American Radiolabeled
Chemicals Inc.

11612 Bowling Green
St. Louis, MO 63146
Toll Free 800-331-6661
In Missouri 314-991-4545

Mr. George M. McCann
Materials Licensing Section
United States Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

November 2, 1987

Reference: License Number 24-21362-01

Dear Mr. McCann:

American Radiolabeled Chemicals, Inc. hereby requests that NRC License No. 24-21362-01 be amended as follows:

ITEM 8, LICENSED MATERIAL
(LICENSE CONDITIONS 6, 7, and 8)

element and mass number	chemical and/or physical form	maximum number of curies possessed at any one time
1. Carbon-14	Any	50 Ci
2. Hydrogen-3	Any	500 Ci
3. Phosphorus-32	Any	10 Ci
4. Sulfur-35	Any	5 Ci
5. Iodine-125	Any	5 Ci
6. Iodine-131	Any	5 Ci
7. Cesium-137	Any	1 Ci
8. Any byproduct material with Atomic Numbers 1-83 inclusive	Any	Not to exceed 1 Ci per radionuclide and 5 Ci total

NOTE: Cs-137 to be used in the form of a sealed source for calibration purposes only.

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Check No. 005647
Amt $120
Type 30
Acct Rcvd
Date Completed 11/14/87
By:

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ITEM 9, STORAGE OF SEALED SOURCES

A specific sealed Cs-137 source has not yet been purchased. Several different manufacturers are presently being evaluated. The probable container and/or device is a sealed glass vial containing liquid Cs-137 in lead shielding which is sufficient to reduce radiation levels at the surface of the shielding to less than 5 mR/hr. The source will be appropriately labeled, and will be stored in a low occupancy area when not in use for calibration purposes.

Sealed source leak testing procedures have been developed and will be implemented upon receipt if, and when, such a sealed source is purchased.

The Cs-137 source is for experimental equipment calibrations so that ARC may eventually develop a program for accurate in-house calibration of survey meters and other such instruments.

ITEM 10, RADIATION DETECTION INSTRUMENTS

	a.	b.	c.	d.	e.	f.
1.	Survey Meter	Ludlum	2	3	beta, gamma	0-50 mR/hr
2.	Alarm-ratemeter	Ludlum	28	1	beta, gamma	0-500 KCPM
3.	Liquid Scintillation Spectometer	Packard	1500	1	alpha, beta	
4.	Scaler/ ratemeter	Ludlum	2200	1	beta, gamma	0-500 KCPM
5.	Survey Meter	Ludlum	3	1	beta, gamma	0-200 mR/hr
6.	Survey Meter	Eberline	Monitor 1A	1	beta, gamma	0-50 mR/hr

NOTE: Several additional survey meters are available for rough measurments only, and are not routinely calibrated. Operational checks are performed only to verify that the meter is functioning. These meters are appropriately labeled "For Rough Measurements Only", and are not used for any health physics or radiation protection related activities.

ITEM 11, CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

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a. calibrated by service company:

Instruments numbered 1, 5 and 6 above will be shipped out for calibration to an authorized facility. (ie. Ludlum or Ludlum Representative) Calibrations are performed every twelve months.

b. calibrated by applicant:

Instrument number 2, the Ludlum Model 28 ratemeter is used for rough measurements only, and although operational checks (response checks) are performed to verify that the meter is functioning, no formal calibration is maintained on this instrument. This meter is appropriately labeled "For Rough Measurements Only".

Instrument number 3 above is an electronically self-calibrating spectrometer. Calibration checks are performed routinely to determine the deviation from expected response (+ or - 10%), and when indicated, recalibration is performed in accordance with the manufacturers recommendations.

The Ludlum Model 2200 is calibrated using a calibration source of known quantity according to the manufacturers recommendation. Specific calibrations for air samples, etc. are performed using calibrated sources of each radionuclide to be monitored. Appropriate non-overlapping regions of interest, and then uCi/CPM are determined for each. Such calibrations are performed at least once every twelve months. Calibration checks are performed prior to each use to determine consistancy of response. Recalibration is required when deviation from expected response exceeds 10%.

ITEM 12, PERSONNEL MONITORING DEVICES

A. Type	B. Supplier	C. Exchange Frequency
2. TLD badges	Landaur, or Radiation Detection or other NVLAP Accredited Dosimetry Processing Service	Quarterly
3. Self-reading pocket dosimeter	Dosimeter Corporation	N/A

ITEM 13, FACILITIES AND EQUIPMENT

ARC recently purchased additional property (11624 Bowling Green Drive)

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which is contiguous to the licensed property at 11612 Bowling Green Drive, St. Louis, MO (See blueprint of property, enclosed).

It is the intent that, with this amendment, this property will be considered an extension of the existing property and will be included in the license.

For clarity, the originally licensed building (11612) will be referred to as Building 1, and the building on the new and contiquous property (11624), as building 2.

