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THE UPJOHN COMPANY

KALAMAZOO, MICHIGAN 49001, U.S.A.

September 3, 1985

Mr. D. J. Sreniawski, Chief
Nuclear Materials Safety Section 2
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Sreniawski:

Subject: NRC By-Product Material Licenses No. 21-00182-03, No. 21-00182-07G, and No. 21-00182-06E. NRC Safety Inspection conducted June 5-7, 1985. Your letter dated June 20, 1985.

The Upjohn Company is pleased that no items of non-compliance with Nuclear Regulatory Commission (NRC) requirements were identified relevant to Licenses No. 21-00182-07G and No. 21-00182-06E.

We herewith submit responses to NRC concerns and to NRC Notice of Violation citations relative to certain conditions of License No. 21-00182-03. NRC concerns and citations have been restated in bold type, for clarity. The Upjohn Company response follows each NRC statement, and is, in some cases, augmented by supplemental information in Appendices I-VI, inclusive, which should be considered part of this letter and our response.

A. NRC Concerns regarding Amendment No. 22.

1. Regarding License Condition No. 21, it appears individuals responsible for gauge "lock outs" are aware of this requirement, and that adequate steps were taken to terminate radiation beams during a maintenance outage in 1984. However, as of June 7, 1985, formal "lock out" procedures have not been established.

UPJOHN RESPONSE

The Upjohn Company has had a long standing practice regarding "lock out" procedures to be used during repair of equipment, irrespective of whether or not the equipment is used for radioactive material. While we believe these general procedures covered equipment used for radiolabeled material, we have nevertheless implemented steps to establish formal lock out procedures to be followed during maintenance of any energizeable equipment. A revised "Locking and Tagging of Equipment" procedure was approved by the Engineering and Maintenance Safety Task Force on August 22, 1985, and a copy is enclosed as Appendix I.

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REG3 LIC30
21-00182-03 PDR

Office of
GUNTHER S. FONKEN, Ph.D.
Vice President
Pharmaceutical Research &
Development Administration &
Support Operations

TELEPHONE (616) 385-7118

~~FILE~~

IED7

SEP 4 1985

2. **Regarding License Condition No. 18, the inspector noted that high and intermediate level laboratories are currently not all being surveyed weekly.**

UPJOHN RESPONSE

We intend to petition NRC to amend Licence Condition No. 18 to establish survey frequencies based on type and quantity of radionuclides actually used in laboratories during active processing of radiolabeled materials on a continuous basis. This approach was discussed during a meeting with Mr. G. M. McCann, Material Licensing Section, and Mr. W. J. Slawinski, Safety Inspection, held at your headquarters on July 24, 1985.

Our petition will propose an alternative survey frequency schedule which will be submitted to the Materials Licensing Section for review and approval. Our intent is to submit this petition in October 1985. We understand that our next inspection will include review of our compliance with Condition No. 18 as now stated or as amended as a result of our petition.

3. **Also, we are concerned that you have no system established for confirming if laboratory researchers are ordering more material than your Radiation Control Committee authorizations allow. Our inspector discovered that some researchers are not aware of their possession limits. Please describe what actions you plan to take regarding these concerns.**

UPJOHN RESPONSE

We are implementing a procedure assuring that the following information will be conspicuously posted in each laboratory approved for use of radiolabeled material:

- name of the Approved Radioisotope Investigator
- approved isotopes and their possession limits
- emergency telephone number

A copy of the posting notice is included as Appendix II.

Concurrently we are updating our computer data bases to reflect approved possession limits. This information will be reviewed by the Radiation Control staff prior to initiation of any radionuclide purchase order.

We believe these actions should allay your concerns regarding inadvertent ordering of materials that exceed authorized possession limits.

