

ENCLOSURE

Description of Violations

Ethicon, Incorporated  
Somerville, New Jersey 08876  
License No. 29-02786-06

One activity under your license appears to be in violation of an AEC requirement. This apparent violation is considered to be of Category II severity:

1. 10 CFR 71.5(a), "Transportation of licensed material", requires, in part, that transportation of licensed material be made in accordance with the applicable requirements of the Department of Transportation in 49 CFR 170-189. 10 CFR 71.5(b) requires that intrastate transportation of licensed material be made in accordance with the standards and requirements specified above.

Contrary to the above, you failed to check radioactive waste barrels, routinely sent in intrastate shipment, to assure that there was no significant removable radioactive contamination on the exteriors, as required by 49 CFR 173.393(h), "General Packaging Requirements."

U.S. REGULATORY OPERATIONS, REGION I  
Inspection Field Notes

Revised 7/2

A. Pocket Number		B. Report Number <b>7401</b>	C. Priority Category <b>E-III</b>	D. Inspection Date <b>7/24-25/74</b>
E. Licensee <b>ETHICON, INC</b> <b>RT 22</b>		F. Facility <b>SOMERVILLE, N.J.</b>		G. License No. <b>29-02736-02</b>
H. Type of Inspection	I. No. and date of last Amendment <b>6/14/74</b> <b># 13</b>		J. Dates of Last Inspection <b>7/68</b>	
K. Principal Inspector and Date of Report <b>W.B. Allen</b>	L. Accompanying Inspector <b>—</b>		M. Other Accompanying Personnel <b>—</b>	
N. Proprietary Info. <b>None</b>	O. Reviewer <b>R. McVintick</b>		P. Date of Review <b>8/5/74</b>	
Q. Individuals Interviewed* and Titles * a. E. Kendra, RSO b. Al Kelafsky, Plant Engineer c. Vincent Forrest, Maint Foreman d. Jim Daven, Group Leader e. Frank Conley, Senior G-60 tech f. Fred Thompson, II g. Dr. Charles Artendi, V.P. for Research h. See OVER. G-60 irradiators			R. Date of Interview <b>7/25/74</b>	
T. Enforcement Action <b>None</b>			S. Place of Interview	
U. Previous Outstanding Items <b>None</b>			V. Unresolved Items 1. Election of H.O. and its monitoring on status 2. Updating manual to D.C.	
W. Previously Reported Infractions <b>None</b>			X. Recom. Reinspection <b>7/76</b>	
Y. Name & Tele. # of RSO <b>A.</b>			Z. RMS Code Number <b>33</b>	
ZZ. Scope of Inspection: ( ) complete, ( ) partial, ( ) special				

Pages from AECL who were also interviewed

i. Frank Warland, Group leader

j. Leo Ashfield, Installer AECL

k. Al Ledner, " "

## DETAILS

### Scope of the Program

-Number of individuals occupationally exposed 5.

-Number of individuals subject to significant\* risk 0. *hopefully*

-Potential for external exposure

Negligible

Slight

Moderate

High

Whole body  
Skin  
Extremities

✓

✓

-Potential for internal exposure (✓) negligible ( ) slight ( ) moderate  
( ) high

-Effluents

*None*

Negligible

Slight

Moderate

High

Airborne  
Liquids

-Unusual aspects

### General

All records examined and all inquiries made by the inspector related to records and events made or experienced in the time interval from the date of the last inspection, or the date of license issuance in the case of initial inspections, until the date of this inspection, unless otherwise noted.

Unless otherwise specified, radiation level measurements, shown in these notes as having been made by the inspector, were made using a radiation survey meter type E, model 120, calibrated 6/78 by BNC.

The findings reported here were based on: (1) observations made by the inspector during his physical inspection of the licensee's facilities (2) a selective examination of procedures and representative records and documents, (3) information furnished by individuals interviewed and (4) Measurements made by the inspector.

\*Reasonable probability of incurring 25% or more of MPC or MPE.



Items of Noncompliance and Safety Found in the Last Inspection

The licensee's action to correct and prevent recurrence of items of noncompliance and/or safety, found in the last inspection, were given particular attention during this inspection. Unless these items are shown under the section below, entitled "Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety", the inspector found that the licensee's corrective and preventive action was adequate.

Findings Indicating Compliance

Annex A identifies the specific procedures followed by the inspector in determining compliance with each relevant section of Title 10. The inspector also made such inquiries, examined such records and made such observations as were necessary for him to determine that the licensee had complied with the requirements of each license condition.

When a section of Annex A is notated "N/I", this means that compliance with this section was not determined during this inspection. During the next inspection this area will be covered.

When a section of Annex A is notated "N/A", this means that it is readily apparent that the section is not applicable to the licensee's program (e.g. the requirements of 10 CFR 20.103 or 106 are not applicable if the licensee possesses only sealed sources).

The paragraphs in Annex A that are initialed by the inspector indicate how the inspector determined compliance.

Status of Previously Reported Unresolved Items

*None*

Additional Information Relating to Incidents Reported Since Last Inspection

Attached as Annex B, or referenced on identified pages of these notes.

Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety

Attached as Annex C, or referenced on identified pages of these notes.

Principals

Persons	Radionuclides	Locations of Use	Rate of Use
<i>Sops</i>	<i>Co-60</i>	<i>irradiate</i>	<i>3 shifts/day</i> <i>5 days/week</i> <i>sources lowered</i> <i>when necessary</i>

Line of Authority (from user to Management)

*me → A → S → Pres*

Facilities

Use: ( ) Radiochemistry labs used exclusively for licensed material; ( ) Conventional labs used exclusively for licensed material; ( ) Conventional labs with shared use; ( ) Room or area used exclusively for preparation and application of licensed material, and storage; (✓) Mfg or processing areas designated for radiologic operations only; ( ) Entire building used exclusively for radiologic operations ( ) Other:

Storage:

(✓) Ample space, (✓) Adequate lighting, (✓) Uncluttered, (✓) Shielding adequate  
(✓) Material identified  
( ) Refrigerator, ( ) cabinet, ( ) fume hood, ( ) cave, (✓) separate room, (✓) separate building

Access Control:

(✓) locked, (✓) posted and administratively controlled  
(✓) locked when unattended, (✓) custodial personnel instructed

Control Devices and Alarms: ( ) 20.203(c)(2), ( ) Other

Comments:

Equipment

Monitoring, portable: ( ) alpha, (✓) beta, (✓) gamma, ( ) neutron  
(✓) adequate no., (✓) accessible, (✓) calibrated, (✓) appropriate sensitivity

Monitoring, area: ( ) alpha, ( ) beta, (✓) gamma, ( ) air sampling, ( ) adequate no.  
(✓) properly located, (✓) calibrated, (✓) tested, (✓) appropriate sensitivity.

Special Equipment:

( ) BZ samplers: ( ) adequate no., ( ) properly used, ( ) accessible  
( ) fume hoods, ( ) glove boxes, (✓) hot cells-large, ( ) hot cells-small (✓) local exhaust ventilation, ( ) remote tongs, ( ) shields,  
( ) protective handwear, ( ) protective footwear, ( ) protective clothing, ( ) absorbent paper, ( ) working trays, ( ) designated radioactive waste disposal sinks, ( ) respirators, ( ) eye wash fountains, ( ) DOP filter testing equipment, ( ) disposable pipettes, ( ) disposable syringes, ( ) Other:

Management Interview

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) gave \_\_\_\_\_ date \_\_\_\_\_ a Form AEC-591 indicating (that no items of) noncompliance had been found during the inspection.

-----

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) informed \_\_\_\_\_ date \_\_\_\_\_ that no items of noncompliance had been found during this inspection. He informed \_\_\_\_\_ that he would receive a letter enclosing a Form AEC-591 confirming these findings (Inspector: No Form AEC-591 may be issued if there were Outstanding Items reviewed during this inspection except, if our acknowledgement letter, written following the issuance of an AEC Form 592, predated July 1, 1971.)

No form AEC-591 was issued because Outstanding Items had been reviewed during this inspection.

-----

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) explained the purpose of the inspection. With respect to the item(s) of noncompliance, the inspector(s) explained the relevant requirements of the AEC regulations and described the inspection findings that indicated noncompliance with these requirements. \_\_\_\_\_ acknowledged the validity of the citation(s) and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar \_\_\_\_\_ of noncompliance would not recur. He signed and dated the Form AEC-591.

-----

The inspector(s) met with \_\_\_\_\_, A and G in G's office, on 7/25/71, at the conclusion of the inspection. The inspector(s) gave \_\_\_\_\_ date \_\_\_\_\_

*unrecorded*  
plained the purpose of the inspection. With respect to the ~~items of non-compliance~~, the inspector(s) ~~explained~~ the relevant requirements of the AEC regulations and/or the conditions of the license and described the inspection findings that indicated noncompliance with these requirements.

acknowledged the validity of the citations and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar items of noncompliance would not recur.

-----  
Other: explained that monitoring of water and/or clean up systems and absolute air filters would give an nearly immediate indication of leaking sources that would be vital to prevent loss of material and minimize the potential of unnecessary exposure. A and G acknowledged and voiced agreement and stated that upon start of production work on 7/30/74 both types of monitoring would be instituted.

The inspector stated that the license required prior approval of any change in procedures. A explained that AECL had modified some equipment and that a new manual would be mailed to DL on 7/26/74 reflecting any changes. He further stated no procedures contained in the manual had been affected and that he held off marking in the

ANNEX A

1.0 10 CFR 20

1.1 20.101, "EXPOSURE OF INDIVIDUAL TO RADIATION IN RESTRICTED AREAS"

I identified by examination of records of ( ) receipts, ( ) inventories, ( ) surveys, ( ) personnel dosimetry, and ( ) disposal transfers, and/or (X) by questioning the RSO and/or (X) these users D-F, (X) and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE external EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.101(a). WR

1.1.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitudes of exposure had been found. WR

1.1.2 I found that the licensee's METHODS of evaluating exposures was in each case APPROPRIATE to the type and energy of the radiation and the area of the individuals body that was at risk. WR

1.1.3 I found that the licensee's evaluations of exposures showed that NO INDIVIDUAL had been EXPOSED IN EXCESS of the limits of 20.101. WR

1.1.4 A stated that the licensee did not avail himself of the provisions of 10 CFR 20.101(b) and therefore NO FORMS AEC-4 WERE MAINTAINED. WR

1.1.5 ( ) I observed a CORRECTLY COMPLETED FORM AEC-4 for each individual whose quarterly whole body exposure exceeded 1.25 rems; or

( ) I identified approximately \_\_\_\_\_% of the individuals whose quarterly whole body exposure had exceeded 1.25 rems and examined each individual's Form AEC-4 and found each to be correctly completed.

