

Mallinckrodt

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NUCLEAR

April 25, 1974

Mr. Bernard Singer, Chief
Materials Branch
Directorate of Licensing
U.S. Atomic Energy Commission
Washington, D. C. 20545

Reference: Control No. 41268
USAEC License
No. 24-04206-01

Dear Mr. Singer:

This letter is in response to your letter dated October 31, 1973, requesting additional information in order to continue your review of our application for renewal of our license.

Enclosed are the following three documents:

1. An outline of the Radiation Safety Lectures.
2. A more complete description of the Radiation Safety Committee's Administrative Procedures.
3. The criteria for performing bioassays and the levels set as action points for bioassays results.

Please advise us if there is any additional information you may require.

Sincerely,

MALLINCKRODT NUCLEAR
MALLINCKRODT CHEMICAL WORKS

Donald W. Soldan

Donald W. Soldan
Chief Radiological
Protection Officer

DWS:ja

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RADIOLOGICAL PROTECTION
SAFETY LECTURE
FOR NEW PERSONNEL

I. Radiation

- A. Beta
- B. Gamma

II Measurements of Radioactive Material

- A. Curie
 - 1. mCi
 - 2. uCi

III Radiation Units and Dose

- A. Roentgen
- B. Rad
- C. Rem

IV. External Exposure

- A. Limits
 - 1. Regulatory
 - 2. Inhouse
- B. Means of Measurements
 - 1. Dosimeter
 - 2. Film Badge
 - 3. Survey Meter

V. Internal Exposure

- A. Limits
 - 1. Regulatory
 - 2. Inhouse
- B. Means of Measurements
 - 1. Uptake Measurements
 - 2. Urinalysis

VI. External Protection

- A. Time - Rate
- B. Distance - Inverse Square
- C. Shielding - Half Value Thickness

VII. Internal Protection

- A. Enclosures
- B. Protective Clothing
- C. Respirators
- D. Protective Measures
 - 1. Air Samples
 - 2. LCLS
 - 3. Uptake Measurements
 - 4. Contamination Surveys

VII. Technique

- A. To Reduce External Exposure
- B. To Reduce Internal Exposure
- C. For Waste

IX. Training Fascicles

- A. Transportation of Radioactive Materials.
- B. Philosophy of Radiation Protection.
- C. Control of Internal Protection Hazards.
- D. Basic Principles of Radiation Protection.
- E. Radiation Protection Guides.
- F. Minimum Shielding Required for Laboratory Areas.
- G. Health Physics Procedures Manual.

X. Documents Available for Review

- A. AEC Regulations.
 - 1. 10 CFR Part 19
 - 2. 10 CFR Part 20
- B. USAEC License No. 24-04206-01.
- C. All ICRP Publications.
- D. Emergency Procedures Manual.
- E. Health Physics Procedures Manual.

RADIATION SAFETY COMMITTEE

The first meeting of the Radiation Safety Committee established that a quorum consisted of four members of the Committee, one of whom must be the Chairman or Alternate Chairman. A quorum now consists of five members. This change was made at a special meeting held on November 29, 1973, considering the fact that the Committee now consists of nine members as submitted to you in our application for renewal of our license dated September 21, 1973.

A memorandum entitled "Radiation Safety Committee Functions" dated November 5, 1969, and attached paragraphs from 10CFR33 were designated as a preamble to existing and new administrative procedures to be developed and documented by the Committee, thus establishing the scope and purpose of the Committee at the second meeting held November 7, 1969.

The main contents of the above memorandum are as follows:

Conceptually, a Radiation Safety Committee is an extension of the USAEC Directorate of Licensing and Directorate of Regulatory Operations. Evaluations otherwise made by the Directorate of Licensing may be made for the Commission by the Committee. Appropriate administrative procedures are to be established by the Committee to assure control of the use and procurement of byproduct materials. Implicit in this statement is the intent that the Committee will perform inspections as would the Directorate of Regulatory Operations. The results of all such evaluations and inspections are to be documented as would the Commission.

Although representatives of the Commission, we as a Committee do not have the prerogative to institute any changes which would constitute an amendment to our license.

