

LE:BJR  
40-2407

SEP 11 1962

Chemical & Company, Inc.

1000 North 10th Street

St. Paul, Minnesota 55102

Mr. Richard E. Carrigan, Chief Chemist  
Vice President in Charge of Production

Re your letter August 14, 1962 informing us of  
the deficiencies in your material program which we brought to your at-  
tention in our letter dated August 9, 1962.

In connection with your "Yracerda Directions - Thorotrast,"  
you are not required to provide the Commission with your  
biological assay and contamination survey results unless  
this information is specifically requested from you. Your  
records on these matters will be reviewed during AEC in-  
spections of your facilities.

Your cooperation is appreciated.

Sincerely yours,

Ever E. Price  
Assistant Director  
Division of Licensing  
and Regulation

bcc: Compliance Div., HQ )  
Compliance Div., III) w/cpy ltr 8/14/62  
Public Document Room) - To be for withholding

OFFICE	LP-ER	LR			
SURNAME	DRICHURCP	ERPRICE			
DATE	9/7/62	9/10/62			

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## DETAILS

### GENERAL INFORMATION

9. This reinspection was conducted on February 7, 1963. Mr. R. H. Carrigan, Vice President of the company, was notified of the scheduled inspection by telephone on February 6, 1963.
10. Mr. V. E. LaVetter of the Industrial Hygiene Department, City of Detroit was also notified of this impending inspection. Mr. LaVetter accompanied the AEC representative during this inspection.
11. During this inspection Mr. R. H. Carrigan, Vice President of Fellows-Testagar Company was interviewed. Mr. Carrigan is the Chief Chemist at this plant and assumes the entire responsibility of this licensed program.

### INSPECTION HISTORY

12. The initial inspection of this program was conducted on February 25, 1958. No items of noncompliance were found during that inspection. Reinspection #1 of this program was conducted on March 30, 1962. As a result of this reinspection the licensee was cited for six items of noncompliance. These were:
  1. An employee received a radiation dose in excess of 1.25 rem during the fourth calendar quarter of 1961.
  2. The Commission was not informed in writing within 30 days following the exposure described in Item 1.
  3. The individual who received the dose as described in Item 1 was not notified of the nature and extent of the exposure.
  4. Surveys had not been made to determine the extent of contamination and levels of radiation encountered in the process room.
  5. Records of personnel exposure to radiation were not maintained on Form AEC-5 or its equivalent.
  6. Source material was exported during 1961 without filing with the Collector of Customs or the Postmaster a marked copy of the shipper's export declaration for transmittal to the Commission.

In a letter dated August 14, 1962 to Division of Licensing and Regulation (DL&R) Mr. Carrigan explained how the items of noncompliance would be corrected.

### CORRECTIVE ACTION

13. As explained in that letter, Items 1 through 3 as listed above are matters of record and cannot be corrected. During the time of this inspection it was noted that Items 4 through 6 had been corrected in the following manner:

Item 4 - Physical radiation surveys have been made within the processing room and adjacent areas to determine the levels of radiation present there. In addition to this the licensee now requires a urinalysis of the three employees who work in this area at approximately six-month intervals. Records of these tests are being maintained by the licensee. (Refer to Paragraph 42.)

Item 5 - All records of personnel exposures to radiation are now being maintained on Form AEC-5 by the licensee. (Refer to Paragraph 43.)

Item 6 - Mr. Carrigan stated that he is now filing with the Collector or Customs a shipper's export declaration for transmittal to the Commission in accordance with 10 CFR 40.23(a).

This was reinspection No. 2 for this licensed program.