Building 1:

A new laboratory has been constructed in Building 1 for processing of Iodine-131, Iodine-125, and P-32 (See Building 1 Floor Plan attached to enclosed revision of ITEM 13). The new facilities and additional equipment are described in the new ITEM 13.

Building 2:

Building 2 is presently unccoupied with the exception of an office area. Several new laboratories as well as a new shipping area are planned for construction in this building (See Building 2 Floor Plan attached to enclosed revision of ITEM 13).

ITEM 15, RADIATION PROTECTION PROGRAM

Due to the changes in licensed material requested in this amendment (specifically the addition of radioiodine), as well as the addition of the new building, the Radiation Protection Program has been expanded and revised beyond easy reference to the previous Program (See enclosed revision of ITEM 15).
As you can see, many areas of the Program have been more specifically defined and several new and additional requirements have been added. These additions and changes have been made with the sole intent of increasing the scope and overall effectiveness of the Program.

ITEM 16, FORMAL TRAINING IN RADIATION SAFETY

The Radiation Protection Program has been expanded to include a description of ARC's policies concerning radiation protection training as well as radiation protection practices for all individuals (See Sections VII and VIII of ITEM 15, ARC's Radiation Protection Program).

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We look forward to hearing from you regarding this request for license amendment. If you have any questions or need additional information, please do not hesitate to contact me. I have enclosed a check for $120 for the license amendment fee. Thank you for your time.

Sincerely yours,

Surendra K. Gupta, Ph.D.
President

Enclosures:

Blueprint-Property Layout
ITEM 13, with attachments
ITEM 15
Standard Operating Procedures
License Amendment Fee

ITEM 15

AMERICAN RADIOLABELED CHEMICALS

RADIATION PROTECTION PROGRAM

ARC
American Radiolabeled Chemicals, Inc.
11612 Bowling Green
St. Louis, MO 63146

TABLE OF CONTENTS

I. PROGRAM SCOPE

This Radiation Protection Program is written to define ARC's procedures for controlling licensed by-product material in accordance with the requirements of the U.S. Nuclear Regulatory Commission.

The program is under the administration of the Radiological Safety Officer and the Radiation Safety Committee and is the means by which radiation protection standards and practices are defined for the safe handling and control of radioactive materials at ARC.

A. PROGRAM REVIEW

The Radiation Protection Program is reviewed in it's entirety at least annually by the Radiation Safety Officer and Radiation Safety Committee to assure that all activities are being performed safely and in accordance with regulatory requirements and license conditions. This review, as a minimum, includes all health physics practices and records, written procedures, effluent releases and personnel exposure trends.

B. ALARA COMMITMENT

ARC has established procedures for maintaining exposures as low as is reasonably achievable in accordance with the basic recommendations set forth in Regulatory Guide 8.10, "Operating Philosophies for Maintaining Occupational Exposures as low as is Reasonably Achievable".

II. DEFINITIONS

A. GENERAL RESTRICTED AREA

Any area to which access is controlled by ARC for purposes of protection of individuals from exposure to radiation and radioactive materials.

B. SPECIFIC RESTRICTED AREA
Areas posted with caution signs bearing the wording "Radioactive Material", "Radiation Area", or "High Radiation Area" automatically fall into this category. Entrance to these areas is restricted to authorized personnel or escorted visitors only.

C. UNRESTRICTED AREA

Any area to which access is not controlled by ARC for purposes of protection of individuals from exposure to radiation and radioactive materials. Reception/office areas would fall into this caregory.

D. AUTHORIZED PERSONNEL

Individuals with sufficient training and experience to use, or supervise the use of, radioactive materials for ARC and under the authorization of the ARC Radiation Safety Committee.

III. RADIATION PROTECTION ORGANIZATION

A. PRESIDENT/RADIATION SAFTEY OFFICER

The President/RSO assures that a competent Radiation Protection Organization is established with well defined responsibilities. The President/RSO prescribes, develops and implements the Radiation Protection Program in accordance with applicable NRC/DOT and other regulations as well as the provisions and conditions of ARC licences.

B. RADIATION SAFETY COMMITTEE

The Radiation Safety Committee administers the Radiation Protection Program to assure control of the receipt, use, and disposition of radioactive materials.

The Committee is composed of a Radiation Safety Officer, Assistant RSO and one other individual trained and experienced in the safe use of radioactive materials. In general, members are selected based on their knowledge of, and experience in, radiation protection, applicable regulations, license conditions, and general health physics practices and principles.

The RSO administers the Radiation Protection Program as established by the Radiation Safety Committee. A quorum consists of simple majority rule, one of whom must be the Radiation Safety Officer, or in his absence, the Assistant RSO.

The Radiation Safety Committee is administratively responsible to the President/RSO, and is delegated sufficient authority to curtail any operation which threatens the safety of personnel or the environment.

C. RADIATION SAFETY COMMITTEE MEETINGS

The Committee reviews bioassay results, radiation exposures, radiation levels and concentrations and takes appropriate action through recommendations or directives to the ARC staff.