B. Notice of Violation

1. **10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage.**

10 CFR 20.207(b) requires that materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)17, an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 6, 1985, licensed materials stored in an unrestricted area were not secured from unauthorized removal from their place of storage, nor were they under constant surveillance or your immediate control. Specifically, licensed materials were stored in unlocked refrigerators, located in a hallway on the third floor of Building 25. This hallway is an unrestricted area accessible to Upjohn employees and visitors.

This is a Severity Level IV violation (Supplement IV).

UPJOHN RESPONSE

Our hallways are not open to the general public. All visitors to our facilities must be escorted by Upjohn personnel. Visitors do not have access to our refrigerators and freezers. Nevertheless, we have required that locks be installed on all refrigerators located in hallways, if they are used for storage of radioactive materials, and have notified management that refrigerators containing licensed materials must be locked. (Please refer to the memorandum in Appendix III.)

2. License Condition No. 17, Amendment 21, and License Condition No. 25, Amendment 22, require that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications, manuals, and letters.

The Radiation Control Manual (revised December 22, 1977) referenced in Amendment 21, and the Manual (revised April 16, 1984) referenced in letter dated December 7, 1983, both state on Page 9 that "users of five millicuries or more of iodine-125 or iodine-131 should have a thyroid monitor test on a regularly scheduled basis, e.g. once a month."

Contrary to the above, thyroid bioassay requirements have not been met. Specifically, two individuals who performed iodinations in April and May 1985, using five millicuries of iodine-125, did not have their thyroids monitored.

This is a Severity Level IV violation (Supplement VI).

UPJOHN RESPONSE

The Radiation Officer has instructed the Radioactive Materials & Controlled Substances Specialist to institute specific changes of internal procedures to assure that all users of I-125 and I-131 have regular thyroid bioassays. (Please refer to the memorandum in Appendix IV.)

3. License Condition No. 25 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced letter dated December 7, 1983, transmitted your Radiation Control Manual (revised April 16, 1984). This manual states on Page 13 that "eating, drinking, smoking and the applications of cosmetics in the radioactive laboratory are forbidden."

Contrary to this requirement, during the course of the NRC inspectors laboratory tours on June 6, 1985, an individual was found to be consuming a soft drink in a laboratory actively using radioactive materials in unsealed form.

This is a Severity Level IV violation (Supplement VI).

UPJOHN RESPONSE

It is against our corporate policy to allow eating, drinking, smoking, and application of cosmetics in our regular laboratories as well as our radioisotope laboratories. Appendix V contains copies of appropriate pages from the "PR&D Safety Policies and Practices" manual and from the "Safety in the Laboratory" pamphlet that is issued to all research employees. We do reaffirm our policy of not allowing eating, drinking, smoking, and application of cosmetics in laboratories. The individual involved was reprimanded by Management and that action was noted in the individual's personnel file.

4. 10 CFR 20.203(f) requires that each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents; this label shall bear the radiation caution symbol and the words "Caution, Radioactive Material" or "Danger, Radioactive Material."

Contrary to this requirement, on June 7, 1985, the radiation caution symbol and identifying information on two level gauges containing 25 and 50 millicuries of cesium-137, respectively, were not visible.

This is a Severity Level V violation (Supplement IV).

UPJOHN RESPONSE

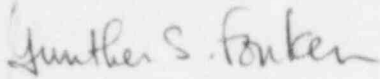
Our instrument maintenance staff have been instructed to remove paint from labels on all level gauges to ensure that they are legible. (Please refer to the memorandum in Appendix VI.)

We believe we have addressed the NRC concerns and each item in the Notice of Violation dated June 20, 1985.

Mr. D. J. Sreniawski
Page 5
September 3, 1985

If questions still remain, please contact Mr. Gellett (616-385-7478) or myself.

Sincerely yours,

A handwritten signature in cursive script that reads "Gunther S. Fonken".