PROGRAM

14. The licensee procures thorium in the form of thorium oxylate. This material is then heated in the presence of oxygen using nickel as a catalyst. During each such burning, 2.5 Kg of thorium oxylate are used. The end product of this process is thorium dioxide. This product is then processed into a colloidal radiological (X-ray) contrast media and sold under the company names of Thorotrast and Umbrathor. This use of thorium is permitted by the license. Mr. Carrigan stated that employees work on this process only about two weeks total during each year. He said personnel will be in the Thorotrast Room three hours each day of use.
15. Mr. Carrigan stated that he orders 100 pounds of thorium oxylate approximately once each year. The last previous shipment to Fellows-Testagar Company was on 11/8/62. After this material is converted to thorium dioxide as described in the previous paragraph, the capsules containing the prepared contrast media are held for six months before they can be shipped to a consumer. Other than the shipment received during November, 1962, receipt records indicated that during May of 1960 the licensee received a shipment of 195.5 pounds of thorium oxylate. The license (License No. C-5155) in effect at that time authorized the licensee to possess 1,000 pounds of source material. Mr. Carrigan stated that this particular shipment of thorium oxylate would not work in their process and therefore he still has 129.5 pounds of thorium oxylate from that shipment. It was therefore determined that on January 10, 1963 the licensee possessed the following amounts of source material: 100 pounds of thorium oxylate, (shipment of November, 1962), 129.5 pounds of thorium oxylate (shipment of May, 1960), and 33.7 pounds of thorium dioxide. Material balance calculations show that on January 10, 1963, the licensee possessed more than 100 pounds of thorium in excess of the authorized possession limit. This overpossession of source material therefore constitutes non-compliance with License Item No. 7, License No. STP-404 in effect at that date which authorizes a maximum quantity of 100 pounds of source material to be possessed at any one time under this license. Overpossession of source by the licensee is also contrary to License Item 7, License No. STP-678, the present license issued January 23, 1963, which authorizes also a maximum possession limit of 100 pounds of source material. Because of the licensee's system of record keeping, it was difficult to determine the exact amount on hand at the time of this inspection. However, Mr. Carrigan agreed that the amount of source material on hand would still be in excess of the authorized 100 pounds of thorium possession limit set forth in the license. He stated that he is planning to have the license amended so that he may possess more than 100 pounds of thorium at any one time.

ORGANIZATION

16. As indicated in a letter from Mr. Carrigan to DL&R dated December 31, 1962, the name of this company was changed from Testagar and Co., Inc. to the Fellows-Testagar Co., Division of Fellows Medical Manufacturing Company, Inc. effective January 1, 1963. Also as indicated in that letter, the organizational structure remains the same in that Mr. Weindrich is still President, and Mr. Carrigan is the Vice-President of the corporate structure. The only changes being that new people have been appointed to the corporate positions of Secretary and Treasurer. At the time of this inspection, Mr. Carrigan stated that there has been no change in the processing of thorium and that radioactive material is being used only at the Fellows-Testagar plant in Detroit. This particular licensed program is the responsibility of Mr. Carrigan who is Vice President of the company and also Chief Chemist.
17. Mr. Carrigan is designated as the Radiation Safety Officer (RSO) under this license. He has the entire responsibility for the use and handling of radioactive materials. He also maintains all records of receipt, transfer, and disposal of material, survey and personnel monitoring records.

ADMINISTRATIVE CONTROL

18. Mr. Richard Carrigan is the highest ranking person in management who controls this program, and he maintains a very direct control over this program. No one of a higher position in management reviews the actions of Mr. Carrigan as the RSO or his actions in connection with the control of this licensed program.
19. All material is ordered by Mr. Carrigan. As described in paragraph 15, the licensee has exceeded his authorized possession limits. Mr. Carrigan stated that this was due to the fact that he had misinterpreted the meaning on his license in that he thought that the 100 pound limit shown authorized him to only procure 100 pounds of thorium oxydate at one time. He stated that he would initiate an amendment to the license to increase the possession limits for this program.

RADIOLOGICAL SAFETY PROCEDURES

20. Only three persons, Mr. Robert Marique, A. Collins and E. Bell actively work with source material within the processing room. Only oral instructions have been given to these people concerning the procedures and the safety precautions to be used in handling this material.
21. At the time of this inspection the licensee was doing no work in converting the thorium oxydate to thorium dioxide. Discussion with Mr. Carrigan indicated that procedures being used by the licensee are in accordance with those described in previous letters to the Atomic Energy Commission as referenced in Condition 8 of this license.

