

University of
Health Sciences / The Chicago
Medical School

Department of
Biological Chemistry
and Structure

3333 Green Bay Road Telephone
North Chicago, Illinois 60064 312-578-3221

July 2, 1985

United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Ref. Control Number 77591

Dear Sirs:

In reply to your letter of January 18, 1985 requesting further information concerning an amendment to our license, we would like to supply clarification to our first request. Also, we wish to cancel our request for medical use of Radioactive Materials and we wish to request an increase in our possession limit of ^{35}S .

We request the following:

1. Proposed changes in the use of Radioactive Materials in Animals.

In addition to the procedures outlined in our letter to the NRC, dated October 1, 1984, the following procedures will also be carried out:

A) In experiments utilizing low-energy Beta-emitters, the areas to be monitored shall be surveyed by taking wipe-tests by a method sufficiently sensitive to detect 100 dpm.

B) Areas will be cleaned if the contamination level exceeds 100 dpm/100 cm².

C) The area in which cages are cleaned shall be included in the survey. See item 3 of page 3 of enclosure.

D) Permanent records will be kept.

E) The above points have been incorporated into a revised document (see enclosed) entitled "Procedures and Precautions for Use of Radioactive Materials in Animals".

2. Medical Use of Radioactive Materials.

We wish to withdraw our request for this amendment.

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3. An Increase in the Possession Level of ^{35}S .

As requested by Dr. J. Keller (see enclosed letter from Dr. Keller), we request that the possession limit for ^{35}S be increased from 50 mCi to 300 mCi. This increase is needed partly to accommodate Dr. Keller's new research and also to allow for expanded use in the event that other investigators begin similar studies with the same new technique which requires 100 μCi of ^{35}S to be applied to a large series of dishes (cell cultures) for short time periods. It should be pointed out that since the experimental conditions do not lead to any air-borne radioactivity, the Committee will allow Dr. Keller to perform these experiments in an appropriate fume hood within his own laboratory. Dr. Keller is aware that such work necessitates daily wipe-test surveys for contamination, and he is meticulous and conscientious in his record-keeping, as was determined recently when Mr. Wayne J. Slawinski conducted an inspection of our premises for the NRC. Dr. Keller's laboratory was one of the laboratories examined during the inspection.

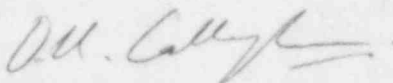
4. Proposal Change in the Posted Regulations on Laboratory Surveys.

Enclosed, please find our proposed rules for laboratory surveys and a separate notice on the use of radioisotopes in the High-Level Isotope Laboratory in Room L.256 (Hot Lab). This amendment is a clarification of our previous submissions to the NRC submitted on 10/31/78 and 4/26/84, and supercedes these previous notices. Mr. Slawinski indicated that there were some ambiguities in our regulations. The notice of 10/31/78 on the subject of "Routine Survey Procedures to be Carried out and Recorded in Each Laboratory Engaged in Work with Radioactive Material" indicates that: "A. All elution, preparation and injection areas will be surveyed daily..." In the proposed new notice, these operations are now included under experiments in the Hot Lab. We have also deleted the name Mr. Henderson from this notice. Further, in the notice enclosed in our letter of 4/26/84 entitled "Surveys for Contamination after experiments involving synthesis of radiolabeled compounds" the first statement reads: "1. A survey for radioactive contamination must be carried out after each experiment involving the synthesis of radiolabelled compound". We have deleted this requirement because this is covered by operation in the Hot Lab. (See item two of enclosure entitled "Special Procedures to be Employed in Room L.256 [Hot Lab]"). We have also included a provision so that Dr. Keller could utilize millicurie quantities of ^{35}S in his own fume hood.