Gunther S. Fonken, Ph.D.
Chairman, Radiation Control Committee

GSF/kw

Appendices I-VI

(RCC:L:Sreniawski at NRC)

APPENDIX I

LOCKING AND TAGGING OFF EQUIPMENT

The purposes of Locking and Tagging Off are to prevent injury to employees repairing, servicing, or manually cleaning equipment and to prevent damage to such equipment when disassembled or faulty. The methods used in Locking and Tagging Off must provide for the ability to perform maintenance on the equipment.

Equipment covered by this Locking/Tagging Off procedure includes, but is not limited to, 1) electrical equipment, 2) mechanical equipment, 3) electrically powered mechanical equipment, 4) any equipment having kinetic (moving) energy, or potential energy such as springs, weights, hydraulic or air pressure which could cause injury, and 5) radiation sources. The following rules must be followed in Locking and Tagging Off such equipment:

- I. Equipment on which work is to be done shall be Tagged Off and padlocked where possible. The tag shall be signed by the employee placing the tag on the equipment. Where applicable, rules A through D (below) shall apply.
 - A. The electrical disconnect switch must be locked in the "off" position and tagged.
 - B. Cord and plug electrical disconnect is permissible as follows:
 1. For voltages of 110 volts or less, the cord cap must be unplugged and tagged.
 2. For voltages higher than 110 volts, the cord cap must be enclosed in a shell or can type device that is locked in place on the cord cap (making it inoperable) and the proper tag installed.
 - C. When preparing for Tank Entry or any other entry permit where electrical powered agitation, fans or other devices could cause physical injury if energized, a physical electrical disconnect by an Electrician is required. The physical electrical disconnect is accomplished by either removing the fuses or physically disconnecting motor leads.
 - D. Radiation sealed beam sources shall have a lead shield locked in place in the beam path and any other protection required by the Radiation Officer.
- II. There may be situations where performance of maintenance or other work would be impossible with a Lock Off. In such situations, the worker is responsible for carrying out the work according to established procedures and in a manner which will not cause injury. Refer to Section III below. Equipment which cannot be Locked Off must be continuously attended or otherwise protected.
- III. When there is any question as to the proper and safe method

of Locking or Tagging Off, or otherwise performing work in a manner which will not cause injury, unit supervision or the Area Engineer shall be consulted. For contractors, the Field Engineer shall be consulted in lieu of the Area Engineer

EXCEPTION: Contact the Radiation Officer for radiation sources.

IV. When more than one trade or organizational unit is working on the same equipment or service, each unit will place its own tag and lock on the equipment.

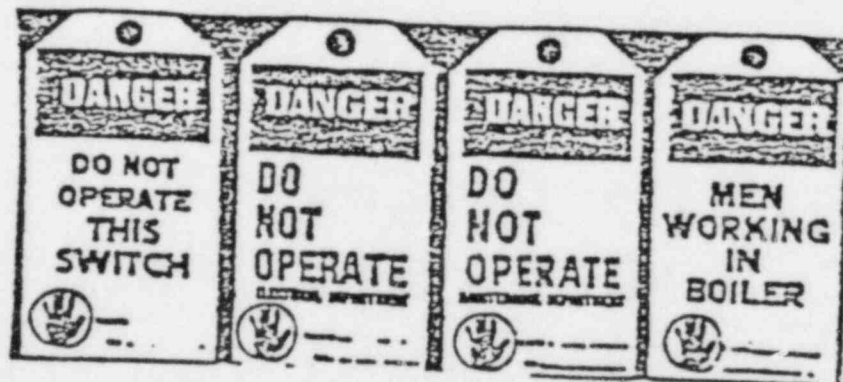
V. No tag or lock shall be removed by any person other than the signer.

EXCEPTION: In case of emergency preventing the signer from removing his/her lock and tag, and after thorough checking of the equipment, the following people are authorized to remove tags and locks, in the order shown below:

A. The signer's immediate supervisor, after attempting to contact the signer.

B. Other supervision representing the signer's unit, after attempting to contact the signer. If the signer is unavailable, an attempt shall be made to contact the signer's immediate supervisor.