1.2 20.103, "EXPOSURE OF INDIVIDUALS TO CONCENTRATIONS OF RADIOACTIVE MATERIAL IN RESTRICTED AREAS"

1.2.1 By examination of records of ( ) receipts, ( ) inventories, ( ) surveys, ( ) personnel dosimetry, ( ) effluent monitoring, ( ) bioassay, and ( ) disposals/transfers, by questioning the RSO and these users \_\_\_\_\_, and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE internal EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.103. N/A

1.2.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitude of exposure had been found.



- 1.2.2 I found that the licensee's METHODS of evaluating compliance with 20.103 was APPROPRIATE to the circumstances of exposure in each case. N/A
- 1.2.3 I found that the licensee's evaluations of exposures showed that in NO instance had an INDIVIDUAL been EXPOSED IN EXCESS of the limits of 20.103. ↓

### 1.3 20.104, "EXPOSURE OF MINORS"

- 1.3.1 I determined by questioning (☒) the RSO, and/or (☐) \_\_\_\_\_, and/or (☐) examining Forms AEC-5 or their equivalents and/or (☐) observing individuals in the restricted areas that NO INDIVIDUALS under 18 years of age had been EXPOSED in the restricted areas, or
- 1.3.2 In the manner indicated above, I IDENTIFIED those INDIVIDUALS under 18 years of age who had been exposed in the restricted areas by questioning (☐) the RSO, (☐) the minors, (☐) the minor's supervisors. I determined the circumstances of exposure and the licensee's method of evaluating the minor's exposures. I determined that the METHOD OF EVALUATION had been ADEQUATE. I found that the evaluations showed that the exposures had NOT EXCEEDED 10% of the limits of 10 CFR 20.101(a).

### 1.4 20.105, "PERMISSIBLE LEVELS OF RADIATION IN UNRESTRICTED AREAS"

- 1.4.1 By questioning the RSO and/or the principal users, and (☒) by examining records of (☒) receipts, (☒) inventories, (☐) disposals/transfers, and (☒) surveys, and by a physical inspection of the restricted areas, I DETERMINED the TIMES AND CIRCUMSTANCES under WHICH the licensee's use and/or storage of materials would have resulted in the generation of exposure levels in the unrestricted area of a magnitude of WARRANTED CALCULATION OR MEASUREMENT to assure compliance with 20.105. WJR
- 1.4.2 I questioned the RSO and/or the involved principal users to determine if these calculations or MEASUREMENTS had been MADE; HOW they had been MADE; and what CONCLUSIONS had been DRAWN. I found that adequate surveys had been made indicating that the levels of radiation in the unrestricted area had not exceeded the limits of 20.105. WJR
- 1.4.3 I MEASURED THE EXPOSURE RATES IN THE UNRESTRICTED AREAS and found that at the time of inspection none exceeded the allowed levels. WJR



114.4 Following the procedures described in paragraph 1.4.1 above, I determined that there had been NO circumstances under which there was any REASONABLE PROBABILITY OF the levels HAVING EXCEEDED the limits of 20.105.

115 20.106, "CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS"

115.1 By questioning the RSO and these principal users \_\_\_\_\_, by examination of records of ( ) receipts, ( ) inventories, ( ) effluent monitoring, and ( ) surveys, ( ) and by observations made during my physical inspection of the restricted areas, I IDENTIFIED those OPERATIONS WHERE there was a REASONABLE PROBABILITY of generation OF CONCENTRATIONS of radioactive material in effluents to the unrestricted area. N/A

115.2 I asked the RSO or the principal user to describe the evaluation that had been made to ASSURE that the CONCENTRATION of radioactive material in these effluents DID NOT EXCEED THE LIMITS of 20.106.

115.3 I determined that the licensee's ( ) calculations, ( ) location of samplers, ( ) collection methods, and ( ) assay methods were SUITABLE for EVALUATION of the concentrations of the types of radioactive material that were discharged (i.e. considering its identity, physical and chemical form, particle size, the presence of dust loading or moisture . . . etc). I noted that the licensee's evaluations showed compliance with 20.106.

115.4 Having assured myself, from the findings of previous AEC inspectors, that the licensee's procedures for calculating, sampling and assaying the samples were in accord with accepted practices I ONLY EXAMINED the RECORDS of his measured concentrations. I found that these showed him to be in compliance with 20.106.

115.5 Following the procedures described in paragraph 115.1 above, I determined that quantities and forms of the material, and the circumstances under which it was handled were such that THERE WAS NO SIGNIFICANT PROBABILITY OF VIOLATION OF THE SECTION. V

116 20.201, "SURVEYS"

116.1 In the course of determining the licensee's status of compliance with all sections of Part 20, I found that ADEQUATE SURVEYS had been CONDUCTED wrt

## 1.7 20.202, "PERSONNEL MONITORING"

1.7.1 As stated in paragraph 1.1.1 above, I identified those individuals whose external exposure might reasonably be expected to exceed 25% of the 20.101(a) limits. I ascertained that a FORM AEC-5 or its equivalent was maintained FOR EACH of these INDIVIDUALS. *WDR*

1.7.1.1 I concurred in the licensee's evaluation that personnel monitoring was not required for any individual using material under this license.

1.7.1.2 *X* stated that each of these individuals had been INSTRUCTED TO WEAR his personnel DOSIMETER while he was in the restricted areas. *WDR*

1.7.1.3 I noted that the licensee's written OPERATING PROCEDURES directed occupants of the restricted areas to wear their personnel dosimeters. *WDR*

1.7.1.4 During my inspection of the restricted areas I OBSERVED that all individuals who I encountered, and who were required to wear PERSONNEL DOSIMETERS, were wearing them. *WDR*

1.7.2 \_\_\_\_\_ identified those individuals under 18 YEARS OF AGE who entered the restricted areas. He DESCRIBED the PROCEDURES followed by each of these individuals and the duration of times spent in the restricted areas. I noted that for each individual whose exposures could reasonably be expected to EXCEED 5% of the LIMITS of 20.101(a) there was on file a Form AEC-5 or its equivalent.

1.7.3 *X* stated that NO individuals UNDER 18 YEARS OF AGE entered the restricted areas. *WDR*

1.7.4 By questioning the following individuals *A D-F*, \_\_\_\_\_, and \_\_\_\_\_ who were responsible for controlling access to High Radiation Areas or who entered these areas, I determined that all INDIVIDUALS WHO ENTERED the HIGH RADIATION AREAS were PROVIDED with PERSONNEL MONITORING equipment. *WDR*

1.7.5 \_\_\_\_\_ stated, and my findings verified the fact, that there were NO HIGH RADIATION AREAS under the licensee's control.

1.8 20.203, "CAUTION SIGNS, LABELS, SIGNALS, AND CONTROLS"

1.8.1 In my physical inspection of the operational areas I observed that EACH ROOM OF AREA I visited was POSTED with the appropriate sign reading ☒ CRM, ☒ CRA, ☒ CHRA, or ☐ CARA, as applicable, and showing the radiation caution symbol. *WZ*

1.8.2 In my physical inspection of the operational area I observed that EACH CONTAINER that required a label was in fact LABELED CRM, showing the radiation caution symbol, the identity of its contents and sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. *WZ*

1.9 20.205, "PROCEDURES FOR OPENING PACKAGES"

1.9.1 I observed that the licensee HAD WRITTEN PROCEDURES for safely opening packages in which radioactive material were received and that these procedures were relevant to the types of packages that were being received. *N/A*

1.9.2 I interviewed the individual(s) who were responsible for following these procedures and found that they had the procedures and understood them. *V*

1.10 20.207, "STORAGE OF LICENSED MATERIALS"

1.10.1 In my inspection of the licensee's facilities, I observed that NO MATERIAL was STORED IN an UNRESTRICTED AREA. *WZ*

1.10.1.1 \_\_\_\_\_ stated that all areas in which MATERIAL was stored were SECURED WHEN UNATTENDED by individuals who had been instructed in the safe use of the material.

1.10.2 I ASCERTAINED by physical inspection that all MATERIAL stored in unrestricted areas was SECURED against unauthorized removal from the place of storage.

1.11 20.301, "WASTE DISPOSAL - GENERAL REQUIREMENTS"

1.11.1 By questioning the RSO and these principal users \_\_\_\_\_, by examination of records of ☐ receipts, ☐ surveys, ☐ effluent monitoring, ☐ inventories, ☐ disposal/transfer, and by my physical inspection of the licensee facilities, I IDENTIFIED the PROCEDURES used by the licensee to dispose of waste material.

1.11.1.1 I determined that no material had been disposed of as waste. *WSP*

1.11.2 I determined that these procedures INVOLVED either one or a combination of the FOLLOWING METHODS: ( ) Transfer to an authorized recipient, ( ) In accordance with a license condition, ( ) Release into sanitary sewage system, ( ) Burial in soil, or ( ) As allowed by 20.106.

1.12 20.303, "DISPOSAL BY RELEASE INTO SANITARY SEWAGE SYSTEMS"

1.12.1 *A* stated that no licensed material had been released into the sanitary sewage system. *WSP*

1.12.2 In the manner indicated in Paragraph 1.11.1, I IDENTIFIED those OPERATIONS from which waste was discharged to the sanitary sewage system.

1.12.3 By questioning the RSO and these principal users \_\_\_\_\_ regarding the details of the procedures being followed, I determined that the effluent was READILY SOLUBLE or \_\_\_\_\_ water. *DISPERSIBLE*

1.12.4 By questioning the RSO and these principal users \_\_\_\_\_, and by my examination of records of ( ) receipts, ( ) disposals/transfers, ( ) survey of sewage release rates, ( ) calculations of concentrations of material per unit volume of sewage, or ( ) measurements of concentration of material per unit volume of sewage, I determined that:

1. The QUANTITY of radioactive material RELEASED in any one DAY did not exceed the larger of the following limits: (a) Appendix B, Table 1, Col. 2 concentrations averaged over any one day or (b) Ten times the quantity of such material specified in Appendix C.
2. The MONTHLY average did not exceed Appendix B, Table I, Col. 2 CONCENTRATIONS.
3. The GROSS quantity of radioactive MATERIAL did not exceed 1 curie/year.

1.13 20.304, "DISPOSAL BY BURIAL IN SOIL"

1.13.1 By questioning the RSO and these principal users \_\_\_\_\_ and by examination of records of burials I DETERMINED that the LICENSEE had MET the requirements of this section.

1.13.2 A stated that no licensed material was disposed of by burial in soil.

1.13a 20.305, "TREATMENT OR DISPOSAL BY INCINERATION"

1.13a.1 Having noted that incineration was AUTHORIZED BY THE LICENSE, I questioned the RSO and these principal users who utilized this method of disposal, I EXAMINED the RECORDS, which showed the identity of the material, its quantity, and the date of incineration. I also determined that the QUANTITY LIMITATIONS (if any) given in the license had NOT been EXCEEDED. I determined that the licensee had made valid surveys to ensure that the EFFLUENT AND ASH limits given in the license had not been exceeded. I did this by examining his sample collection techniques and his assay procedures.