A formal meeting of the Radiation Safety Committee is held at least once every six months and will also be called when requested by any Committee Member for any reason. The minutes of formal Committee meetings are documented and filed for review by the Nuclear Regulatory Commission.

Informal meetings are held frequently and take place through the routine interactions of the RSO and Committee Members on a day to day basis. These informal meetings are not documented.

D. RADIATION PROTECTION STAFF

The Radiation Protection Staff functions as the working body of the Radiation Safety Committee by monitoring daily operations to achieve the goals of the Radiation Protection Program.

The Radiation Protection Staff presently consists of the President/RSO, Assistant RSO and one Health Physics Technician.

The Radiation Protection Staff is administratively responsible to the President/RSO.

IV. PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

A. EXTERNAL RADIATION EXPOSURE OF INDIVIDUALS IN RESTRICTED AREAS

Control and safety procedures for restricted areas at ARC will be enforced to the extent that no individual will receive an exposure in excess of the maximum permissible external exposure as limited by the Nuclear Regulatory Commission (Title 10 CFR, Part 20.101) as follows:

i. 1.25 Rems to the whole body, head and trunk, active blood forming organs, lens of eyes, or gonads.

ii. 3.0 Rems to the whole body, head and trunk, active blood forming organs, lens of eyes, or gonads, providing that a determination of the individual's total accumulated occupational exposure has been made and is less than 5(N-18) Rems where N is the age in years at the last birthday.

iii. 18.75 Rems to the hands and forearms, feet and ankles.

iv. 7.5 Rems to the skin of the whole body.

The external exposure of members of the public (visitors), office staff of ARC (non-radiation workers), and minors (under age 18) are limited to 10% of the above listed limits.

B. EXTERNAL PERSONNEL MONITORING/DOSIMETRY

It is the policy of the Radiation Safety Committee to provide suitable personnel monitoring devices for all personnel working with ionizing radiation. In order to assure compliance with 10 CFR 20.202, "Personnel Monitoring", NVLAP accredited dosimetry (whole body, skin of whole body and extremity TLDs) is first issued to any employee working with or around gamma radiation or high energy beta radiation. The normal wearing period is quarterly.

Self reading pocket dosimeters are issued to employees or visitors who do not require routine monitoring, but will be temporarily entering an area where gamma radiation or high energy beta radiation is handled or stored.

C. EXPOSURE OF INDIVIDUALS TO CONCENTRATIONS OF RADIOACTIVITY IN AIR IN RESTRICTED AREAS

Airborne concentrations of radioactive material are controlled to the extent that at any time during any one calendar quarter an individual will not inhale the same quantity as that which would result from inhalation for 40 hours per week (for 13 weeks) at uniform concentrations of radioactive material in air as specified in 10 CFR, Part 20, Appendix B, Table I, Column 1. The average concentrations in air are limited to 25 percent of the maximum permissible concentrations through the use of process and/or engineering controls. When more than one radionuclide is present, the percentages are summed and are expressed as total percent of maximum permissible concentration in air. Areas with air concentrations in

excess of 25 percent of the limits are posted as required in 10 CFR 20.203 and are investigated to determine the cause and corrective actions to be taken.

The maximum permissible concentrations in air are based upon a 40-hour occupancy time. In areas where the occupancy time is routinely less than 40-hours per week, the MPCs may be adjusted in the following manner: The tabulated MPC is multiplied by 40 hours and divided by the hours of exposure to an individual (actual occupancy time).

D. INTERNAL RADIATION EXPOSURE OF INDIVIDUALS IN RESTRICTED AREAS

Precautionary procedures, including increased surveillance, limitation of working times, or provision of respiratory equipment, are used to maintain the intake of radioactive materials within any seven consecutive days as far below 40 MPC-hrs equivalent exposure as is reasonably achievable. A 40 MPC-hr equivalent exposure is best defined as an intake of radioactive material which is equal to the intake which would result from inhalation for 40 hours at the maximum permissible concentration in air (10 CFR 20, Appendix B, Table I, Column 1).

E. INTERNAL PERSONNEL MONITORING/BIOASSAYS

Bioassays are performed weekly or more often as appropriate considering the work being performed. In general, NRC guidelines for bioassays and requirements for tritium will be followed (see Appendix F).

1. Thyriod Burden Measurements:

A direct thyroid burden measurement for radioiodine is required under the following circumstances:

i. At least weekly of any individual who works routinely in any area where radioiodine is processed, handled or stored.

ii. When elevated air concentrations of radioiodine are measured.

iii. When an uncontained spill of radioiodine occurs.

iv. Whenever external personal contamination identified as radioiodine is detected upon an individual.

ARC restriction levels are established at 20 MPC-hrs equivalent exposure. An individual is restricted from further exposure to radioiodine if it is determined by bioassay measurements that they have reached or exceeded this in-house limit. The individual is then restricted from work with significant quantities of radioiodine and from any area in which air concentrations of radioiodine exist in excess of 25 percent of the maximum permissible concentrations in air as defined in 10 CFR 20, Appendix B, Table I, Column 1. They will remain restricted until the equivalent exposure averages below this 20 MPC-hr restriction level for a period not less than one week.