VI. Only approved tags and locking devices shall be used for Tagging Off. These may be obtained from Central Stores. Examples are shown below.



VII. Only locks supplied by the Carpenter Shop shall be used. These locks are keyed individually and also to a common master key which shall be issued to supervision only. Special locks used to chain fermentor valves are excepted from this rule. The lock shall be identified as to unit number by either stamping the unit number on the lock, color coding, or equivalent marking.

- VIII. All employees working on and/or operating equipment covered by these procedures must be instructed in the procedures.
- IX. Wherever possible, equipment must be tested after Locking Off.
- X. Supervision or the Area Engineer or Field Engineer have the responsibility for informing persons doing work of potential chemical hazards, related hazards, permits and/or procedures to deal with them.

APPENDIX II

LABORATORY: _____ BLDG: _____
RADIOISOTOPE & POSSESSION LIMITS: _____



RESPONSIBLE APPROVED
RADIOISOTOPE INVESTIGATOR: _____

IN CASE OF EMERGENCY CALL EXT: _____

APPENDIX III

Upjohn

MEMO

80-126 8/83

COPIES TO

TO	PR&D Supervision (List #569)	SUBJECT	Storage of Radio- active Materials in Refrigerators, Freezers and Cabinets Located in Common Hallways
FROM	C.F. Gellett, Radiation Officer <i>CF</i>	DATE	August 23, 1985

The Nuclear Regulatory Commission (NRC), the Federal agency responsible for regulation of use of radioisotopes, conducted a safety inspection of our facilities and audited our records on June 5-7, 1985. The NRC inspector also interviewed some of the Approved Radioisotope Investigators and other staff regarding their knowledge of our operational procedures which have been established to comply with NRC regulations.

The inspector observed several unlocked refrigerators and freezers containing radiolabeled material which were located in common hallways. Storage of licensed radioactive material in unlocked refrigerators, freezers, and cabinets located in unrestricted areas is a violation of 10 CFR 20.207. As a result, we were cited with a Notice of Violation.

Therefore, to comply with NRC regulations, you must take action necessary to assure that any refrigerator, freezer or cabinet located in a common hallway adjacent to your laboratory, if used to store radiolabeled material, be secured to prevent removal of that material by unauthorized personnel. Please assure that by November 1, 1985, all such refrigerators in common hallways can be locked. Please notify me in writing when you have complied with this request.

Your cooperation in this matter is greatly appreciated. Do not hesitate to contact me if you have any questions.

My extension is 5-7478.

CFG/lms

APPENDIX IV

Upjohn**MEMO**

80-126 8/85

COPIES TO

TO

D.M. Devendorf,
Radioactive Material &
Controlled Substance
Specialist

SUBJECT

Monitoring of
Approved Radioisotope
Users by Thyroid
Uptake Tests

FROM

C.F. Gellett,
Radiation Officer

DATE

August 21, 1985

Before processing purchase orders for radioiodine, such as I-125 and I-131, please check our master list of personnel taking Thyroid Uptake Tests to assure that the person is in our file. If the person is a new candidate, they must have a background monitoring test at Bronson Hospital, Radiation and Oncology Department, before using radioiodine. In addition, each person should be scheduled for regular uptake tests according to the extent of their monthly usage of radioiodine. The schedule is listed below:

< 5mCi/Month of I-125 & I-131	Bi-monthly
5 to 6mCi/Month of I-125 & I-131	Monthly
> 6 to 10mCi/Month of I-125 & I-131	Semi-Monthly

Please notify Lois M. Swain, Secretary, Environmental Regulatory Affairs, for scheduling the appropriate monitoring test before the person actually uses radioiodine.

CFG/lms

APPENDIX V



PR&D SAFETY POLICIES and PRACTICES

General Policies

PRACTICE

Uniforms

1. Laundry Services regularly provides clean uniforms, towels and other linens to laboratory and service personnel. These are for use while at work and are not to be taken home.
2. Details of the laundry program can be obtained from the Henrietta Site linen room in Bldg. 17-1, 5-7630.