In summary, our new proposed notice on Routine Survey Procedures supercedes the previous notice of 10/31/78, while our proposed new notice on "Special Procedures to be employed in Room L.256 (Hot Lab)" supercedes the notice of 4/26/84 relating to Synthesis of radiolabeled compounds. The latter new notice also permits investigators such as Dr. Keller to work with low-energy Beta-emitters in his own fume hood under carefully circumscribed conditions.

We hope that this meets with your approval.

Sincerely,

A handwritten signature in dark ink, appearing to read "O.H. Callaghan", with a stylized flourish at the end.

O.H. Callaghan, Ph.D.
Chairman, Radiation Safety Committee

OHC/jp
Enclosures.

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE
MATERIAL IN ANIMALS

A. Investigators wishing to use radioisotopes in lower animals must submit in detail their procedures to the Radiation Safety Committee for approval. The Committee dictates necessary safety procedures concerning use, care, disposal of waste and carcasses, cleaning of cages, and surveys of areas involved.

B. Care of Radioactive Animals

1. Investigators who wish to use radioisotopes in animals must have approval of the Radiation Safety Committee for such use.
2. Animals that have been given radioactive isotopes will not be stored in the general animal quarters.
3. Animals used for radioisotope experiments (not exceeding that working day in duration) may be kept in the investigator's laboratory under his supervision or in a separate animal room under investigator's supervision.
4. Experiments involving housing of radioactive animals for longer periods of time must be specifically approved. (Greater than one day).
5. All cages are to be marked with "Caution, Radioactive Material" tape and the following shall be listed on the cage card:
 - a) Name of the isotope
 - b) Activity per animal
 - c) Date of administration
 - d) Investigator's name
6. Rooms containing unattended radioactive animals must always be locked.
7. Animal care and cage cleaning shall be the responsibility of the authorized user, unless there exists personnel trained for this work.
8. Any dry waste bedding, excreta shall be treated as radioactive waste, if monitoring them with an appropriate instrument, indicates any detectable activity. Each package must be labeled indicating its contents.
9. The bodies of radioactive animals will be placed in labeled bags and stored in a freezer set aside for that purpose.
10. Animal cages and operating instruments will be cleaned by the investigator using gloves, soap and water.

11. Used cages shall not be used for non-isotope work until checked for detectable activity. Any contamination will be reduced to no greater than twice background.
 12. For experiments in which radioactivity may become airborne (as in the use *invivo* of ^3H - or ^{14}C - labelled metabolites) the metabolic cages having closed air - space must be used. The investigators must discuss this matter with the Animal House Director and obtain his written approval.
- C. The following procedures shall be followed in the Animal Research Facility:
1. The experimental work area shall be covered with plastic backed absorbent material.
 2. The work area shall be marked with warning tape.
 3. All instruments, equipment, absorbent coverings, surgical drapes shall be surveyed for contamination as described below. If the counting is in excess of 100 cpm, above background, the instruments and equipment should be decontaminated and the coverings treated as radioactive waste.
 4. Survey Procedures
 - a) Areas where only small quantities of radioactive material are used (less than 100 μCi) will be surveyed monthly.
 - b) All other laboratory areas will be surveyed weekly.
 - c) The weekly and monthly survey must utilize a technique capable of detecting the isotope used and will consist of either:
 - (i) A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr., or
 - (ii) A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm.
 - d) A permanent record will be kept of all survey results, including negative results. The record will include:
 - (i) Location, date, and type of equipment used.
 - (ii) Name of person conducting survey.
 - (iii) Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - (iv) Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

(v) Detected contamination levels, keyed to locations on drawing.

(vi) Corrective action taken in case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

INSTRUCTIONS FOR CLEANING AND DECONTAMINATING ANIMAL CAGES

1. Cages used to house radioactive animals shall be checked for residual radioactivity.
2. Cages found to have radioactivity greater than twice the background shall be washed or put aside and allowed to decay until their radioactivity level has returned to background level.
3. The cage washer and the area around the cage washer shall be surveyed after cleaning radioactive cages.
4. When washing floors of rooms housing animals containing radioactive material, personnel should use plenty of water, but avoid splashing.
5. To prevent personnel contamination, the personnel should wear laboratory coats, rubber gloves, and boots.