2. Urinalysis:

A urinalysis for radionuclides other than radioiodine is requir d under the following conditions:

i. At least weekly of all individuals who work routinely in areas where significant quantities of radionuclides are handled or stored.

ii. When elevated air concentrations are measured.

iii. When an uncontained spill of radioactive material occurs.

iv. Whenever external personal contamination is detected upon an individual.

3. Action Levels and Recommended Actions:

Restriction levels have been established for all radioisotopes handled routinely at ARC.

Maximum Permissible Body Burdens

Radionuclide	Microcuries
Carbon-14	400 uCi
Hydrogen-3	1000 uCi
Phosphorus-32	30 uCi
Sulfur-35	400 uCi

Whenever the calculated body burden to an individual exceeds the quantity specified above, the following actions will be taken:

i. An investigation will be performed to determine the cause of the elevated body burden and any corrective actions to be taken.

ii. The worker will be restricted from further exposure until the burden has reduced itself below the applicable limit.

4. ALARA Policies and Internal Personnel Exposure

A concerted effort will be made to maintain personnel exposure at less than 10 % of 40 MPC-hours equivalent exposure as defined in Section D of this Radiation Protection Program. Should an individual exposure reach or exceed this level, the following actions will be taken:

i. An investigation will be performed to determine the cause of the elevated exposure and any corrective actions to be taken. Procedures and

equipment which may have contributed to the exposure will be examined and modified or replaced as necessary to prevent a similar occurence.

ii. Results of such investigations and any corrective actions taken will be reviewed in the next Radiation Safety Committee meeting.

F. PRENATAL EXPOSURE

It is the policy of ARC that during the entire gestation period, the dose equivalent to the fetus from occupational radiation exposure should not exceed 0.5 Rem (See Appendix C).

G. RADIATION EXPOSURE LEVELS IN UNRESTRICTED AREAS

Radiation exposure levels are controlled so that no individual in an unrestricted area will receive an exposure in excess of 2 millirems in any one hour, or, 100 millirems in any seven consecutive days, independant of occupancy time. An action level of 0.6 millirem per hour is used as a guideline.

H. RADIOACTIVE CONCENTRATIONS IN AIR EFFLUENTS

The yearly average concentrations in air effluents are controlled to the extent that the limits specified in 10 CFR 20, Appendix B, Table II, Column 1 are not exceeded. The ARC goal is to maintain air effluent releases well below such limits.

Effluent air concentrations are routinely monitored at exhaust stack locations and efficiency studies of effluent air treatment systems are performed to determine the need for corrective action. Air effluent releases are carefully reviewed in each Radiation Safety Committee meeting.

I. REMOVABLE SURFACE CONTAMINATION LEVELS

Removable surface contamination levels are performed routinely throughout the facility. Such surveys are performed on a weekly basis, as a minimum, and daily in areas where, and when, radioiodines are being processed.

Action levels are established at 2200 dpm/100cm2 in specific restricted areas and 220 dpm/100cm2 in unrestricted areas and general restricted areas (lunchroom, office, etc.). As an extra precaution, shoecovers are required to be worn in all specific restricted areas.

Areas in which removable contamination levels are determined to exceed these limits are decontaminated until reduced to an acceptable level.

J. RADIATION LEVEL SURVEYS

Radiation level surveys are also performed routinely throughout the facility and are performed on the same frequency as those surveys listed above. Informal surveys are performed by each individual in their own work area on a daily basis. Significantly elevated levels are investigated

immediately to determine the cause and corrective action to be taken.

Survey records are kept of all survey results. Records include the detected contamination and radiation levels and are keyed to the location on a floor plan of the area surveyed. Corrective actions are also thoroughly documented.

V. RECEIPT OF INCOMING RADIOACTIVE MATERIAL

Generally, all radioactive materials are received during normal working hours. On other occasions, arrangements are made by ARC for receipt on delivery.

The Radiation Safety Staff is responsible for incoming material check-in. Incoming packages are promptly surveyed and monitored to assure that no leakage has occurred in transit. Radiation level and removeable contamination level surveys are performed within 3 hours of receipt during working hours and 18 hours if received after normal working hours. The following information is recorded at check-in:

i. Date of receipt

ii. Radionuclide

iii. Quantity

iv. Chemical and physical form

v. Surface and transport index measurements

vi. Removable contamination levels on the surface of the inner and outer containers

Radiation levels in excess of 200 millirem per hour at the surface of the package or in excess of 10 millirem per hour at one meter from the package; or removable contamination levels in excess of 22,000 dpm/100cm2 are indications of leakage.

If leakage is indicated, immediate notification will be made by telephone and telegram or facimile to the Director of the appropriate NRC Regional Office, and to the final delivering carrier.