1.13a.2 By examination of waste disposal records, by questioning the principal users and the RSO, and by physical inspection of the licensee's facilities, I determined that he had NOT UTILIZED INCINERATION as a means of treatment or disposal of material.

1.14 20.401 "RECORDS OF SURVEYS, RADIATION MONITORING, AND DISPOSAL"

1.14.1 I examined ( ) all, (☒) approximately 50 % of, the RECORDS OF RADIATION EXPOSURE of all individuals for whom monitoring was required under 20.202. I found that these records were maintained on FORMS AEC-5 or on clear and legible forms containing all the information required by Form AEC-5. I found they were kept in accordance with the INSTRUCTIONS contained ON THE REVERSE SIDE of Form AEC-5.

1.14.2 As indicated in paragraph 1.7.1.1 of these notes no individuals were required to wear personnel monitoring equipment.

1.14.3 I examined ( ) all records; (☒) a representative number of records, of surveys conducted in accordance with (☒) 20.201(b), disposals made under ( ) 20.302 (As allowed by License Amendment), ( ) 20.303 (Release to Sanitary Sewers) and ( ) 20.304 (Burial in Soil) and found that the records contained the essential elements for adequate evaluation of compliance.

1.15 20.402 "REPORTS OF THEFT OR LOSS OF LICENSED MATERIAL"

1.15.1 A STATED that there had been NO LOSS OR THEFT of licensed material in such quantities and under such circumstances that a substantial hazard might result to persons in unrestricted areas.

1.15.1.1 I VERIFIED this fact by comparison of records of (☒) receipts, (☒) inventories, and ( ) disposal/transfer, taking into consideration the decay rates of the various radionuclides.



1.16 20.403, "NOTIFICATION OF INCIDENTS"

1.16.1 In the course of my inspection of all sections of Part 20 I found that there had been NO CIRCUMSTANCES that WARRANTED the submission of NOTIFICATION under 20.403. *WJA*

1.16.2 In the course of my inspection of all sections of Part 20 I found that in each instance where NOTIFICATION had been required such notification HAD BEEN MADE in accordance with the specifications of this section.

1.17 20.405, "REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS"

1.17.1 In the course of my inspection of all sections of Part 20, I found that there had been NO CIRCUMSTANCES that WARRANTED the SUBMISSION of reports under 20.405. *WJA*

1.17.2 In the course of my inspection of all sections of Part 20, I found that in each instance where a 20.405 REPORT had been required the report HAD BEEN SUBMITTED in accordance with the specifications of the section.

1.18 20.407, "PERSONNEL EXPOSURE AND MONITORING REPORTS"

1.18.1 By comparing the licensee's program with the specifications of this section I determined that the provisions of THIS SECTION DID NOT APPLY to the licensee. *WJA*

1.18.2 I compared the licensee's copies of REPORTS with the specifications of this section and determined that they MET THE REQUIREMENTS.

1.19 20.408, "REPORTS OF PERSONNEL EXPOSURE ON TERMINATION OF EMPLOYMENT OR WORK"

1.19.1 As indicated above, I determined that the requirements of 20.407, and hence 20.408, were NOT APPLICABLE to this licensee. *WJA*

1.19.2 By questioning \_\_\_\_\_ and by examining all records that gave evidence of the presence or absence of individuals who were using licensed materials (e.g. Forms AEC-5, B.Z. sampling, bioassay isotope committee authorizations, etc.) I IDENTIFIED those INDIVIDUALS who had TERMINATED employment or work. I examined the licensee's copies of reports of their exposures which he had submitted to the AEC. I found that they had been completed in accordance with the requirements of this section.



2.1 30.3, 40.3 and 70.3 "ACTIVITIES REQUIRING LICENSE"

2.1.1 By questioning (✓) the RSO and/or (✓) the following individuals, D - F, and/or (✓) by examination of records of (✓) receipts and ( ) transfer/disposal, I determined that the licensee had neither manufactured, produced, transferred, received, acquired, owned, possessed, used imported or exported licensed material except as authorized in a specific or general license issued pursuant to the regulations of Title 10. WTR

2.2 30.51, 40.61 and 70.51, "RECORDS"

2.2.1 I inspected the licensee's records of receipt, transfer, export and disposal and found them to be complete; indicating the identities of the materials and the dates of change of status. WTR

3.1 19.11 "POSTING OF NOTICES TO WORKERS"

3.1.1 I observed that the licensee had posted current copies of the following documents:

- (1) 10 CFR 19 and 20
- (2) License with conditions and back-up
- (3) Operating procedures
- (4) Notice of Violations, civil penalties and responses from licensee

3.1.2 I observed that the licensee had posted a notice describing documents (1), (2), and (3) and stating where they might be examined. WTR

3.1.3 I observed that Forms AEC-3 were posted wherever individuals work in or frequent and portion of a restricted area WTR

OR

3.1.3.1 The licensee's activities were such that he was not obliged to designate a restricted area.

3.1.4 I observed that the documents, notices or forms appeared in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applied. WTR

I observed that the documents were conspicuously posted and neither defaced nor altered. WTR

3.1.6 \_\_\_\_\_ stated that all enforcement correspondence had been posted not later than 2 days following its dispatch or receipt and had remained posted for a minimum of 5 working days or until corrective action had been completed, whichever was later.

3.1.7 By examination of Region I files, I determined that no enforcement correspondence had been exchanged with the licensee since ( ) the issuance of the license (✓) the last inspection. *WOM*

### 3.2 19.12, "INSTRUCTIONS TO WORKERS"

3.2.1 I examined a copy of an instruction that \_\_\_\_\_ stated had been issued to all individuals working in or frequenting any portion of a restricted area. I noted that this instruction was commensurate with the potential radiological health problems in the restricted areas, and covered:

- a. Protection problems associated with exposure to relevant radioactive materials or radiation.
- b. Precautions or procedures to minimize exposure.
- c. The purpose and functions of protective devices employed.
- d. The applicable provisions of AEC regulations and licenses.
- e. Responsibility to report unsafe conditions or unnecessary exposures.
- f. Responses to emergency warnings.
- g. Availability of radiation exposure records.

3.2.2 A stated that all individuals working in or frequenting any portion of a restricted area had been given oral instructions in the areas described above. *WOM*

3.2.3 The licensee's activities were such that he was not obliged to establish any restricted area.

### 3.3 19.13, "NOTIFICATIONS AND REPORTS TO INDIVIDUALS"

3.3.1 I asked A if any worker or former worker had requested a copy of his external or internal exposure data since ( ) the issuance of the license (✓) the last inspection. He stated that (✓) no one had requested such data or ( ) one or more workers or former workers had requested such data. *WOM*

A-II

3.3.1.1 I examined copies of the reports that \_\_\_\_\_ stated had been given to these workers. I observed that these reports: (a) provided the appropriate data and this data was in agreement with the data shown on the licensee's records. (b) identified the licensee and the worker (including SSN) (c) contained the boiler plate statement (d) identified the time periods during which the exposures were incurred and the locations at which they were incurred, and (e) were given to the workers within 30 days of request or within 30 days of determination, whichever was later.

3.3.2 By examination of exposure records and questioning of A, I determined that there had been no requirement to submit a 20.405 report since ( ) the issuance of the license or (x) since the last inspection. *WZ*

3.3.3 My examination of exposure records and questioning of the licensee revealed that 20.405 reports had been submitted since ( ) the issuance of the license or ( ) since the last inspection. I examined these reports, following the guidance of 3.3.1.1 above, and found that the reports were complete.

3.3.4 This licensee was not subject to the provisions of 20.407 and hence to 20.408. *WZ*

3.3.5 \_\_\_\_\_ stated that no worker had terminated his assignment since ( ) the issuance of the license or ( ) since the last inspection.

3.3.6 I identified all individuals whose names appeared on 20.408 reports and examined copies of exposure reports which \_\_\_\_\_ stated had been given to each of these individuals. Following the guidance of 3.3.1.1 above, I determined that each report was complete.

3.4 19.14 "PRESENCE OF REPRESENTATIVES OF LICENSEES AND WORKERS DURING INSPECTIONS"

19.15, "CONSULTATION WITH WORKERS DURING INSPECTIONS"

3.4.1 I experienced no conflict with the provisions of these sections *WZ*  
During Inspections

REGULATORY AGENCY FOR FOOD & DRUGS  
Inspection Field Notes

Packet Number	B. Report Number 7401	C. Priority/Category K-V	D. Inspection Date 7/25/74
Licensee ETHICON, INC Rt 22		E. Facility SOMERVILLE N.J.	
		G. License No. 29-02786-04 29-02786-05	
Type of Inspection Announced Initials	I. No. and date of last Amendment - 04 - #4. 8/17/73 - 05 2/27/74		J. Dates of last inspection N/A
Principal Inspector and Date of Report W.D. Allen	L. Accompanying Inspector —	M. Other Accompanying Personnel —	
Proprietary Info. None	O. Reviewer R.D. McIntosh		P. Date of Review 8/5/74
Individuals Interviewed* and Titles * a. E. Kendra, RSO e. b. Dr. S. Romano, Asst. Chemist f. c. R. Vetrucchio, Chemist g. * d. Dr. Charles Artandi V.P. for Research h.			R. Date of Interview 7/25/74 S. Place of Interview
Enforcement Action None - clear 591's		U. Previous Outstanding Items N/A	
Unresolved Items None		W. Previously Reported Categories —	
X. Recom. Reinspection —	Y. Name & Tele. # of RSO A 201-524-0400	Z. RMS Code Number 34	
YY. Scope of Inspection: (X) complete, ( ) partial, ( ) special			

## DETAILS

### Scope of the Program

- Number of individuals occupationally exposed 04-1  
-Number of individuals subject to significant\* risk 05-2  
-Potential for external exposure 0

Negligible      Slight      Moderate      High

- Whole body  
• Skin  
• Extremities

-Potential for internal exposure ( ) negligible ( ) slight ( ) moderate  
( ) high

- Effluents

*None*  
Negligible      Slight      Moderate      High

- Airborne  
Liquids

- Unusual aspects

### General

All records examined and all inquiries made by the inspector related to records and events made or experienced in the time interval from the date of the last inspection, or the date of license issuance in the case of initial inspections, until the date of this inspection, unless otherwise noted.

Unless otherwise specified, radiation level measurements, shown in these notes, as having been made by the inspector, were made using a radiation survey meter type E, model 120, calibrated 6/74 by BNL.

The findings reported here were based on: (1) observations made by the inspector during his physical inspection of the licensee's facilities (2) a selective examination of procedures and representative records and documents, (3) information furnished by individuals interviewed and (4) Measurements made by the inspector.

\*Reasonable probability of incurring 25% or more of MPC or MPE.



## Items of Noncompliance and Safety Found in the Last Inspection

The licensee's action to correct and prevent recurrence of items of noncompliance and/or safety, found in the last inspection, were given particular attention during this inspection. Unless these items are shown under the section below, entitled "Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety", the inspector found that the licensee's corrective and preventive action was adequate.