FACILITIES

22. All processing of thorium is still being conducted in the Thorotrast Room which is located on the ground level floor of the Fellows-Testagar plant at 135 $\frac{1}{2}$  West Lafayette, Detroit 26, Michigan.
23. There are no living quarters located in these facilities. The licensee maintains exclusive control over them. The processing room is now kept locked by means of a padlock at all times when not in use. In addition to this the licensee has recently built a row of storage cabinets along the wall in the anteroom.
24. The storage cabinets are used to store some processed thorium and also the masks and gowns which are worn by the employees when they are working in the process room. These cabinets are also locked at all times when not in use. The front surface of these storage cabinets are constructed of 1/2 inch plywood. A sealer has been applied to the floor of this anteroom.
25. The charging process is conducted in the processing room. Each person working in this room is required to wear a gown and a Pulmonex Type 1750 air mask. This room is equipped with a furnace, a centrifuge scale, work benches, storage bottles and a large fan in the window which exhausts the air from the processing room directly to the atmosphere. The floor is constructed of rubberized tile. The room has a general dusty contaminated appearance.

EQUIPMENT

26. Utilization devices in the process room include the furnace, scales and work benches. The licensee also possesses gloves, hoods, overshoes and face masks which are used by employees during the charging process. The thorium oxydate is received in large card board barrels. After processing, the thorium dioxide is stored in gallon bottles. The containers themselves are not locked, but all storage is in locked areas.

EQUIPMENT, Cont'd.

27. At the time of this inspection the licensee possessed one radiation survey instrument. This instrument was the Civil Defense Model V-700 survey instrument having a range of from 0 to .2, 2, 20 mr/hr. Mr. Carrigan stated that this instrument is not calibrated at any regular interval. He stated that only the incorporated check source and the battery check have been used to determine operability. The instrument appeared to be in proper operating condition at the time of the inspection.

PERSONNEL MONITORING AND EXPOSURE DETERMINATION

28. Film badges are required by the licensee to be worn by each person who works regularly in handling of the thorium materials. The film badges are supplied by the Nuclear Chicago Corp. on a weekly basis.
29. Beginning in June, 1962 the licensee initiated a program for analyzing urine of those people regularly employed in the process room. These are the same three persons for whom film badges are required. Two such tests have been made and the licensee stated he plans to make these surveys at six-month intervals.

RADIATION SURVEYS AND/OR EVALUATION

30. Mr. Carrigan stated that he has made physical radiation surveys of the area when the material is being used and stored using the Civil Defense Model V-700 survey instrument. One survey was made in conjunction with Mr. V. E. LaVetter, Detroit Department of Industrial Hygiene. The results from the urinalysis program, as described in the previous paragraph, are also used by Mr. Carrigan as a means of evaluation of the dose received by employees.

POSTING AND LABELING

31. The door leading to the Thorotrast Process Room was posted with a sign in the conventional colors of magenta on yellow bearing the radiation caution symbol and the words "Caution Radiation Area."
32. Each door of the storage cabinets located in the anteroom was also posted with a sign in the conventional colors of magenta on yellow bearing the radiation caution symbol and the words "Caution Radioactive Materials."
33. At the time of this inspection three 55-gallon drums being used for the storage of radioactive waste material were setting in the anteroom. Mr. Carrigan stated that these barrels contained broken glassware used in the processing of thorium, old rags used for decontaminating the anteroom and process room and other contaminated garments. One of these barrels was labeled with a sign bearing the radiation caution symbol and the words "Caution Radioactive Materials."
34. Mr. Carrigan had in his possession a current copy of the AEC source material license, copies of 10 CFR 20, and 10 CFR 40.
35. Form AEC-3 was posted on the door leading to the process room.

WASTE DISPOSAL

36. Broken equipment which has been used in the processing of thorium, contaminated clothes which have been worn by employees, and rags used for cleaning the thorium processing area were all stored in waste barrels. These will be shipped to an authorized recipient according to Mr. Carrigan, for disposal.

REPORTS OF THEFT AND LOSS

37. Mr. Carrigan stated that no source material has been lost or stolen.