VI. CAUTION SIGNS, LABELS, AREA POSTING, AND ACCESS CONTROL

A. CAUTION LABELS

"Caution Radioactive Material Labels" are affixed to all containers within which radioactive material is present in excess of the applicable quantity specified in 10 CFR 20, Appendix C, or in concentrations in excess of those listed in 10 CFR 20, Appendix B, Table I, Column 2. These labels have sufficient information to allow individuals who are working with or around the activity to take precautions to minimize their exposure (radionuclide, quantity, calibration date). These labels are not required when the material is constantly attended (ie. production in process), when accessible only to authorized individuals, or when packaged and labeled in accordance with D.O.T. regulations, providing that written records are available which identify the radioactive material.

Radioactive material containers are always labeled in accordance with the requiremants of 10 CFR 20.203(f). Labeling on radioactive material packaged for shipment is as required by the Department of Transportation regulations as defined in 49 CFR 172.403.

B. AREA POSTING AND ACCESS CONTROL

"Caution Radioactive Materials" signs are posted to define all areas in which radioactive materials are used or stored in excess of ten times the applicable quantity specified in 10 CFR 20, Appendix C.

"Caution Radiation Area" signs are posted to define all areas in which a major portion of the body could receive an exposure of 5 millirems in any one hour of 100 millirems in any 5 consecutive days.

"Caution High Radiation Area" signs are posted to define all areas in which a major portion of the body could receive an exposure of 100 millirems in any one hour. Access to "High Radiation Areas" are controlled for radiation protection purposes. The area is kept locked with positive control over entry by limited issuance of keys. Direct surveillance of the area may be substituted only if the high radiation area exists for less than 30 days.

"Caution Airborne Radioactivity Area" signs are posted to define those areas in which air concentrations of radioactive material exist in excess of 25% of the limits specified in 10 CFR 20, Appendix B, Table I, Column 1.

C. CONTROL OF RADIOACTIVE MATERIAL IN UNRESTRICTED AREAS

Radioactive Materials are not stored in unrestricted areas unless secured from unauthorized removal. If radioactive materials are placed temporarily in unrestricted areas, they are maintained under constant surveillance and control.

VII. RADIATION PROTECTION TRAINING

All new personnel are trained in good radiation protection practices as well as regulatory requirements prior to their authorization to handle radioactive materials. Such authorization is granted by the Radiation Safety Committee and/or Radiation Safety Officer and is followed up with periodic reviews of the individuals practical application of such knowledge.

The following is a brief outline of subjects covered in both the initial and refresher training programs:

i. The ARC Radiation Protection Program

ii. Form NRC-3, "Notice to Employees"

iii. Regulatory Guide 8.13, "Instructions Concerning Prenatal Exposure"

iv. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Exposures As Low As Is Reasonably Achievable"

v. 10 CFR 19, "Notices, Instructions and Reports to Workers; Inspections"

vi. 10 CFR 20, "Standards for Protection"

vii. ARC's Radiation Protection Practices (see Section VII, herein)

viii. Areas where radioactive materials are handled or stored.

ix. Health risks and radiation exposure

x. Practical methods to minimize exposure, both internal and external

xi. Employee responsibility to report unsafe conditions

xii. Response to alarms and emergency situations involving radioactive materials.

xiii. Rights concerning access to reports of personal radiation exposure

xiv. Locations of notices, copies of regulations, the license and license conditions, as well as notices of violations concerning licensed materials

VIII. ARC'S RADIATION PROTECTION PRACTICES

A. PREFACE

No Radiation Protection Program can be effective without the complete cooperation of all individual's under it's guidance. The following radiation protection practices have been established as a basis for radiation safety in daily operations for all individuals, at all levels of responsibility.

B. GENERAL PRECAUTIONS

Smoking, eating and drinking are permitted only on areas where radioactive materials are not used or stored.

Mouth pipetting is prohibited.

All items being removed from restricted areas are to be surveyed to prevent the inadvertent transfer of contamination to unrestricted areas.

Individuals should wash their hands each time upon leaving a radiation area and each time after handling potentially contaminated items.

Individuals should curb any personal habits such as the biting of fingernails, placing objects in the mouth, head scratching, nose rubbing, etc. which may contribute to internal or external contamination.

Individuals should be aware of locations where radioactive materials are handled or stored, and of the radiation levels in their working area at all times. Qualitative checks for removable contamination should also be performed periodically by wiping large areas with a paper towel and then surveying the towel with a suitable detector in a low background area. Any detectable activity indicates removable contamination.

C. HANDLING OF RADIOACTIVE MATERIALS

Any operation involving volatile, liquid, gaseous, or uncontained radioactive material must be handled inside a well exhausted hood or glovebox. All fume hoods are to be checked at least weekly for proper airflow (greater than 125 LFPM).

All work with radioactive materials should be performed over a benchtop or cart to minimize the potential consequences of a spill. Disposable paper or plastic should first be placed on these work surfaces to prevent contamination of the permanent surfaces.