### Findings Indicating Compliance

Annex A identifies the specific procedures followed by the inspector in determining compliance with each relevant section of Title 10. The inspector also made such inquiries, examined such records and made such observations as were necessary for him to determine that the licensee had complied with the requirements of each license condition.

When a section of Annex A is notated "N/I", this means that compliance with this section was not determined during this inspection. During the next inspection this area will be covered.

When a section of Annex A is notated "N/A", this means that it is readily apparent that the section is not applicable to the licensee's program (e.g. the requirements of 10 CFR 20.103 or 106 are not applicable if the licensee possesses only sealed sources).

The paragraphs in Annex A that are initialed by the inspector indicate how the inspector determined compliance.

### Status of Previously Reported Unresolved Items

### Additional Information Relating to Incidents Reported Since Last Inspection

Attached as Annex B, or referenced on identified pages of these notes.

### Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety

Attached as Annex C, or referenced on identified pages of these notes.

### Principals

Persons	Radionuclides	Locations of Use	Rate of Use
A	Sr 90	Storage	N/A
B, C	N. 63	Chemistry	none in last few years



Line of Authority (from user to Management)

USER → A → D → President

Facilities

Use: ( ) Radiochemistry labs used exclusively for licensed material; ( ) Conventional labs used exclusively for licensed material; (✓) Conventional labs with shared use; ( ) Room or area used exclusively for preparation and application of licensed material, and storage; ( ) Mfg or processing areas designated for radiologic operations only; ( ) Entire building used exclusively for radiologic operations ( ) Other:

Storage:

(✓) Ample space, (✓) Adequate lighting, (✓) Uncluttered, (✓) Shielding adequate  
(✓) Material identified  
( ) Refrigerator, ( ) cabinet, ( ) fume hood, ( ) cave, (✓) separate room, ( ) separate building

Access Control:

(✓) locked, (✓) posted and administratively controlled  
(✓) locked when unattended, (✓) custodial personnel instructed

Control Devices and Alarms: ( ) 20.203(c)(2), ( ) Other

Comments:

None

Equipment

Monitoring, portable: ( ) alpha, (✓) beta, (✓) gamma, ( ) neutron  
(✓) adequate no., (✓) accessible, (✓) calibrated, (✓) appropriate sensitivity

Monitoring, area: ( ) alpha, ( ) beta, ( ) gamma, ( ) air sampling, ( ) adequate no.  
( ) properly located, ( ) calibrated, ( ) tested, ( ) appropriate sensitivity.

Special Equipment:

( ) BZ samplers: ( ) adequate no., ( ) properly used, ( ) accessible  
( ) fume hoods, ( ) glove boxes, ( ) hot cells-large, ( ) hot cells-small  
( ) local exhaust ventilation, ( ) remote tongs, ( ) shields,  
( ) protective handwear, ( ) protective footwear, ( ) protective clothing,  
( ) absorbent paper, ( ) working trays, ( ) designated radioactive waste disposal sinks,  
( ) respirators, ( ) eye wash fountains, ( ) DCP filter resting equipment, ( ) disposable pipettes,  
( ) disposable syringes, ( ) Other: *n/p*

Management Interview

The inspector(s) met with A,        and D in D's office, on 7/25/74, at the conclusion of the inspection. The inspector(s) gave        date

D a Form AEC-591 indicating (that no items of) noncompliance had been found during the inspection.

-----  
The inspector(s) met with       ,       , and        in       's office, on       , at the conclusion of the inspection. The inspector(s) informed        date

       that no items of noncompliance had been found during this inspection. He informed        that he would receive a letter enclosing a Form AEC-591 confirming these findings (Inspector: No Form AEC-591 may be issued if there were Outstanding Items reviewed during this inspection except, if our acknowledgement letter, written following the issuance of an AEC Form 592, predated July 1, 1971.)

No form AEC-591 was issued because Outstanding Items had been reviewed during this inspection.

-----  
The inspector(s) met with       ,       , and        in       's office, on       , at the conclusion of the inspection. The inspector(s) explained the purpose of the inspection. With respect to the item(s) of noncompliance, the inspector(s) explained the relevant requirements of the AEC regulations and described the inspection findings that indicated noncompliance with these requirements.        acknowledged the validity of the citation(s) and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar        of noncompliance would not recur. He signed and dated the Form AEC-591.

-----  
The inspector(s) met with       ,        and        in       's office, on       , at the conclusion of the inspection. The inspector(s) ex-  
date

plained the purpose of the inspection. With respect to the items of non-compliance, the inspector(s) explained the relevant requirements of the AEC regulations and/or the conditions of the license and described the inspection findings that indicated noncompliance with these requirements.

acknowledged the validity of the citations and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar items of noncompliance would not recur.

- - - - -

Other:

ANNEX A

1.0 10 CFR 20

1.1 20.101, "EXPOSURE OF INDIVIDUAL TO RADIATION IN RESTRICTED AREAS"

1.1.1 by examination of records of (✓) receipts, (✓) inventories, (✓) surveys, ( ) personnel dosimetry, and ( ) disposal transfers, and/or (✓) by questioning the RSO and/or (✓) these users B C, (✓) and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE external EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.101(a). WTR

1.1.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitudes of exposure had been found. WTR

1.1.2 I found that the licensee's METHODS of evaluating exposures was in each case APPROPRIATE to the type and energy of the radiation and the area of the individuals body that was at risk. WTR

1.1.3 I found that the licensee's evaluations of exposures showed that NO INDIVIDUAL had been EXPOSED IN EXCESS of the limits of 20.101. WTR

1.1.4 A stated that the licensee did not avail himself of the provisions of 10 CFR 20.101(b) and therefore NO FORMS AEC-4 WERE MAINTAINED. WTR

1.1.5 ( ) I observed a CORRECTLY COMPLETED FORM AEC-4 for each individual whose quarterly whole body exposure exceeded 1.25 rems; or

( ) I identified approximately \_\_\_\_\_% of the individuals whose quarterly whole body exposure had exceeded 1.25 rems and examined each individual's Form AEC-4 and found each to be correctly completed.

1.2 20.103, "EXPOSURE OF INDIVIDUALS TO CONCENTRATIONS OF RADIOACTIVE MATERIAL IN RESTRICTED AREAS"

1.2.1 By examination of records of ( ) receipts, ( ) inventories, ( ) surveys, ( ) personnel dosimetry, ( ) effluent monitoring, ( ) bioassay, and ( ) disposals/transfers, by questioning the RSO and these users B C, and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE internal EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.103. N/A

1.2.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitude of exposure had been found. ↓

1.2.2 I found that the licensee's METHODS of evaluating compliance with 20.103 was APPROPRIATE to the circumstances of exposure in each case. 11/1

1.2.3 I found that the licensee's evaluations of exposures showed that in NO instance had an INDIVIDUAL been EXPOSED IN EXCESS of the limits of 20.103. ✓

### 1.3 20.104, "EXPOSURE OF MINORS"

1.3.1 I determined by questioning (✓) the RSO, and/or ( ) \_\_\_\_\_, and/or ( ) examining Forms AEC-5 or their equivalents and/or (✓) observing individuals in the restricted areas that NO INDIVIDUALS under 18 years of age had been EXPOSED in the restricted areas, or WR

1.3.2 In the manner indicated above, I IDENTIFIED those INDIVIDUALS under 18 years of age who had been exposed in the restricted areas by questioning ( ) the RSO, ( ) the minors, ( ) the minor's supervisors. I determined the circumstances of exposure and the licensee's method of evaluating the minor's exposures. I determined that the METHOD OF EVALUATION had been ADEQUATE. I found that the evaluations showed that the exposures had NOT EXCEEDED 10% of the limits of 10 CFR 20.101(a).

### 1.4 20.105, "PERMISSIBLE LEVELS OF RADIATION IN UNRESTRICTED AREAS"

1.4.1 By questioning the RSO and/or the principal users, and (✓) by examining records of (✓) receipts, (✓) inventories, ( ) disposals/transfers, and ( ) surveys, and by a physical inspection of the restricted areas, I DETERMINED the TIMES AND CIRCUMSTANCES under WHICH the licensee's use and/or storage of materials would have resulted in the generation of exposure levels in the unrestricted area of a magnitude of WARRANTED CALCULATION OR MEASUREMENT to assure compliance with 20.105. WR

1.4.2 I questioned the RSO and/or the involved principal users to determine if these calculations or MEASUREMENTS had been MADE; HOW they had been MADE; and what CONCLUSIONS had been DRAWN. I found that adequate surveys had been made indicating that the levels of radiation in the unrestricted area had not exceeded the limits of 20.105.

1.4.3 I MEASURED THE EXPOSURE RATES IN THE UNRESTRICTED AREAS and found that at the time of inspection none exceeded the allowed levels.



11444 Following the procedures described in paragraph 11411 above, I determined that there had been NO circumstances under which there was any REASONABLE PROBABILITY OF the levels HAVING EXCEEDED the limits of 20.105. *WDR*

115 20.106, "CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS"

11511 By questioning the RSO and these principal users *B C*, by examination of records of ( ) receipts, ( ) inventories, ( ) effluent monitoring, and ( ) surveys, ( ) and by observations made during my physical inspection of the restricted areas, I IDENTIFIED those OPERATIONS WHERE there was a REASONABLE PROBABILITY of generation OF CONCENTRATIONS of radioactive material in effluents to the unrestricted area. *N. 63 fuel were vented to separate exhaust* *WDR*

11512 I asked the RSO or the principal user to describe the evaluation that had been made to ASSURE that the CONCENTRATION of radioactive material in these effluents DID NOT EXCEED THE LIMITS of 20.106.

11513 I determined that the licensee's ( ) calculations, ( ) location of samplers, ( ) collection methods, and ( ) assay methods were SUITABLE for EVALUATION of the concentrations of the types of radioactive material that were discharged (i.e. considering its identity, physical and chemical form, particle size, the presence of dust loading or moisture . . . etc). I noted that the licensee's evaluations showed compliance with 20.106.

11514 Having assured myself, from the findings of previous AEC inspectors, that the licensee's procedures for calculating, sampling and assaying the samples were in accord with accepted practices I ONLY EXAMINED the RECORDS of his measured concentrations. I found that these showed him to be in compliance with 20.106.

11515 Following the procedures described in paragraph 11511 above, I determined that quantities and forms of the material, and the circumstances under which it was handled were such that THERE WAS NO SIGNIFICANT PROBABILITY OF VIOLATION OF THE SECTION. *WDR*

116 20.201, "SURVEYS"

11611 In the course of determining the licensee's status of compliance with all sections of Part 20, I found that ADEQUATE SURVEYS had been CONDUCTED *WDR*



## 1.7 20.202, "PERSONNEL MONITORING"

1.7.1 As stated in paragraph 1.1.1 above, I identified those individuals whose external exposures might reasonably be expected to exceed 25% of the 20.101(a) limits. I ascertained that a FORM AEC-5 or its equivalent was maintained FOR EACH of these INDIVIDUALS. 6

1.7.1.1 I concurred in the licensee's evaluation that personnel monitoring was not required for any individual using material under this license. WDR

1.7.1.2 \_\_\_\_\_ stated that each of these individuals had been INSTRUCTED TO WEAR his personnel DOSIMETER while he was in the restricted areas.

