

U. S. ATOMIC ENERGY COMMISSION  
DIVISION OF COMPLIANCE

REGION III

INSPECTION REPORT

CO Report No. 71-02

Subject: Mallinckrodt Chemical Works  
Mallinckrodt/Nuclear  
Box 10172, Lambert Field  
St. Louis, Missouri 63145

License No. 24-04206-01  
Priority: I  
Category: B

Type of Licensee: Radiopharmaceutical Manufacturer and Distributor

Type of Inspection: Announced Reinspection

Dates of Inspection: December 6 - 9, 1971

Dates of Previous Inspection: May 10 - 14, 1971

Principal Inspector: *James M. Allan*  
E. C. Ashley *for*

12-27-71  
(Date)

Accompanying Inspectors: None

Other Accompanying Personnel: None

Reviewed By: *James M. Allan*  
James M. Allan, Senior Radiation Specialist

12-27-71  
(Date)

Proprietary Information: None

## SECTION I

### Enforcement Action

- A. 10 CFR 20.103(a) - Exposure of personnel to excessive concentrations of iodine 131. (Paragraph 5)
- B. 10 CFR 20.401(b) - Failure to maintain records of an evaluation of personnel exposure. (Paragraph 7)
- C. 10 CFR 20.405(a) - Failure to submit a report to the Commission concerning the personnel exposure noted above in Item A. (Paragraph 6)
- D. 10 CFR 20.405(b) - Failure to submit a report in writing to the exposed individual as noted above in Item A. (Paragraph 6)
- E. 10 CFR 20.408 - Failure to submit reports to the Commission and to individuals who have terminated employment or work assignment as required. (Paragraph 8)

### Licensee Action on Previously Identified Enforcement Matters

The last previous reinspection was conducted on May 10 - 14, 1971. The licensee was cited for four items of noncompliance in a letter from the Division of Compliance, Headquarters, dated July 28, 1971. The licensee responded to this letter in a letter dated August 13, 1971. During this inspection conducted on December 6 - 9, 1971, each of the previously noted items of noncompliance were reviewed as to licensee action. These items and corrective actions are noted below:

- A. 10 CFR 20.105(b)(2) - Excessive radiation levels during January and February 1971 on an unrestricted roof of a building across from the licensee's facilities.

This item was corrected by the licensee moving his waste handling area prior to the inspection of May 1971 and the modification of the air handling system on the roof of the licensee's Building 100, including shielding, following the May 1971 inspection.

- B. 10 CFR 20.201(b) - No stack sampling was performed of the Building 300 Dispensing Lab laboratory exhaust during January 11, 1971, to May 11, 1971.

It was noted during this inspection that stack sampling at that location began on May 11, 1971, and stated in the licensee's August 13, 1971 letter.

- C. 10 CFR 20.201(b) - No inplant air sampling was performed in Building 300 dispensing laboratory during January 11, 1971, to May 10, 1971.

The licensee's August 13, 1971 letter advises that air sampling was begun at that location on January 11, 1971, using portable air samplers, and later added to the in-house air sampling system. Records reviewed during the inspection of December 6 - 9, 1971, showed that temporary portable air samplers were used in the Dispensing Laboratory of Building 300 on January 11 and 12, 1971. Also, permanent air sample stations were begun there on January 20, 1971.

- D. 10 CFR 20.201(b) - The licensee performed inadequate evaluation of high TLD results, re Item A above.

The licensee's August 13, 1971 letter advised that the TLD results were received from the supplier too late for them to act on this matter. It is noted that this problem resulted from the licensee's dismantling and moving of their waste handling area and the necessity to make the filter change during the period in question due to a Mo-99 processing problem which caused a high radiation level at the absolute filter on the roof of Building 100.

Unresolved Items: None

Status of Previously Reported Unresolved Items: None reported.

Unusual Occurrences: None

Persons Contacted

The following Mallinckrodt/Nuclear personnel were contacted during the inspection:

Norman E. Drissell, Director of Operations  
Donald W. Soldan, Supervisor, Radiological Protection Department  
(Health Physics) and Chairman of the Isotope Committee  
Ralph Nuelle, Group Leader, Health Physics  
Warren Fadling, Group Leader, Health Physics  
Robert Wester, Technician, Health Physics  
Robert Ament, Special Warehouseman (Building 300 Shipping Area)  
Mrs. Diane M. DuVall, Technician, Quality Control Department  
Robert Granger, Jr., Technician, Production Department

Management Discussion

The following subjects were specifically discussed with Messrs. Drissell and Soldan on December 9, 1971:

A thyroid burden of greater than 0.14 microcuries of iodine 131 averaged over seven consecutive days to one individual and failure to report this to the Commission and to the individual. It was noted that they interpreted seven consecutive days as taking place in one calendar week rather than any seven consecutive days, therefore, the numerical average by calendar week was not considered excessive and as a result was not reported. (Paragraphs 5 and 6)

Failure to maintain records of results of an evaluation of personnel exposure. It was stated that normally, records of these evaluations are maintained, but somehow this was overlooked this time. (Paragraph 7)

Failure to submit reports to the Commission or to terminated individuals as required. It was stated that this was an oversight on their part. (Paragraph 8)

## SECTION II

### Additional Subjects Inspected, Not Identified in Section I, Where No Deficiencies or Unresolved Items Were Found

#### 1. Employee Personnel Exposures

- a. Whole body and extremity film badge results, second and third quarters 1971.
- b. Urine samples and thyroid counting results May 1 to December 3, 1971.

#### 2. Air and Water Effluents

- a. Stack and sanitary sewer discharges, May 6 to December 2, 1971.
- b. Rooftop sampling results, May 6 to December 2, 1971.

#### 3. Inplant and Shipment Surveys

- a. Contamination survey results, 1971 through November 23, 1971.
- b. Radiation level survey results, 1971 through November 17, 1971.
- c. Air sampling results, 1971 through December 2, 1971.
- d. Receiving and shipping packages survey results, 1971 to December 1, 1971.

#### 4. Review of Unrestricted Area Surveys

- a. Unrestricted area survey results, May 1 to December 1, 1971.

### Details of Subjects Discussed in Section I

#### 5. Overexposure to Concentrations of Radioactive Material

Routine thyroid counting on the morning of July 2, 1971, one individual showed a thyroid burden of  $1.49 \times 0.14$  microcurie of iodine 131 in the thyroid. Subsequent thyroid counting of this individual on July 6 showed 1.14 times permissible, on July 7, 1971, a thyroid count of

97% was found and on July 8, a thyroid count of 90% was found. Subsequent daily thyroid counting showed the thyroid burden of this person to be reduced to 10% by July 28, 1971. The thyroid burden of this individual for the seven consecutive day period July 2 through July 8, 1971, was, therefore, an average of approximately  $1.24 \times 0.14$  microcurie.

This individual was interviewed alone on December 7, 1971, regarding this July 1971 occurrence. It was said that no work was performed before the routine 8 a.m. thyroid counting on July 2. The individual was performing a triolein and oleic acid iodine 131 on July 1, 1971, in a glove box. The individual remembers using hot tap water from a nearby sink to get hot water to be placed in the glove box for part of this prep work. The individual thinks the sink must have been contaminated with iodine 131 when the hot water splashed causing contamination to the face and head. This individual stated that upon leaving the laboratory area, no contamination was detected on feet, hands, or general body area according to this person. On the morning of July 2, 1971, after the high thyroid count, head decontamination was accomplished.

This individual stated that instructions have been issued to prohibit the use of hot water in this method and also that any sink to be used in the laboratory area must have a prior survey.

The individual's statement generally agrees with information gathered from Health Physics personnel.

The exposure of the above referenced individual to excessive concentrations of iodine 131, as evidenced by thyroid gland counting, constitutes noncompliance with 10 CFR 20.103(a).

#### 6. Reports of Personnel Exposures

The licensee had not, up to the date of this inspection, reported the overexposure of the person, noted above in Paragraph 5, to the Commission or to the individual which constitutes noncompliance with 10 CFR 20.103(a) and (b).

The licensee did not consider the individual's high thyroid count as a reportable overexposure because they considered "averaged over seven consecutive days" as meaning seven consecutive calendar days (Monday through Sunday). It was clearly explained to the licensee that the thyroid does not know of the existence of calendars and that the

presence of iodine in the thyroid gland in excess of 0.14 microcurie, averaged over any seven consecutive days, is considered by the Commission as an excessive thyroid burden and is reportable under 10 CFR 20.405 pursuant to 10 CFR 20.103(a).

7. Records of Personnel Exposure Evaluations

During the week of July 29 through August 5, 1971, two air samplers in the Quality Control Department showed results of 1.33 and 1.65  $\times 9 \times 10^{-9}$  microcuries per ml, respectively. Although it was determined during this inspection that personnel exposure evaluations were made to show that no one was exposed to excessive concentrations of iodine 131, no records of these evaluations were available for inspection which constitutes noncompliance with 10 CFR 20.401(b).

8. Reports of Personnel Exposure on Termination of Employment or Work

During this inspection, the licensee advised that a total of 31 persons have terminated employment or work assignment in the licensee's facilities during the year 1971 up to the date of this inspection, but required reports have not been submitted to the Commission or to the individuals which constitutes noncompliance with 10 CFR 20.408.