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TO: Dr. Owen Callaghan, Chairman, Radiation Safety Committee

FROM: Dr. John M. Keller, Professor *WK*

DATE: June 25, 1985

SUBJECT: ^{35}S -Sulphate

I am requesting that the institution raise its limit for the possession of ^{35}S . As described below, we are currently performing experiments in which 10-20mCi of ^{35}S -sulphate (as sulfuric acid) is used. Thus, in a single week we could use up to 40mCi. In order to take advantage of price breaks and bulk shipping costs, we would like to be able to order this isotope in 50mCi amounts. Since we need to use this material at its peak activity, we usually time our experiments to the shipping dates from the supplier. As indicated below, the experiments last less than 24 hours, so that essentially all isotope is discarded within 1-2 days after receipt. All radioisotopes are stored in a labeled refrigerator in room 3.131C.

Purpose of experiments: to identify clones of cells, on filter replicas of master plates, that have defective uptake systems for or pathways of utilization of sulfate.

Protocol:

Day 1 (manipulations performed in laminar flow hood in room 3.131D)

- To each of 100-200 cell culture dishes (100mm) containing 1 filter replica and 5ml medium, 100 μCi ^{35}S -sulfate is added with a sterile disposable pipet tip.
- These plates are then held at 37° overnight in incubators in room 3.131D.

Day 2 (manipulations performed in room 3.174)

- The medium and first wash (5 ml) are collected with disposable pipets for immediate disposal as bulk high level radioactive waste (see below).
- The subsequent 2 washes are disposed of as usual for radioactive waste.
- The filters are dried and subjected to radioactivity. From analyses of at least four experiments, there is only minimal radioactivity associated with the washed filters and culture plates. These are disposed of as normal radioactive waste at appropriate times.

Dr. Owen Callaghan
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Special Procedures for use of mCi Amounts of ^{35}S -Sulfate:

In addition to the standard procedures regarding the unpacking of new radioisotope, monitoring of work areas, disposal of low level waste and smoking, eating, drinking bans in the laboratories, the following procedures will be implemented:

- 1) The high level waste is transported as soon as possible from the work area to the main institutional radioactive waste facility.
- 2) After completion of work, on any day, the work surfaces will be monitored for radioisotope by performing wipe tests. Areas will be cleaned if the contamination level exceeds 100 cpm/100cm². All surveys are recorded in the laboratory log book, dated and signed by an investigator.

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TO: Authorized Users of Radioisotopes at UHS/CMS

FROM: Owen H. Callaghan, Ph.D., *OHC*
 Chairman Radiation Safety Committee

DATE: July 1, 1985

SUBJECT: Special Procedures to be employed in Room L.256 (Hot Lab)

1. As indicated previously, any experiment involving millicurie amounts of an isotope must be performed in the Hot Lab, Room L.256. The key to this lab may be obtained from the secretary of the Department of Biological Chemistry & Structure. Surveys of this lab should be correctly entered in the log book after each experiment. This lab has a hood running continuously under negative pressure and the outflow of the duct has a filter. The use of millicurie amounts of non-volatile low-energy beta-emitters may be permitted in a hood in a separate laboratory provided that the user can provide the committee with evidence of adequate safety procedures. Any procedure in which volatile radionuclides may be released into the air, including Iodination procedures using ^{131}I or ^{125}I , must be performed in the hood in Room L.256 or, if lower amounts are used, in another hood (yet to be designated). The following precautions must be followed for iodination procedures and other experiments where radioisotopes may become airborne.
2. A survey for radioactive contamination must be carried out after each experiment involving the synthesis of radiolabelled compound.
3. The survey must cover the area in which the work was done and must be performed on the same day as the experiment.
4. The survey shall utilize wipe tests or a survey meter according to the isotope used* and the findings must be recorded in the log book of the Hot Lab which will be dated and signed by the person performing the survey.