1.7.1.3 I noted that the licensee's written OPERATING PROCEDURES directed occupants of the restricted areas to wear their personnel dosimeters.

1.7.1.4 During my inspection of the restricted areas I OBSERVED that all individuals who I encountered, and who were required to wear PERSONNEL DOSIMETERS, were wearing them.

1.7.2 \_\_\_\_\_ identified those individuals under 18 YEARS OF AGE who entered the restricted areas. He DESCRIBED the PROCEDURES followed by each of these individuals and the duration of times spent in the restricted areas. I noted that for each individual whose exposures could reasonably be expected to EXCEED 5% of the LIMITS of 20.101(a) there was on file a Form AEC-5 or its equivalent.

1.7.3 A stated that NO individuals UNDER 18 YEARS OF AGE entered the restricted areas. WDR

1.7.4 By questioning the following individuals \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ who were responsible for controlling access to High Radiation Areas or who entered these areas, I determined that all INDIVIDUALS WHO ENTERED the HIGH RADIATION AREAS were PROVIDED with PERSONNEL MONITORING equipment.

1.7.5 A stated, and my findings verified the fact, that there were NO HIGH RADIATION AREAS under the licensee's control. WDR

1.8 20.203, "CAUTION SIGNS, LABELS, SIGNALS, AND CONTROLS"

1.8.1 In my physical inspection of the operational areas I observed that EACH ROOM OR AREA I visited was POSTED with the appropriate sign reading ( ☒ ) CRM, ( ) CRA, ( ) CHRA, or ( ) CARA, as applicable, and showing the radiation caution symbol. *WRA*

1.8.2 In my physical inspection of the operational area I observed that EACH CONTAINER that required a label was in fact LABELED CRM, showing the radiation caution symbol, the identity of its contents and sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. *WRA*

1.9 20.205, "PROCEDURES FOR OPENING PACKAGES"

1.9.1 I observed that the licensee HAD WRITTEN PROCEDURES for safely opening packages in which radioactive material were received and that these procedures were relevant to the types of packages that were being received. *N I*

1.9.2 I interviewed the individual(s) who were responsible for following these procedures and found that they had the procedures and understood them. *↓*

1.10 20.207, "STORAGE OF LICENSED MATERIALS"

1.10.1 In my inspection of the licensee's facilities, I observed that NO MATERIAL was STORED IN an UNRESTRICTED AREA. *WRA*

1.10.1.1 \_\_\_\_\_ stated that all areas in which MATERIAL was stored were SECURED WHEN UNATTENDED by individuals who had been instructed in the safe use of the material.

1.10.2 I ASCERTAINED by physical inspection that all MATERIAL stored in unrestricted areas was SECURED against unauthorized removal from the place of storage.

1.11 20.301, "WASTE DISPOSAL - GENERAL REQUIREMENTS"

1.11.1 By questioning the RSO and these principal users \_\_\_\_\_, by examination of records of ( ) receipts, ( ) surveys, ( ) effluent monitoring, ( ) inventories, ( ) disposal/transfer, and by my physical inspection of the licensee facilities, I IDENTIFIED the PROCEDURES used by the licensee to dispose of waste material.

1.11.1.1 I determined that no material had been disposed of as waste. *WTH*

1.11.2 I determined that these procedures INVOLVED either one or a combination of the FOLLOWING METHODS: ( ) Transfer to an authorized recipient, ( ) In accordance with a license condition, ( ) Release into sanitary sewage system, ( ) Burial in soil, or ( ) As allowed by 20.106.

1.12 20.303, "DISPOSAL BY RELEASE INTO SANITARY SEWAGE SYSTEMS"

1.12.1 A stated that no licensed material had been released into the sanitary sewage system. *WTH*

1.12.2 In the manner indicated in Paragraph 1.11.1, I IDENTIFIED those OPERATIONS from which waste was discharged to the sanitary sewage system.

1.12.3 By questioning the RSO and these principal users \_\_\_\_\_ regarding the details of the procedures being followed, I determined that the effluent was READILY SOLUBLE or \_\_\_\_\_ water. *DISPERSED*

1.12.4 By questioning the RSO and these principal users \_\_\_\_\_, and by my examination of records of ( ) receipts, ( ) disposals/transfers, ( ) survey of sewage release rates, ( ) calculations of concentrations of material per unit volume of sewage, or ( ) measurements of concentration of material per unit volume of sewage, I determined that:

1. The QUANTITY of radioactive material RELEASED in any one DAY did not exceed the larger of the following limits: (a) Appendix B, Table 1, Col. 2 concentrations averaged over any one day or (b) Ten times the quantity of such material specified in Appendix C.
2. The MONTHLY average did not exceed Appendix B, Table I, Col. 2 CONCENTRATIONS.
3. The GROSS quantity of radioactive MATERIAL did not exceed 1 curie/ year.

1.13 20.304, "DISPOSAL BY BURIAL IN SOIL"

1.13.1 By questioning the RSO and these principal users \_\_\_\_\_ and by examination of records of burials I DETERMINED that the LICENSEE had MET the requirements of this section.

1.13.2 A stated that no licensed material was disposed of by burial in soil. *WTR*

1.13a 20.305, "TREATMENT OR DISPOSAL BY INCINERATION"

1.13a.1 Having noted that incineration was AUTHORIZED BY THE LICENSE, I questioned the RSO and these principal users who utilized this method of disposal, I EXAMINED the RECORDS, which showed the identity of the material, its quantity, and the date of incineration. I also determined that the QUANTITY LIMITATIONS (if any) given in the license had NOT BEEN EXCEEDED. I determined that the licensee had made valid surveys to ensure that the EFFLUENT AND ASH limits given in the license had not been exceeded. I did this by examining his sample collection techniques and his assay procedures.

1.13a.2 By examination of waste disposal records, by questioning the principal users and the RSO, and by physical inspection of the licensee's facilities, I determined that he had NOT UTILIZED INCINERATION as a means of treatment or disposal of material. *WTR*

1.14 20.401 "RECORDS OF SURVEYS, RADIATION MONITORING, AND DISPOSAL"

1.14.1 I examined ( ) all, ( ) approximately \_\_\_% of, the RECORDS OF RADIATION EXPOSURE of all individuals for whom monitoring was required under 20.202. I found that these records were maintained on FORMS AEC-5 or on clear and legible forms containing all the information required by Form AEC-5. I found they were kept in accordance with the INSTRUCTIONS contained ON THE REVERSE SIDE of Form AEC-5.

1.14.2 As indicated in paragraph 1.7.1.1 of these notes no individuals were required to wear personnel monitoring equipment. *WTR*

1.14.3 I examined ( ) all records; (✓) a representative number of records, of surveys conducted in accordance with (✓) 20.201(b), disposals made under ( ) 20.302 (As allowed by License Amendment), ( ) 20.303 (Release to Sanitary Sewers) and ( ) 20.304 (Burial in Soil) and found that the records contained the essential elements for adequate evaluation of compliance. *WTR*

1.15 20.402 "REPORTS OF THEFT OR LOSS OF LICENSED MATERIAL"

1.15.1 A STATED that there had been NO LOSS OR THEFT of licensed material in such quantities and under such circumstances that a substantial hazard might result to persons in unrestricted areas. *WTR*

1.15.1.1 I VERIFIED this fact by comparison of records of ( ) receipts, ( ) inventories, and ( ) disposal/transfer, taking into consideration the decay rates of the various radionuclides.

1.16 20.403, "NOTIFICATION OF INCIDENTS"

1.16.1 In the course of my inspection of all sections of Part 20 I found that there had been NO CIRCUMSTANCES that WARRANTED the submission of NOTIFICATION under 20.403. *WDR*

1.16.2 In the course of my inspection of all sections of Part 20 I found that in each instance where NOTIFICATION had been required such notification HAD BEEN MADE in accordance with the specifications of this section.

1.17 20.405, "REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS"

1.17.1 In the course of my inspection of all sections of Part 20, I found that there had been NO CIRCUMSTANCES that WARRANTED the SUBMISSION of reports under 20.405. *WDR*

1.17.2 In the course of my inspection of all sections of Part 20, I found that in each instance where a 20.405 REPORT had been required the report HAD BEEN SUBMITTED in accordance with the specifications of the section.

1.18 20.407, "PERSONNEL EXPOSURE AND MONITORING REPORTS"

1.18.1 By comparing the licensee's program with the specifications of this section I determined that the provisions of THIS SECTION DID NOT APPLY to the licensee. *WDR*

1.18.2 I compared the licensee's copies of REPORTS with the specifications of this section and determined that they MET THE REQUIREMENTS.

1.19 20.408, "REPORTS OF PERSONNEL EXPOSURE ON TERMINATION OF EMPLOYMENT OR WORK"

1.19.1 As indicated above, I determined that the requirements of 20.407, and hence 20.408, were NOT APPLICABLE to this licensee. *WDR*

1.19.2 By questioning \_\_\_\_\_ and by examining all records that gave evidence of the presence or absence of individuals who were using licensed materials (e.g. Forms AEC-5, B.Z sampling, bioassay isotope committee authorizations, etc.) I IDENTIFIED those INDIVIDUALS who had TERMINATED employment or work. I examined the licensee's copies of reports of their exposures which he had submitted to the AEC. I found that they had been completed in accordance with the requirements of this section.



2.1 30.3, 40.3 and 70.3 "ACTIVITIES REQUIRING LICENSE"

2.1.1 By questioning (✓) the RSO and/or (✓) the following individuals, B C, and/or (✓) by examination of records of (✓) receipts and (✓) transfer/disposal, I determined that the licensee had neither manufactured, produced, transferred, received, acquired, owned, possessed, used imported or exported licensed material except as authorized in a specific or general license issued pursuant to the regulations of Title 10. *Wm*

2.2 30.51, 40.61 and 70.51, "RECORDS"

2.2.1 I inspected the licensee's records of receipt, transfer, export and disposal and found them to be complete; indicating the identities of the materials and the dates of change of status. *Wm*

3.1 19.11 "POSTING OF NOTICES TO WORKERS"

3.1.1 I observed that the licensee had posted current copies of the following documents:

- (1) 10 CFR 19 and 20
- (2) License with conditions and back-up
- (3) Operating procedures
- (4) Notice of Violations, civil penalties and responses from licensee

3.1.2 I observed that the licensee had posted a notice describing documents (1), (2), and (3) and stating where they might be examined. *Wm*

3.1.3 I observed that Forms AEC-3 were posted wherever individuals work in or frequent and portion of a restricted area *Wm*

OR

3.1.3.1 The licensee's activities were such that he was not obliged to designate a restricted area.

3.1.4 I observed that the documents, notices or forms appeared in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applied. *Wm*

I observed that the documents were conspicuously posted and neither defaced nor altered. *Wm*

3.1.6 \_\_\_\_\_ stated that all enforcement correspondence had been posted not later than 2 days following its dispatch or receipt and had remained posted for a minimum of 5 working days or until corrective action had been completed, whichever was later.