Shielding of the appropriate form (lucite, aluminum, concrete, or lead) should be utilized whenever possible to minimize external exposure.

D. PROTECTIVE CLOTHING

Shoecovers must be worn in all specific restricted areas posted as "Radiation Areas" or "High Radiation Areas" and must be removed before leaving the radiation area.

Gloves are to be worn as a precautionary measure while handling radioactive materials which may be contaminated. Heavier gloves should be worn when handling items which are known to be contaminated.

Additional outer protective clothing such as labcoats, gowns or aprons may be worn as an extra precautionary measure for certain operations. Such outer clothing should be surveyed before leaving the radiation area.

Special care should be taken when removing protective clothing to prevent the spread of contamination.

E. PERSONAL CONTAMINATION SURVEYS

Individuals should perform a personal contamination level survey each time upon leaving a radiation area. Any detectable contamination above background is indicative of elevated removable contamination levels and should be reported to the Radiation Protection Staff. Surveys should be performed with an appropriate monitoring instrument, paying particular attention to:

i. the hands, face, and other exposed body surfaces.

ii. personal items such as wristwatch, pens, calculators, and dosimetry devices or badges.

iii. clothing to be worn upon leaving the area, particularly the sleeves, pockets, waistband area and shoes.

F. PERSONAL DOSIMETRY

Each individual is to wear all issued dosimetry devices and badges at all times while on site. Badges are to be carefully surveyed prior to leaving each day and are to be immediately reported if contamination is detected. Under no circumstances should an individual work without appropriate dosimetry. Lost or misplaced badges should also be reported.

G. HANDLING OF RADIOACTIVE WASTE

Radioactive waste is to be disposed of in properly labeled containers which are used specifically for this purpose. High level radioactive waste (greater than 30 mR per hour) should be sufficiently shielded or removed from the area. Radioiodine waste should be placed in tightly sealed containers to prevent the spread of airborne contamination.

Never dispose of radioactive waste in a non-radioactive waste container or by means of a non-radioactive sink or drain.

IX. RADIOACTIVE SPILLS

Spill response procedures are posted throughout the facility and are updated as changes are made.

A. MINOR SPILLS

i. Notify persons in the immediate area that a spill has occurred.

ii. Cover the spill with an absorbant material to prevent spreading the contaminant.

iii. Clean the area with the use of disposable gloves, absorbent materials, plastic bags, and decontaminating cleaners. shielding and respiratory protection equipment should be used as appropriate.

iv. Perform radiation level surveys and removable contamination level surveys to determine that the area has been decontaminated sufficiently.

vi. If the spill involves radioiodine, perform air samples in the area to determine air concentrations.

vi. Notify the radiation protection staff.

B. MAJOR SPILLS

i. Clear the area of all personnel by announcing that a spill has occurred.

ii. Cover the spill with an absorbent material to stop the spread of contamination.

iii. Restrict access to the spill area and restrict movement of all potentially contaminated personnel. If the spill involves radioiodine, allow no entry to the area without respiratory protective equipment.

iv. Do not attempt to clean up the spill without the assistance of the Radiation Protection Staff or Radiation Safety Officer.

ARC STANDARD OPERATING PROCEDURE

SUBJECT: AIR SAMPLING FOR RADIOIODINE

PURPOSE:

1. To determine the fraction of maximum permissible concentration of radioiodine in air in restricted and unrestricted areas as defined in 10 CFR 20, Appendix B, Table I, Columns 1 and 2.

2. To determine the total quantities of radioiodine released in air effluents.

EQUIPMENT:

1. Charcoal air filter cartridge
2. Ludlum Model 2200 single channel analyzer with NaI detector.

PROCEDURE:

1. Verify the following settings:
   a. Switch to "RATE"
   b. Minutes to 05, switch to "x1"
   c. Window "on"

2. Set 10-turn Potentiometers to:
   a. for Iodine-125 Window 0.40
      Threshold 0.25

   b. for Iodine-131 Window 0.50
      Threshold 3.35

3. For each region listed above, count background and document results.

4. For each region listed above, count the charcoal cartridge and document results.

5. Determine Net CPM for each radioiodine by subtracting the background counts from the gross sample counts. Document the calculated Net CPM.

6. Multiply the Net CPM for each radioiodine by the appropriate conversion factor in uCi/CPM (listed on the Ludlum 2200 calibration form) to determine total uCi of Iodine-125 and Iodine-131, respectively, on the cartridge.

7. Determine total air flow through the cartridge by multiplying the average LPM x 1000 to determine mls/min. Multiply the mls/min by the sampling time in minutes to determine the total milliliters sampled.

8. Divide the total uCi of iodine-125 and iodine-131, respectively, by the total milliliters of air sampled to determine the concentration of each in the air sampled.