The paragraphs excerpted and attached from 10CFR33 were:

33.1, 33.11 (a), 33.13, and 33.17 (a) and (b) with key phrases in paragraphs 33.13 (b) (3) and 33.17 (b) underlined for attention.

A proposed procedure for the control of new uses of radioactive materials by individual departments was submitted to and approved by the Radiation Safety Committee at its third meeting held November 14, 1969.

This procedure adapted the activities listed in paragraph 33.100, Schedule A, as new use limits in the following manner:

1. Any proposed new use of radioactive materials in quantities in excess of those specified in Column I, Schedule A, must be approved by the Radiation Safety Committee prior to use of the byproduct material.
2. Any proposed new use of radioactive material in quantities in excess of those specified in Column II, Schedule A, must be approved by the Radiological Safety Officer prior to use of the byproduct material.
3. Any proposed new use of radioactive materials in quantities less than those specified in Column II, Schedule A, must be approved by an individual approved by the Radiation Safety Committee to use or supervise the use of byproduct materials prior to use.
4. Independent of the above guidelines, prior approval for any new use of radioactive materials must be obtained from the Radiation Safety Committee if the proposed processing or experimentation is of a sufficiently hazardous nature.

The applicable radionuclides excerpted from paragraph 33.100, Schedule A, are as follows:

<u>Schedule A</u> <u>Radionuclide</u>	<u>Column I</u> <u>Curies</u>	<u>Column II</u> <u>Curies</u>
Carbon-14	100	1
Chromium-51	100	1
Hydrogen-3	100	1
Technetium-99m	100	1

<u>Radionuclide</u>	<u>Millicuries</u>	<u>Millicuries</u>
Cesium-137	100	1
Cobalt-57	100	1
Cobalt-60	100	1
Gold-198	10,000	100
Iodine-125	100	1
Iodine-131	100	1
Iron-59	1,000	10
Mercury-197	10,000	100
Mercury-203	1,000	10
Molybdenum-99	10,000	100
Phosphorous-32	1,000	10
Selenium-75	1,000	10
Strontium-85	1,000	10

In addition to the guidelines established above, a memorandum dated August 20, 1973, from Mr. Richard L. Holgate, Director of Operations, to all Department Managers stated the following:

Any contemplated increase in the amount of activity or change in the method to be used or new use of radioactive materials which might affect the Radiation Safety Program in your area must be reviewed by Don Soldan, as Chairman of the Radiation Safety Committee, before the plan is put into effect. Don may approve the plan if he decides that the change will not increase the exposure of personnel or the general populace. If uncertain, he will call a meeting of the Radiation Safety Committee for joint review of the planned change.

Inherent in the decision making process are the following considerations:

1. The experience and qualifications of the individuals who will use the radioactive material.
2. The adequacy of the facilities including the containment systems, shielding and apparatus.
3. The methodology to be used.
4. The quantity of radioactive material involved.
5. The decay scheme and halflife of the radionuclide.
6. The biological fate of the radionuclide in the body.

It is worthwhile to note that the quantities listed in

Schedule A were determined by the Commission using many of the above considerations which was the reason we adopted them as guidelines.

The Committee also approved a list of individuals to use or directly supervise the use of byproduct material at its third meeting held November 14, 1969. This list essentially consisted of members of the Radiation Safety Committee and line managers and supervisors.

Considering the many personnel changes that have taken place since the original list was approved, a memorandum dated February 12, 1974, a copy of which is enclosed, was distributed to update our classifications of all individuals in accordance with our Health Physics Procedures Manual.

A meeting of the Radiation Safety Committee is held under any of the following circumstances:

1. The minutes of the first Committee meeting established that the Secretary would inquire on a monthly basis to determine whether any of the members were aware of any situation which required the attention of the Committee.
2. Any Committee member may request the Chairman to call a meeting at any time for any reason.
3. Any exposures or excessive levels of radiation or air concentrations which require a report to the Commission also require a Committee meeting for joint resolution of the problem.
4. A meeting is held to resolve any items of non-compliance noted during an inspection by the Commission.
5. A meeting is held prior to any new use of radioactive materials within the scope of the Committee.