3.1.7 By examination of Region I files, I determined that no enforcement correspondence had been exchanged with the licensee since (X) the issuance of the license ( ) the last inspection. *WJR*

### 3.2 19.12, "INSTRUCTIONS TO WORKERS"

3.2.1 I examined a copy of an instruction that \_\_\_\_\_ stated had been issued to all individuals working in or frequenting any portion of a restricted area. I noted that this instruction was commensurate with the potential radiological health problems in the restricted areas, and covered:

- a. Protection problems associated with exposure to relevant radioactive materials or radiation.
- b. Precautions or procedures to minimize exposure.
- c. The purpose and functions of protective devices employed.
- d. The applicable provisions of AEC regulations and licenses.
- e. Responsibility to report unsafe conditions or unnecessary exposures.
- f. Responses to emergency warnings.
- g. Availability of radiation exposure records.

3.2.2 A stated that all individuals working in or frequenting any portion of a restricted area had been given oral instructions in the areas described above. *WJR*

3.2.3 The licensee's activities were such that he was not obliged to establish any restricted area.

### 3.3 19.12, "NOTIFICATIONS AND REPORTS TO INDIVIDUALS"

3.3.1 I asked A if any worker or former worker had requested a copy of his external or internal exposure data since (X) the issuance of the license ( ) the last inspection. He stated that (X) no one had requested such data or ( ) one or more workers or former workers had requested such data. *WJR*

3.3.1.1 I examined copies of the reports that \_\_\_\_\_ stated had been given to these workers. I observed that these reports: (a) provided the appropriate data and this data was in agreement with the data shown on the licensee's records. (b) identified the licensee and the worker (including SSN) (c) contained the boiler plate statement (d) identified the time periods during which the exposures were incurred and the locations at which they were incurred, and (e) were given to the workers within 30 days of request or within 30 days of determination, whichever was later.

3.3.2 By examination of exposure records and questioning of A, I determined that there had been no requirement to submit a 20.405 report since (✓) the issuance of the license or ( ) since the last inspection. *WTR*

3.3.3 My examination of exposure records and questioning of the licensee revealed that 20.405 reports had been submitted since ( ) the issuance of the license or ( ) since the last inspection. I examined these reports, following the guidance of 3.3.1.1 above, and found that the reports were complete.

3.3.4 This licensee was not subject to the provisions of 20.407 and hence to 20.405. *WTR*

3.3.5 \_\_\_\_\_ stated that no worker had terminated his assignment since ( ) the issuance of the license or ( ) since the last inspection.

3.3.6 I identified all individuals whose names appeared on 20.405 reports and examined copies of exposure reports which \_\_\_\_\_ stated had been given to each of these individuals. Following the guidance of 3.3.1.1 above, I determined that each report was complete.

#### 3.4 19.14 "PRESENCE OF REPRESENTATIVES OF LICENSEES AND WORKERS DURING INSPECTIONS"

#### 19.15, "CONSULTATION WITH WORKERS DURING INSPECTIONS"

3.4.1 I experienced no conflict with the provisions of these sections during my inspection. *WTR*

U.S. AEROSPACE BOARD  
REGULATORY OPERATIONS, REGION I  
Inspection Field Notes

Reo 664/3

A. Docket Number		B. Report Number 7401		C. Priority/ Category E-III		D. Inspection Dates July 24-25, 1974	
E. Licensee ETHICON, INC RT 22				F. Facility SOMERVILLE N.J.		G. License No. 29-02796-06	
I. Type of inspection Unannounced Reinspection		L. No. and date of last Amend- ment # 7 11/9/72		J. Dates of Last Inspection 1/71			
K. Principal Inspector and Date of Report WD Allen		L. Accompanying Inspector —		M. Other Accompanying Personnel —			
N. Proprietary Info. None		O. Reviewer R. McVittich		P. Date of Review 8/5/74			
Q. Individuals Interviewed* and Titles a. E. Kendra, RSO b. M. McTernan, Research Scientist c. T. Salt house, Res Scientist d. S. Welyntchak, Tech e. Dr. Charles Artandi, V.P. for Research f. g. h.						R. Date of Interview 7/25/74	
						S. Place of Interview E's office	
T. Enforcement Action 1. 71.5(b) labels } See A-2 2. 71.5(b) surveys }				U. Previous Outstanding Items None			
V. Unresolved Items None				W. Previously Reported Interferences None			
X. Recom. Reinspection 3 years July 77		Y. Name & Tele. # of RSO A- 201-524-0400		Z. RMS Code Number 35			
ZZ. Scope of Inspection: (X) complete, ( ) partial, ( ) special							

## DETAILS

### Scope of the Program

- Number of individuals occupationally exposed 5.
- Number of individuals subject to significant\* risk 1.
- Potential for external exposure

Negligible      Slight      Moderate      High

- Whole body ✓
- Skin ✓
- Extremities

-Potential for internal exposure (✓) negligible (✓) slight ( ) moderate  
( ) high

- Effluents

Negligible      Slight      Moderate      High

- Airborne ✓
- Liquids ✓

- Unusual aspects

### General

All records examined and all inquiries made by the inspector related to records and events made or experienced in the time interval from the date of the last inspection, or the date of license issuance in the case of initial inspections, until the date of this inspection, unless otherwise noted.

Unless otherwise specified, radiation level measurements, shown in these notes as having been made by the inspector, were made using a radiation survey meter type C, model 20, calibrated 6/71 by BVL.

The findings reported here were based on: (1) observations made by the inspector during his physical inspection of the licensee's facilities (2) a selective examination of procedures and representative records and documents, (3) information furnished by individuals interviewed and (4) Measurements made by the inspector.

\*Reasonable probability of incurring 25% or more of MPC or MPE.



### Items of Noncompliance and Safety Found in the Last Inspection

The licensee's action to correct and prevent recurrence of items of noncompliance and/or safety, found in the last inspection, were given particular attention during this inspection. Unless these items are shown under the section below, entitled "Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety", the inspector found that the licensee's corrective and preventive action was adequate.

### Findings Indicating Compliance

Annex A identifies the specific procedures followed by the inspector in determining compliance with each relevant section of Title 10. The inspector also made such inquiries, examined such records and made such observations as were necessary for him to determine that the licensee had complied with the requirements of each license condition.

When a section of Annex A is notated "N/I", this means that compliance with this section was not determined during this inspection. During the next inspection this area will be covered.

When a section of Annex A is notated "N/A", this means that it is readily apparent that the section is not applicable to the licensee's program (e.g. the requirements of 10 CFR 20.103 or 106 are not applicable if the licensee possesses only sealed sources).

The paragraphs in Annex A that are initialed by the inspector indicate how the inspector determined compliance.

### Status of Previously Reported Unresolved Items

### Additional Information Relating to Incidents Reported Since Last Inspection

Attached as Annex B, or referenced on identified pages of these notes.

### Findings Indicating Noncompliance or Conditions Prejudicial to Health and Safety

Attached as Annex C, or referenced on identified pages of these notes.

### Principals

Persons	Radionuclides	Locations of Use	Rate of Use
B	H-3, C-14 some Co 57	3 labs at Ethicon Research Foundation	see - mci/pk

Line of Authority (from user to Management)

user → B → A → E → President

Facilities

Use: (☒) Radiochemistry labs used exclusively for licensed material; (☒) Conventional labs used exclusively for licensed material; (☒) Conventional labs with shared use; ( ) Room or area used exclusively for preparation and application of licensed material, and storage; ( ) Mfg or processing areas designated for radiologic operations only; ( ) Entire building used exclusively for radiologic operations ( ) Other:

Storage:

(☒) Ample space, (☒) Adequate lighting, (☒) Uncluttered, (☒) Shielding adequate  
(☒) Material identified  
(☒) Refrigerator, ( ) cabinet, (☒) fume hood, ( ) cave, (☒) separate room, ( ) separate building

Access Control:

(☒) locked, (☒) posted and administratively controlled  
(☒) locked when unattended, (☒) custodial personnel instructed

Control Devices and Alarms: ( ) 20.203(c)(2), ( ) Other

Comments:

Equipment

Monitoring, portable: ( ) alpha, (☒) beta, (☒) gamma, ( ) neutron  
(☒) adequate no., (☒) accessible, (☒) calibrated, (☒) appropriate sensitivity

Monitoring, area: ( ) alpha, ( ) beta, ( ) gamma, ( ) air sampling, ( ) adequate no.  
( ) properly located, ( ) calibrated, ( ) tested, ( ) appropriate sensitivity.

Special Equipment:

( ) BZ samplers: ( ) adequate no., ( ) properly used, ( ) accessible  
(✓) fume hoods, ( ) glove boxes, ( ) hot cells-large, ( ) hot cells-small  
(✓) local exhaust ventilation, ( ) remote tongs, ( ) shields,  
(✓) protective handwear, (✓) protective footwear, (✓) protective clothing,  
(✓) absorbent paper, (✓) working trays, ( ) designated radioactive waste disposal sinks,  
( ) respirators, ( ) eye wash fountains, ( ) DOP filter testing equipment, (✓) disposable pipettes,  
(✓) disposable syringes, ( ) Other:

Management Interview

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) gave date \_\_\_\_\_ a Form AEC-591 indicating (that no items of) noncompliance had been found during the inspection.

-----

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) informed date \_\_\_\_\_ that no items of noncompliance had been found during this inspection. He informed \_\_\_\_\_ that he would receive a letter enclosing a Form AEC-591 confirming these findings (Inspector: No Form AEC-591 may be issued if there were Outstanding Items reviewed during this inspection except, if our acknowledgement letter, written following the issuance of an AEC Form 592, predated July 1, 1971.)

No form AEC-591 was issued because Outstanding Items had been reviewed during this inspection.

-----

The inspector(s) met with \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ in \_\_\_\_\_'s office, on \_\_\_\_\_, at the conclusion of the inspection. The inspector(s) explained the purpose of the inspection. With respect to the item(s) of noncompliance, the inspector(s) explained the relevant requirements of the AEC regulations and described the inspection findings that indicated noncompliance with these requirements. \_\_\_\_\_ acknowledged the validity of the citation(s) and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar \_\_\_\_\_ of noncompliance would not recur. He signed and dated the Form AEC-591.