9. Determine the fraction of maximum permissible concentrations in air (FMPCa) by dividing the concentration in air by the listed MPC value:

Iodine-125	Iodine-131
Restricted: 5E-9uCi/cc	Restricted: 9E-9uCi/cc
Unrestricted: 8E-11uCi/cc	Unrestricted: 1E-10uCi/cc

10. Areas in excess of 25% FMPCa total for all nuclides must be posted as Airborne Radioactivity Areas, and should be investigated to determine the cause and corrective action to be taken.

11. To determine air effluent release totals, multiply the average concentration for each radionuclide measured in the stack air sample (from step 8) by the sampling time in minutes, and again by the total airflow up the stack in mls/min.

ARC STANDARD OPERATING PROCEDURE

SUBJECT: LIQUID WASTE ANALYSIS AND DISCHARGE

PURPOSE: To assure that releases of liquid radioactive waste are within NRC limits and in support of the ALARA concept.

EQUIPMENT: 1) Ludlum Model 2200 with NaI detector
and
2) Packard Scintillation Spectrometer

PROCEDURE:

NOTE: Only readily soluble radionuclides may be disposed of in this manner.

1. Count sample of liquid waste on both systems listed above.

2. Determine the uCi/cc for each radionuclide measured in the sample.

3. Multiply these concentrations by the total volume (in cc's) of liquid waste to be discharged to determine total activity to be released.

4. Divide total (for each radionuclide) by ARC's average water usage volume (per 24 hrs), to determine the diluted concentrations.

5. For each nuclide: Divide the concentration determined in step 4 above by the respective MPC value listed below (if not listed, see 10 CFR 20, Appendix B, Table I, Column 2):

CARBON-14 _____ 2E-2uCi/cc

HYDROGEN-3 _____ 1E-1uCi/cc

PHOSPHORUS-32 _____ 5E-4uCi/cc

SULFUR-35 _____ 2E-3uCi/cc

IODINE-125 _____ 4E-5uCi/cc

IODINE-131 _____ 6E-5uCi/cc

6. Total the FMPCw values for all nuclides, excluding C-14 and H-3. The sum total for all other nuclides must not exceed unity (1.0).

7. The FMPCw values for C-14 and H-3, separately, must not exceed unity (1.0).

8. Maintain running Year to Date release totals of quantities released (from step 3, above) for 1) C-14, 2) H-3, and 3) all other nuclides. YTD totals must not exceed: 1) 1 Ci for C-14, 2) 5 Ci for H-3, and 3) 1 Ci sum total for all other nuclides.

9. If these conditions are met, the liquid radioactive waste may be disposed through the sanitary sewer.

ITEM 13

AMERICAN RADIOLABELED CHEMICALS

USE OF LICENSED MATERIAL

I. LABORATORY FACILITIES

A. LOCATION

American Radiolabeled Chemicals
11612 and 11624 Bowling Green
St. Louis, MO 63146

B. PROPERTY DESCRIPTION

The property is located in a heavy industrial area which is zoned K (unrestricted).

C. BUILDING 1 DESCRIPTION

Building 1 occupies a total floor space of 3200 square feet and is a one story concrete block building with no basement. The laboratory areas have concrete floors covered with waterproof enamel paint. The exterior walls of the building are painted.

D. BUILDING 2 DESCRIPTION

Building 2 occupies a total floor space of 5000 square feet and is a one story concrete block building with no basement. The laboratory areas have concrete floors covered with waterproof enamel paint. The exterior walls of the building are painted.

E. EQUIPMENT

Seven radiochemistry fume hoods are installed in the general laboratory areas of building 1. Hoods in this area are exhausted by two blower systems. Effluent air is hepa filtered at the point of exit from these hoods. Face velocities are maintained at 125LFM with doors in normal operating position. There are no operative sinks in these hoods.

In the Iodine/P-32 laboratory, there are two radiochemistry fume hoods and an iodine-designated glovebox which are exhausted by a single blower system. Effluent air is filtered through a particulate and/or charcoal filter as appropriate at the point of exit. A 100% plexiglass glovebox is used for the processing of P-32.

Independant heating and air conditioning systems are used for the office and laboratory areas, and an additional separate system is used for the Iodine/P-32 laboratory.

F. AIR SAMPLING EQUIPMENT

Air samples are located in front of the hoods in the general laboratory area and Iodine/P-32 area. Additional air samples are located over the main benchtops which are centrally located in the general laboratory. Because no gamma radiation is handled in the general laboratory, this area is sampled for particulates only. Combination air-samples, utilizing both particulate and charcoal filters, are used in the Iodine/P-32 laboratory and at the point of exhaust from this area as well. Particulate and charcoal filters are separated after sampling and counted individually on appropriate counting equipment. Air flow through the samples is maintained at greater than 1.0 LPM and flows continuously.

G. BATCH SIZES

At present, batch sizes generally involve less than 1,000 mCi of Carbon-14 or Hydrogen-3. The maximum batch size for any radionuclide will be limited to 5-10 Ci.