A Committee meeting was held on March 19, 1974, to review and approve the classifications of individuals submitted as per the February 12, 1974, memorandum on this subject. As a result of this meeting, an additional classification was established. All individuals were classified by the Committee in one of the following five classifications:

1. Class I Members of the Radiation Safety Committee who by recognition of their knowledge and experience are licensed users of byproduct materials.
2. Class II Individuals approved by the Committee to use or directly supervise the use of byproduct materials.
3. Class III Individuals approved by the Committee to use or directly supervise the use of byproduct materials within their specific area of responsibility.
4. Class IV Individuals who may use byproducts materials only under direct supervision.
5. Class V Individuals who do not use byproduct materials.

It was also established that Mallinckrodt drivers in Class IV are exempt from direct supervision when picking up or delivering byproduct materials packaged in accordance with DOT regulations.

February 12, 1974

ATTENTION: All Department Managers

INFORMATION: W. K. Fadling
R. E. Nuelle

Our Health Physics Procedures Manual defines authorized personnel in four classifications.

1. Class I Members of the Radiation Safety Committee who by recognition of their knowledge and experience are licensed users of byproduct materials.
2. Class II Individuals approved by the Committee to use or directly supervise the use of byproduct materials.
3. Class III Individuals who may use byproduct materials only under direct supervision.
4. Class IV Individuals who do not use byproduct materials.

We must update our classifications of all individuals considering the many personnel changes that have taken place in order to meet the requirements of our license as established in previous Radiation Safety Committee Meetings.

Please submit to me promptly a listing of all individuals who report directly or indirectly to you and classify each individual II, III or IV according to the above definitions.

Your listing of all individuals in Class II will be reviewed by the Radiation Safety Committee for possible approval to use or supervise the use of byproduct materials.

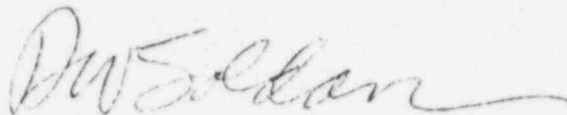
The USAEC has established criteria for "users" of byproduct materials in 10 CFR33.15,(b) (1) and (2) as follows:

- (1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

- (2) Training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used:

You should use the above criteria as a guide in classifying your personnel. Future approval shall be required by the Committee before you may advance an individual into a Class III category or from Class III to Class II.

It is my intention to use the above 10 CFR33.15 paragraph as the criteria for approval by our Committee of authorized users as requested in the Commission's October 31, 1973, response to our application for renewal of our license.



D.W. Soldan

DWS:ja

MALLINCKRODT/NUCLEAR
BIOASSAY PROGRAM

CRITERIA FOR PERFORMING BIOASSAYS

Iodine-131 and Iodine-125

A direct thyroid burden measurement using an external gamma probe is required:

1. If prescribed on certain Master Batch Sheets immediately before processing and after completion.
2. At least weekly of all individuals who work routinely in areas wherein Iodine products are processed, handled or stored.
3. Of all individuals working in an area within which elevated air concentrations of Iodine are measured.
4. Of all individuals working in an area within which an uncontained spill of Iodine occurs.
5. Whenever external personal contamination identified as Iodine is detected upon an individual.

Mercury-203 and Mercury-197

A direct kidney burden measurement using an external gamma probe is required:

1. If prescribed on certain Master Batch Sheets immediately before processing and after completion.
2. Of all individuals working in an area within which elevated concentrations of Mercury are measured.
3. Of all individuals working in an area within which an uncontained spill of Mercury occurs.
4. Whenever external personal contamination identified as Mercury is detected upon an individual.

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All Radionuclides

A urinalysis is required:

1. At least monthly of all individuals who work routinely in areas within which Radionuclides are processed, handled or stored.
2. Of all individuals working in an area within which elevated air concentrations of radioactive materials are measured.
3. Of all individuals working in an area within which an uncontained spill of radioactive materials occurs.
4. Whenever external personal contamination by radioactive materials is detected upon an individual.

CRITERIA FOR LEVELS SET AS ACTION POINTS

The derived investigation levels established in ICRP 10 shall be used as action points.