-----

The inspector(s) met with \_\_\_\_\_, A and E in E's office, on 7/25/74, at the conclusion of the inspection. The inspector(s) ex-date

plained the purpose of the inspection. With respect to the items of non-compliance, the inspector(s) explained the relevant requirements of the AEC regulations and/or the conditions of the license and described the inspection findings that indicated noncompliance with these requirements.

E acknowledged the validity of the citations and stated that prompt action would be taken to correct them. He also described procedures whereby he would assure that these and similar items of noncompliance would not recur.

- - - - -

Other:

ANNEX A

1.0 10 CFR 20

1.1 20.101, "EXPOSURE OF INDIVIDUAL TO RADIATION IN RESTRICTED AREAS"

1.1.1 by examination of records of (✓) receipts, (✓) inventories, (✓) surveys, (✓) personnel dosimetry, and (✓) disposal transfers, and/or (✓) by questioning the RSO and/or (✓) these users B, ( ) and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE external EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.101(a). WTR

1.1.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitudes of exposure had been found. WTR

1.1.2 I found that the licensee's METHODS of evaluating exposures was in each case APPROPRIATE to the type and energy of the radiation and the area of the individuals body that was at risk. WTR

1.1.3 I found that the licensee's evaluations of exposures showed that NO INDIVIDUAL had been EXPOSED IN EXCESS of the limits of 20.101. WTR

1.1.4 A stated that the licensee did not avail himself of the provisions of 10 CFR 20.101(b) and therefore NO FORMS AEC-4 WERE MAINTAINED. WTR

1.1.5 ( ) I observed a CORRECTLY COMPLETED FORM AEC-4 for each individual whose quarterly whole body exposure exceeded 1.25 rems; or

( ) I identified approximately \_\_\_\_\_% of the individuals whose quarterly whole body exposure had exceeded 1.25 rems and examined each individual's Form AEC-4 and found each to be correctly completed.

1.2 20.103, "EXPOSURE OF INDIVIDUALS TO CONCENTRATIONS OF RADIOACTIVE MATERIAL IN RESTRICTED AREAS"

1.2.1 By examination of records of (✓) receipts, (✓) inventories, (✓) surveys, ( ) personnel dosimetry, ( ) effluent monitoring, (✓) bioassay, and (✓) disposals/transfers, by questioning the RSO and these users B - D, and by my physical inspection of the restricted areas, I IDENTIFIED those INDIVIDUALS WHOSE internal EXPOSURES MIGHT reasonably be expected to EXCEED 25% OF THE LIMITS of 20.103. WTR  
*weekly urine - no indication*

1.2.1.1 I asked the RSO and/or the principal users HOW the EXPOSURES to these individuals had been EVALUATED and what magnitude of exposure had been found. WTR



1.2.2 I found that the licensee's METHODS of evaluating compliance with 20.103 was APPROPRIATE to the circumstances of exposure in each case. *WTR*

1.2.3 I found that the licensee's evaluations of exposures showed that in NO instance had an INDIVIDUAL been EXPOSED IN EXCESS of the limits of 20.103. *WTR*

### 1.3 20.104, "EXPOSURE OF MINORS"

1.3.1 I determined by questioning (☒ the RSO, and/or (☒ <sup>B</sup> and/or (☒ examining Forms AEC-5 or their equivalents and/or (☒ observing individuals in the restricted areas that NO INDIVIDUALS under 18 years of age had been EXPOSED in the restricted areas, or *WTR*

1.3.2 In the manner indicated above, I IDENTIFIED those INDIVIDUALS under 18 years of age who had been exposed in the restricted areas by questioning ( ) the RSO, ( ) the minors, ( ) the minor's supervisors. I determined the circumstances of exposure and the licensee's method of evaluating the minor's exposures. I determined that the METHOD OF EVALUATION had been ADEQUATE. I found that the evaluations showed that the exposures had NOT EXCEEDED 10% of the limits of 10 CFR 20.101(a).

### 1.4 20.105, "PERMISSIBLE LEVELS OF RADIATION IN UNRESTRICTED AREAS"

1.4.1 By questioning the RSO and/or the principal users, and (☒ by examining records of (☒ receipts, (☒ inventories, (☒ disposals/transfers, and (☒ surveys, and by a physical inspection of the restricted areas, I DETERMINED the TIMES AND CIRCUMSTANCES under WHICH the licensee's use and/or storage of materials would have resulted in the generation of exposure levels in the unrestricted area of a magnitude of WARRANTED CALCULATION OR MEASUREMENT to assure compliance with 20.105. *WTR*

1.4.2 I questioned the RSO and/or the involved principal users to determine if these calculations or MEASUREMENTS had been MADE; HOW they had been MADE; and what CONCLUSIONS had been DRAWN. I found that adequate surveys had been made indicating that the levels of radiation in the unrestricted area had not exceeded the limits of 20.105.

1.4.3 I MEASURED THE EXPOSURE RATES IN THE UNRESTRICTED AREAS and found that at the time of inspection none exceeded the allowed levels.

114.4 Following the procedures described in paragraph 1.4.1 above, I determined that there had been NO circumstances under which there was any REASONABLE PROBABILITY OF the levels HAVING EXCEEDED the limits of 20.105. *WTR*

115 20.106, "CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS"

115.1 By questioning the RSO and these principal users B, by examination of records of (X) receipts, (T) inventories, (.) effluent monitoring, and (.) surveys, (T) and by observations made during my physical inspection of the restricted areas, I IDENTIFIED those OPERATIONS WHERE there was a REASONABLE PROBABILITY of generation OF CONCENTRATIONS of radioactive material in effluents to the unrestricted area. *WTR*

115.2 I asked the RSO or the principal user to describe the evaluation that had been made to ASSURE that the CONCENTRATION of radioactive material in these effluents DID NOT EXCEED THE LIMITS of 20.106. *WTR*

115.3 I determined that the licensee's (X) calculations, (.) location of samplers, (.) collection methods, and (.) assay methods were SUITABLE for EVALUATION of the concentrations of the types of radioactive material that were discharged (i.e. considering its identity, physical and chemical form, particle size, the presence of dust loading or moisture . . . etc). I noted that the licensee's evaluations showed compliance with 20.106.

115.4 Having assured myself, from the findings of previous AEC inspectors, that the licensee's procedures for calculating, sampling and assaying the samples were in accord with accepted practices I ONLY EXAMINED the RECORDS of his measured concentrations. I found that these showed him to be in compliance with 20.106.

115.5 Following the procedures described in paragraph 115.1 above, I determined that quantities and forms of the material, and the circumstances under which it was handled were such that THERE WAS NO SIGNIFICANT PROBABILITY OF VIOLATION OF THE SECTION. *No releases*

*all H-3 is contained in undiluted form - no*  
116 20.201, "SURVEYS" *open work until extremely dilute*

116.1 In the course of determining the licensee's status of compliance with all sections of Part 20, I found that ADEQUATE SURVEYS had been CONDUCTED - *with exception of surveys*

*of barrels prior to shipment - see A-2*

## 1.7 20.202, "PERSONNEL MONITORING"

1.7.1 As stated in paragraph 1.1.1 above, I identified those individuals whose external exposure might reasonably be expected to exceed 25% of the 20.101(a) limits. I ascertained that a FORM AEC-5 or its equivalent was maintained FOR EACH of these INDIVIDUALS. *WTH*

1.7.1.1 I concurred in the licensee's evaluation that personnel monitoring was not required for any individual using material under this license.

1.7.1.2 A stated that each of these individuals had been INSTRUCTED TO WEAR his personnel DOSIMETER while he was in the restricted areas. *WTH*

1.7.1.3 I noted that the licensee's written OPERATING PROCEDURES directed occupants of the restricted areas to wear their personnel dosimeters. *WTH*

1.7.1.4 During my inspection of the restricted areas I OBSERVED that all individuals who I encountered, and who were required to wear PERSONNEL DOSIMETERS, were wearing them. *WTH*

1.7.2        identified those individuals under 18 YEARS OF AGE who entered the restricted areas. He DESCRIBED the PROCEDURES followed by each of these individuals and the duration of times spent in the restricted areas. I noted that for each individual whose exposures could reasonably be expected to EXCEED 5% of the LIMITS of 20.101(a) there was on file a Form AEC-5 or its equivalent.

1.7.3 A stated that NO individuals UNDER 18 YEARS OF AGE entered the restricted areas. *WTH*

1.7.4 By questioning the following individuals       ,       , and        who were responsible for controlling access to High Radiation Areas or who entered these areas, I determined that all INDIVIDUALS WHO ENTERED the HIGH RADIATION AREAS were PROVIDED with PERSONNEL MONITORING equipment.

1.7.5 A stated, and my findings verified the fact, that there were NO HIGH RADIATION AREAS under the licensee's control. *WTH*

1.8 20.203, "CAUTION SIGNS, LABELS, SIGNALS, AND CONTROLS"

1.8.1 In my physical inspection of the operational areas I observed that EACH ROOM OR AREA I visited was POSTED with the appropriate sign reading (✓) CRM, ( ) CRA, ( ) CHRA, or ( ) CARA, as applicable, and showing the radiation caution symbol. *WJ*

1.8.2 In my physical inspection of the operational area I observed that EACH CONTAINER that required a label was in fact LABELED CRM, showing the radiation caution symbol, the identity of its contents and sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. *WJ*

1.9 20.205, "PROCEDURES FOR OPENING PACKAGES"

1.9.1 I observed that the licensee HAD WRITTEN PROCEDURES for safely opening packages in which radioactive material were received and that these procedures were relevant to the types of packages that were being received. *NI*

1.9.2 I interviewed the individual(s) who were responsible for following these procedures and found that they had the procedures and understood them. *✓*

1.10 20.207, "STORAGE OF LICENSED MATERIALS"

1.10.1 In my inspection of the licensee's facilities, I observed that NO MATERIAL was STORED IN an UNRESTRICTED AREA. *WJ*

1.10.1.1 \_\_\_\_\_ stated that all areas in which MATERIAL was stored were SECURED WHEN UNATTENDED by individuals who had been instructed in the safe use of the material.

1.10.2 I ASCERTAINED by physical inspection that all MATERIAL stored in unrestricted areas was SECURED against unauthorized removal from the place of storage.

1.11 20.301, "WASTE DISPOSAL - GENERAL REQUIREMENTS"

1.11.1 By questioning the RSO and these principal users *B - P*, by examination of records of (✓) receipts, ( ) surveys, ( ) effluent monitoring, ( ) inventories, (✓) disposal/transfer, and by my physical inspection of the licensee facilities, I IDENTIFIED the PROCEDURES used by the licensee to dispose of waste material. *WJ*

1.11.1.1 I determined that no material had been disposed of as waste.

1.11.2 I determined that these procedures INVOLVED either one or a combination of the FOLLOWING METHODS: (✓) Transfer to an authorized recipient, ( ) In accordance with a license condition, ( ) Release into sanitary sewage system, ( ) Burial in soil, or ( ) As allowed by 20.106. WJ

1.12 20.303, "DISPOSAL BY RELEASE INTO SANITARY SEWAGE SYSTEMS"

1.12.1 A stated that no licensed material had been released into the sanitary sewage system. *only trace amounts in 3d washing of glassware* WJ

1.12.2 In the manner indicated in Paragraph 1.11.1, I IDENTIFIED those OPERATIONS from which waste was discharged to the sanitary sewage system.