Safety Shoes

1. The Company will pay about one-half the price of safety shoes selected by the employee, for use on jobs where supervision determines there is a need for foot protection.
2. Contact Occupational Health and Safety for details and procedures.

EATING AND FOOD STORAGE

POLICY

Eating and food storage is restricted to certain areas within the laboratory complex to protect the employee's health.

PRACTICE

Within the laboratory complex, food and beverages must be consumed only in cafeterias and snack bars.

If an employee wishes to bring food or beverages into the laboratory complex for birthdays, anniversaries, holidays or retirements, arrangements must be made with the Food Services staff to use a cafeteria or snack bar refrigerator for storage. Under no circumstances are laboratory refrigerators, laboratories or chemical storage areas to be used for food or beverage storage.

WATER SAFE FOR DRINKING (POTABLE WATER)

POLICY

Safe drinking water is provided in specific areas. Employees shall be alerted to water that is not potable.

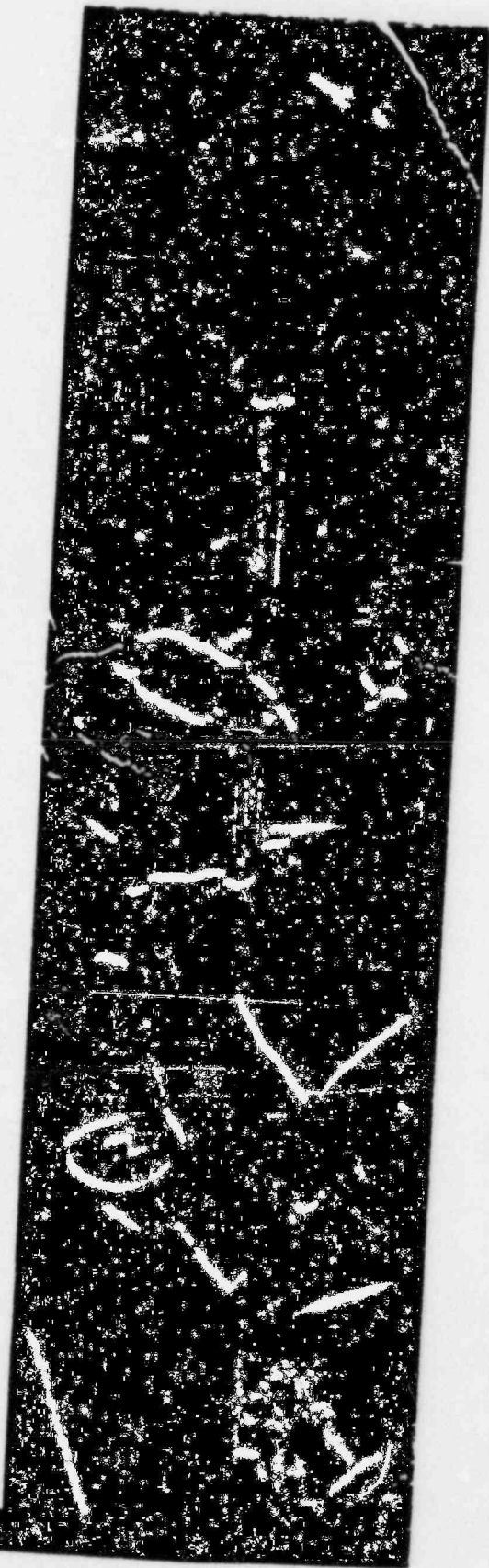
PRACTICE

Potable water is provided to drinking fountains, cafeterias, restrooms, safety showers and eye baths.

No water piped to laboratories, including deionized water, is potable. All laboratory faucets shall be labeled "DO NOT DRINK THIS WATER". Employees discovering a faucet without such a label should notify the Pipe Shop.

