procedures that apply in these cases of planned exposure is found in the ORNL Health Physics Manual - Procedure No. 20 (Personnel Radiation Exposure Limits), page 3:
 - (a) The following recommendations shall be used as a guide in planning and conducting operations involving personnel radiation exposure... " and,
 - 2.(b) Internal Exposure - The intake of radioactive materials by an individual in any single week should not exceed 1/13 of the MPI/calendar quarter..."

In the case of [redacted] and [redacted] the total intake in seven (7) days was 0.092 μc I^{131} , which is the highest total intake in one week. This is less than 1/3 of the weekly intake limit imposed by ORNL procedures (0.332 μc I^{131}).

2. To consider this study in the context of fallout exposures to the general public and of other comparable investigators (whole body counter operators) who have participated in similar (howbeit less valuable) deliberate exposures to I^{131} during the same general period of time included in these ORNL studies:

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2. (continued)

(a) During July and August (approx. 60 days), farm families in Heber Valley region of Utah reached levels of 4 to 11 nc I^{131} in the thyroid and, in that same period, adults in Salt Lake City averaged 0.5 to about 1.5 nc. By comparison, the highest average thyroid burdens for the participating ORNL employees during any 60-day period were : [REDACTED], 4.5 nc; [REDACTED], 2.0 nc; [REDACTED], 0.78 nc (63 days); [REDACTED], 0.29 nc; [REDACTED], 0.18 nc. These are about equal to or lower than the thyroid burdens of many thousands of persons exposed via their normal milk supply during the summer of 1962.

(b) In connection with their whole body counter programs (for calibration purposes only), three people at MIT took one (1) μc I^{131} each and three persons at Vanderbilt took 3 μc I^{131} (orally). In contrast, the largest total intake in our study was 0.1 μc I^{131} , from which we obtained some useful metabolic data in addition to calibrations.

3. It is my opinion that the data obtained in this study are very valuable. Radiation doses received were very low and comparable with natural and fallout background. The only criticism that I would make in retrospect, is that the chronic doses should have been higher by a factor of about 4, more individuals should be followed for about 60 days, and the milk need not have been resin treated. Further studies are needed and are being planned.
4. All five persons participating in these studies have submitted blood samples which were analyzed for protein-bound iodine by the ORNL Health Division. The samples were submitted after the studies were completed and show that all subjects are euthyroid.
5. Although we object to signing a waiver of claim on the grounds that the exposures were trivial in comparison to those we might get in visiting certain local laboratories, still, if it is felt necessary, I am sure that all of us will sign any reasonable disclaimer.

BRF:br