1.12.3 By questioning the RSO and these principal users \_\_\_\_\_ regarding the details of the procedures being followed, I determined that the effluent was READILY SOLUBLE or \_\_\_\_\_ water. IMPERMISSIBLE

1.12.4 By questioning the RSO and these principal users \_\_\_\_\_, and by my examination of records of ( ) receipts, ( ) disposals/transfers, ( ) survey of sewage release rates, ( ) calculations of concentrations of material per unit volume of sewage, or ( ) measurements of concentration of material per unit volume of sewage, I determined that:

1. The QUANTITY of radioactive material RELEASED in any one DAY did not exceed the larger of the following limits: (a) Appendix B, Table 1, Col. 2 concentrations averaged over any one day or (b) Ten times the quantity of such material specified in Appendix C.
2. The MONTHLY average did not exceed Appendix B, Table I, Col. 2 CONCENTRATIONS.
3. The GROSS quantity of radioactive MATERIAL did not exceed 1 curie/year.

1.13 20.304, "DISPOSAL BY BURIAL IN SOIL"

1.13.1 By questioning the RSO and these principal users \_\_\_\_\_ and by examination of records of burials I DETERMINED that the LICENSEE had MET the requirements of this section.



1.13.2 D stated that no licensed material was disposed of by burial in soil. *WTR*

1.13a 20.305, "TREATMENT OR DISPOSAL BY INCINERATION"

1.13a.1 Having noted that incineration was AUTHORIZED BY THE LICENSE, I questioned the RSO and these principal users who utilized this method of disposal, I EXAMINED the RECORDS, which showed the identity of the material, its quantity, and the date of incineration. I also determined that the QUANTITY LIMITATIONS (if any) given in the license had NOT been EXCEEDED. I determined that the licensee had made valid surveys to ensure that the EFFLUENT AND ASH limits given in the license had not been exceeded. I did this by examining his sample collection techniques and his assay procedures.

1.13a.2 By examination of waste disposal records, by questioning the principal users and the RSO, and by physical inspection of the licensee's facilities, I determined that he had NOT UTILIZED INCINERATION as a means of treatment or disposal of material. *WTR*

1.14 20.401 "RECORDS OF SURVEYS, RADIATION MONITORING, AND DISPOSAL"

1.14.1 I examined ( ) all, (✓) approximately 50 % of, the RECORDS OF RADIATION EXPOSURE of all individuals for whom monitoring was required under 20.202. I found that these records were maintained on FORMS AEC-5 or on clear and legible forms containing all the information required by Form AEC-5. I found they were kept in accordance with the INSTRUCTIONS contained ON THE REVERSE SIDE of Form AEC-5. *WTR*

1.14.2 As indicated in paragraph 1.7.1.1 of these notes no individuals were required to wear personnel monitoring equipment.

1.14.3 I examined ( ) all records; (✓) a representative number of records, of surveys conducted in accordance with (✓) 20.201(b), disposals made under ( ) 20.302 (As allowed by License Amendment), ( ) 20.303 (Release to Sanitary Sewers) and ( ) 20.304 (Burial in Soil) and found that the records contained the essential elements for adequate evaluation of compliance. *WTR*

1.15 20.402 "REPORTS OF THEFT OR LOSS OF LICENSED MATERIAL"

1.15.1 A STATED that there had been NO LOSS OR THEFT of licensed material in such quantities and under such circumstances that a substantial hazard might result to persons in unrestricted areas. *WTR*

1.15.1.1 I VERIFIED this fact by comparison of records of (✓) receipts, (✓) inventories, and (✓) disposal/transfer, taking into consideration the decay rates of the various radionuclides. *WTR*

1.16 20.403, "NOTIFICATION OF INCIDENTS"

1.16.1 In the course of my inspection of all sections of Part 20 I found that there had been NO CIRCUMSTANCES that WARRANTED the submission of NOTIFICATION under 20.403. *WTR*

1.16.2 In the course of my inspection of all sections of Part 20 I found that in each instance where NOTIFICATION had been required such notification HAD BEEN MADE in accordance with the specifications of this section.

1.17 20.405, "REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS"

1.17.1 In the course of my inspection of all sections of Part 20, I found that there had been NO CIRCUMSTANCES that WARRANTED the SUBMISSION of reports under 20.405. *WTR*

1.17.2 In the course of my inspection of all sections of Part 20, I found that in each instance where a 20.405 REPORT had been required the report HAD BEEN SUBMITTED in accordance with the specifications of the section.

1.18 20.407, "PERSONNEL EXPOSURE AND MONITORING REPORTS"

1.18.1 By comparing the licensee's program with the specifications of this section I determined that the provisions of THIS SECTION DID NOT APPLY to the licensee. *WTR*

1.18.2 I compared the licensee's copies of REPORTS with the specifications of this section and determined that they MET THE REQUIREMENTS.

1.19 20.408, "REPORTS OF PERSONNEL EXPOSURE ON TERMINATION OF EMPLOYMENT OR WORK"

1.19.1 As indicated above, I determined that the requirements of 20.407, and hence 20.408, were NOT APPLICABLE to this licensee. *WTR*

1.19.2 By questioning \_\_\_\_\_ and by examining all records that gave evidence of the presence or absence of individuals who were using licensed materials (e.g. Form AEC-5, B.Z. sampling, bioassay isotope committee authorizations, etc.) I IDENTIFIED those INDIVIDUALS who had TERMINATED employment or work. I examined the licensee's copies of reports of their exposures which he had submitted to the AEC. I found that they had been completed in accordance with the requirements of this section.

2.1 30.3, 40.3 and 70.3 "ACTIVITIES REQUIRING LICENSE"

2.1.1 By questioning (✓) the RSO and/or (✓) the following individuals, re - e, and/or (✓) by examination of records of (✓) receipts and (✓) transfer/disposal, I determined that the licensee had neither manufactured, produced, transferred, received, acquired, owned, possessed, used imported or exported licensed material except as authorized in a specific or general license issued pursuant to the regulations of Title 10. *WTH*

2.2 30.51, 40.61 and 70.51, "RECORDS"

2.2.1 I inspected the licensee's records of receipt, transfer, export and disposal and found them to be complete; indicating the identities of the materials and the dates of change of status. *WTH*

3.1 19.11 "POSTING OF NOTICES TO WORKERS"

3.1.1 I observed that the licensee had posted current copies of the following documents:

- (1) 10 CFR 19 and 20
- (2) License with conditions and back-up
- (3) Operating procedures
- (4) Notice of Violations, civil penalties and responses from licensee

3.1.2 I observed<sup>2</sup> that the licensee had posted a notice describing documents (1), (2), and (3) and stating where they might be examined. *WTH*

3.1.3 I observed that Forms AEC-3 were posted wherever individuals work in or frequent and portion of a restricted area *WTH*

OR

3.1.3.1 The licensee's activities were such that he was not obliged to designate a restricted area.

3.1.4 I observed that the documents, notices or forms appeared in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applied. *WTH*

I observed that the documents were conspicuously posted and neither defaced nor altered. *WTH*

3.1.6 \_\_\_\_\_ stated that all enforcement correspondence had been posted not later than 2 days following its dispatch or receipt and had remained posted for a minimum of 5 working days or until corrective action had been completed, whichever was later.

3.1.7 By examination of Region I files, I determined that no enforcement correspondence had been exchanged with the licensee since ( ) the issuance of the license (✓) the last inspection. *WTA*

3.2 19.12, "INSTRUCTIONS TO WORKERS"

3.2.1 I examined a copy of an instruction that \_\_\_\_\_ stated had been issued to all individuals working in or frequenting any portion of a restricted area. I noted that this instruction was commensurate with the potential radiological health problems in the restricted areas, and covered:

- a. Protection problems associated with exposure to relevant radioactive materials or radiation.
- b. Precautions or procedures to minimize exposure.
- c. The purpose and functions of protective devices employed.
- d. The applicable provisions of AEC regulations and licenses.
- e. Responsibility to report unsafe conditions or unnecessary exposures.
- f. Responses to emergency warnings.
- g. Availability of radiation exposure records.

3.2.2 A. J. stated that all individuals working in or frequenting any portion of a restricted area had been given oral instructions in the areas described above. *WTA*

3.2.3 The licensee's activities were such that he was not obliged to establish any restricted area.

3.3 19.12, "NOTIFICATIONS AND REPORTS TO INDIVIDUALS"

3.3.1 I asked \_\_\_\_\_ if any worker or former worker had requested a copy of his external or internal exposure data since ( ) the issuance of the license (✓) the last inspection. He stated that (✓) no one had requested such data or ( ) one or more workers or former workers had requested such data. *WTA*

A-II

3.3.1.1 I examined copies of the reports that \_\_\_\_\_ stated had been given to these workers. I observed that these reports: (a) provided the appropriate data and this data was in agreement with the data shown on the licensee's records. (b) identified the licensee and the worker (including SSN) (c) contained the boiler plate statement (d) identified the time periods during which the exposures were incurred and the locations at which they were incurred, and (e) were given to the workers within 30 days of request or within 30 days of determination, whichever was later.

3.3.2 By examination of exposure records and questioning of A, I determined that there had been no requirement to submit a 20.405 report since ( ) the issuance of the license or ( ) since the last inspection. *WA*

3.3.3 My examination of exposure records and questioning of the licensee revealed that 20.405 reports had been submitted since ( ) the issuance of the license or ( ) since the last inspection. I examined these reports, following the guidance of 3.3.1.1 above, and found that the reports were complete.

3.3.4 This licensee was not subject to the provisions of 20.407 and hence to 20.408. *WA*

3.3.5 \_\_\_\_\_ stated that no worker had terminated his assignment since ( ) the issuance of the license or ( ) since the last inspection.

3.3.6 I identified all individuals whose names appeared on 20.408 reports and examined copies of exposure reports which \_\_\_\_\_ stated had been given to each of these individuals. Following the guidance of 3.3.1.1 above, I determined that each report was complete.

3.4 19.14 "PRESENCE OF REPRESENTATIVES OF LICENSEES AND WORKERS DURING INSPECTIONS"

19.15. "CONSULTATION WITH WORKERS DURING INSPECTIONS"

3.4.1 I experienced no conflict with the provisions of these sections *WB*  
during my inspections



Small research program  
very tightly controlled by B. Libs  
were spotted, locked and properly  
posted. Thorough ~~some~~ survey  
done 1/3 mo by <sup>last 7/2/74</sup> Teledyne in all  
areas of use. No releases, spot  
check done by B. Records very  
neat and thorough. No iodine  
work to date. Last inventory 5/1/71  
all OK.