*(for high-energy beta or gamma emitters a calibrated survey meter may be used).

i. A charcoal filter trap must be attached to the closed reaction vessel. These are supplied routinely with certain iodination kits, e.g. FROM NEW ENGLAND NUCLEAR CO. THE CHARCOAL TRAP SHOULD BE SURVEYED AT THE END OF THE EXPERIMENT.

II. The experiment must be carried out in a hood with the hood fan drawing air into the hood. The hood fan must run continuously thereafter.

iii. Appropriate surveys of hands, clothing and the area must be made after each experiment. Investigators are invited to consult the Chairman (Ext. 473) or the Radiation Safety Officer (Ext. 405) for additional information.

iv. Decontamination of a hood (defined as a restricted area) by washing should result in surface levels in a hood of no more than $10^{-3} \mu\text{Ci}/\text{cm}^2$ in the case of ^{32}P or ^{125}I . For low risk B-emitters such as ^3H or ^{14}C the acceptable level would be $10^{-2} \mu\text{Ci}/\text{cm}^2$. In unrestricted areas (open lab surfaces) of the Hot Lab these levels may not exceed $10^{-6} \mu\text{Ci}/\text{cm}^2$. (About 200 dpm/100cm²)

If these levels cannot be achieved, contamination should be reported immediately and the work should be suspended.

Such values can be easily assessed by wiping an area 10 x 10 cm and either counting the wipe in a counter or holding the wipe close to (but not touching) the survey meter window.

v. If personal contamination is found or suspected the Radiation Safety Officer must be informed so that thyroid burden, urinary assay or other medical procedures may be carried out. Personnel should not resume work with isotopes until the Radiation Safety Officer has investigated the case and given clearance.

vi. Urinary assays are also mandatory for Tritium or Iodine isotopes if the following levels of use are exceeded:

	^3H	^{125}I or ^{131}I
In a fume hood	100 mCi	10 mCi
Unconfined (open) spaces	10 mCi	1 mCi

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TO: All Authorized Users of Radioisotopes

FROM: Radiation Safety Committee - O.H. Callaghan, Ph.D., *OHC*
Chairman

DATE: July 1, 1985

SUBJECT: Routine Survey Procedures to be Carried out and Recorded
in Each Laboratory Engaged in Work With Radioactive
Material. This notice supercedes previous notices relating
to Survey Procedures.

1. The procedures given below are to be carried out by an authorized user in the laboratory or his designated competent alternate.
2. These surveys are separate from the quarterly surveys conducted by our Physicist.
3. ALL personnel in any laboratory who may receive exposure to radiation of X-rays, γ -rays, or high-energy β -emitters (e.g., 32 -Phosphorus) in that laboratory or adjacent area must wear film badges.

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SURVEY PROCEDURES

- A. Experiments involving the use of millicurie amounts of radiochemicals must be performed in room L.256 (Hot Lab). For further details and for an exception to this rule, please see the attached memorandum for procedures to be used in the Hot Lab.
- B. Laboratory areas where only small quantities of radioactive material are used (less than 100 μ Ci) will be surveyed monthly.
- C. All other laboratory areas will be surveyed weekly.
- D. According to the isotope used the weekly and monthly survey will either consist of:
 - 1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
 - 2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm.
- E. A permanent record will be kept of all survey results, including negative results. The record will include:
 - 1. Location, date, and type of equipment used.
 - 2. Name of person conducting survey.
 - 3. Drawing of area surveyed, indentifying relevant features such as active storage areas, active waste areas, etc.
 - 4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).
 - 5. Detected contamination levels, keyed to locations on drawing.
 - 6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
- F. Area will be cleaned if the contamination level exceeds 100 dpm/100 cm².