Safety in the Laboratory

Upjohn



Personal safety considerations



Cleanliness and orderly housekeeping are essential in an effective laboratory safety program. Avoid skin irritations by washing off suspected irritant materials thoroughly. In case of an emergency exposure to a chemical, use the nearest safety shower. Immediate washing is more important than neutralizing the chemical and should be continued for at least 15 minutes. Contaminated clothing must be removed. Safety showers are conveniently located—it is important that you are familiar with the locations of the showers near your own lab.

Do not wash your skin with solvents, bleach, alkali or any other chemical solution.

Observe all no smoking areas (all laboratories are no smoking areas). Check with your supervisor before lighting a cigarette in an area not clearly marked. Be sure to dispose of ashes in the proper container.

Do not eat, drink or smoke in work areas where chemical contamination is a possibility. Eating is strictly limited to cafeterias. Also, be sure your hands are washed before eating.

Don't work in your own clothing. Use the uniforms provided by the company and change them whenever necessary. Don't wear the work clothes home—you might transport chemicals into your home.

Wear clothes suitable for the type of work you do. Loose sleeves and garments are easily caught in moving apparatus. Do not wear rings or jewelry when working around machinery. If you wear long sleeves, keep them buttoned. Pant legs should be ankle length and free of catch-hazards like loose cuffs. Utilize gloves or hand pads when handling rough or sharp-edged materials.

Personal protective equipment

For the eyes: An integral portion of any laboratory safety program is eye protection. Plano or prescription safety glasses which meet government specifications as well as an initial eye examination are provided by the company. Safety glasses are meant as minimum protection and must be worn at all times in designated areas.

Some tasks may require additional protection such as goggles or face shields. If you wear contact lenses, goggles are highly recommended. It is suggested that in environments where chemicals are routinely used, contact lenses not be worn. Severe eye damage may result from chemicals being trapped behind a contact or absorbed into the lenses.

If exposure to ultraviolet radiation is possible, colored safety lenses must be utilized. Damage from uv radiation is not obvious at first, but can result in serious injury.

When evacuating glass apparatus, use a shatter-proof shield for face and eye protection. Only use glassware and equipment specifically designed for vacuum work, and never evacuate scratched, cracked or etched glassware.

APPENDIX VI

Upjohn

MEMO

80-128 8/83

COPIES TO

TO	N. Kuiper	SUBJECT	Radioactive Level Gauges
FROM	C.F. Gellet, Radiation Officer	DATE	August 21, 1985

DLCarlson
RMusselman

For Info
GSFonker.
RRHerr
TMMansager
HJVostrat

The Nuclear Regulatory Commission (NRC), The Federal agency responsible for regulation of use of radioisotopes, conducted a safety inspection of our facilities and audited our records on June 5-7, 1985. The NRC inspector also interviewed some of the Approved Radioisotope Investigators and other staff regarding their knowledge of our operational procedures which have been established to comply with NRC regulations.

Radioactive level gauges were physically inspected. Procedures for access and handling of the radioactive sources were audited. The inspector observed several 25mCi and 50mCi cesium-137 level gauges which did not have legible labels. This is a violation of 10 CFR 20.203. As a result we received a Notice of Violation. We were also cited for not having lock-out procedures in place.

We are in the process of formalizing our lock-out procedures to include radioactive sealed sources (level gauges). H.C. Molise will be contacting you for your help in establishing these procedures.

To comply with NRC regulations, you must remove paint from labels on all level gauges to assure that they are legible and can be read by persons working on the gauges. Please assure that by November 1, 1985 labels on level gauges are legible. In addition, each level gauge should be inspected quarterly to assure that this condition continues to be met. Please notify me in writing when you have complied with this request.

Your cooperation in this matter is greatly appreciated. Do not hesitate to contact me if you have questions.

My extension is 5-7478.

CFG/lms