H. LABILE AND VOLATILE FORMS OF RADIOACTIVITY

All operations involving the potential release of labile radioactivity are conducted inside a fume hood. Operations involving Hydrogen-3 byproducts will be done using sodium borotritide (non-volatile) or products from which the volatile form of tritium has been removed at another licensed facility. Volatile forms of radioiodine are handled in gloveboxes or fume hoods with appropriate charcoal filtration.

I. RADIOACTIVE WASTE

Solid radioactive waste is segregated according to half-lives and when possible, stored for complete decay. Complete decay is determined by holding the material for a minimum of ten half-lives and then resurveying in a low background area for any detectable activity. If activity is detected, the waste material will be returned for further storage. If no activity is detected, the waste material will be disposed of as non-radioactive refuse. Waste contaminated with longer lived radionuclides is

packaged and labeled in accordance with the requirements of the Department of Transportation and other regulatory agencies and shipped to a licensed disposal facility.

Liquid radioactive waste is also separated according to half-life as much as possible. Longer lived liquid radioactive waste is solidified and disposed of as solid radioactive waste. Shorter lived liquid radioactive waste is disposed of in accordance with the regulations in 10 CFR 20.303. When this is not possible (ie. the radionuclide is not readily soluble in water), the shorter lived radioactive waste will either be held for complete decay, or, solidified and disposed of as solid waste as indicated above.

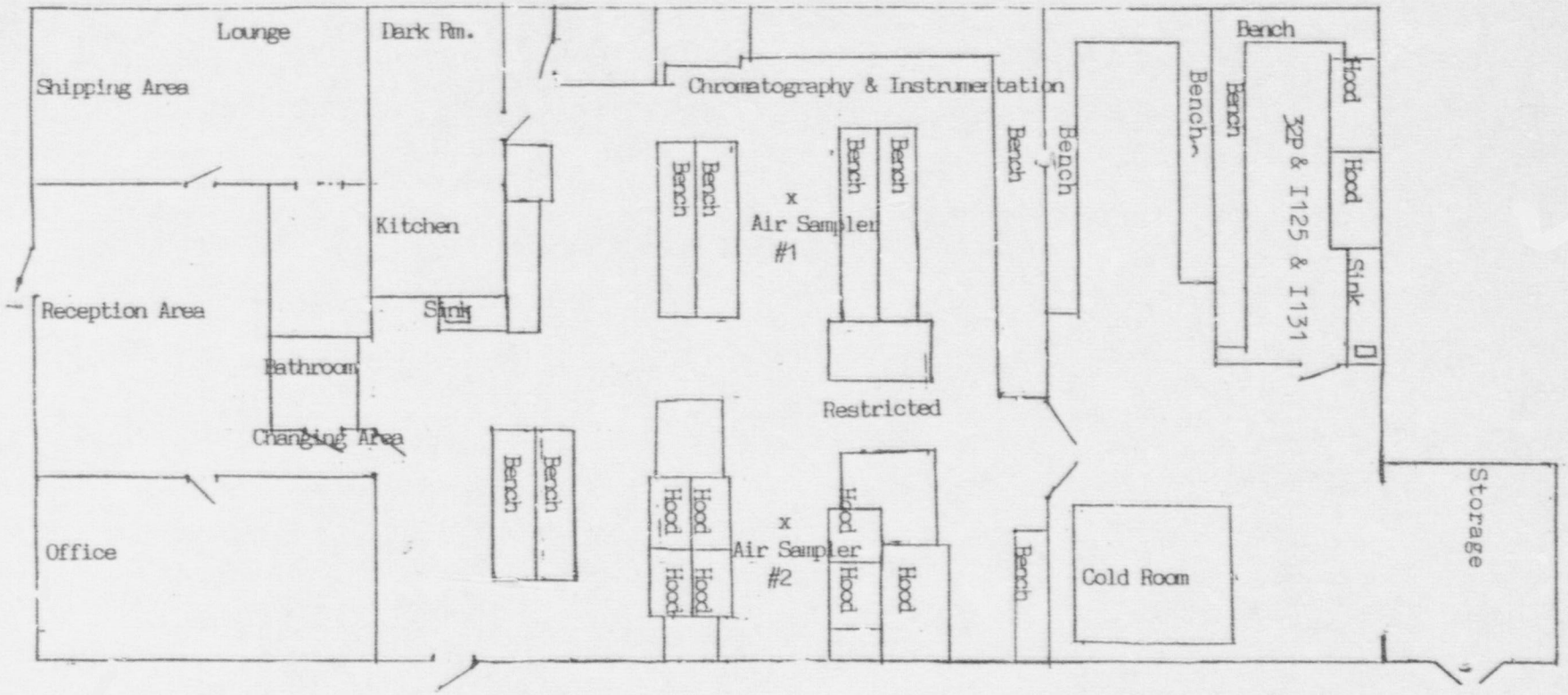
J. FIRE PROTECTION.

Local fire departments are aware of this facility and the radiological hazards associated with a fire at ARC.

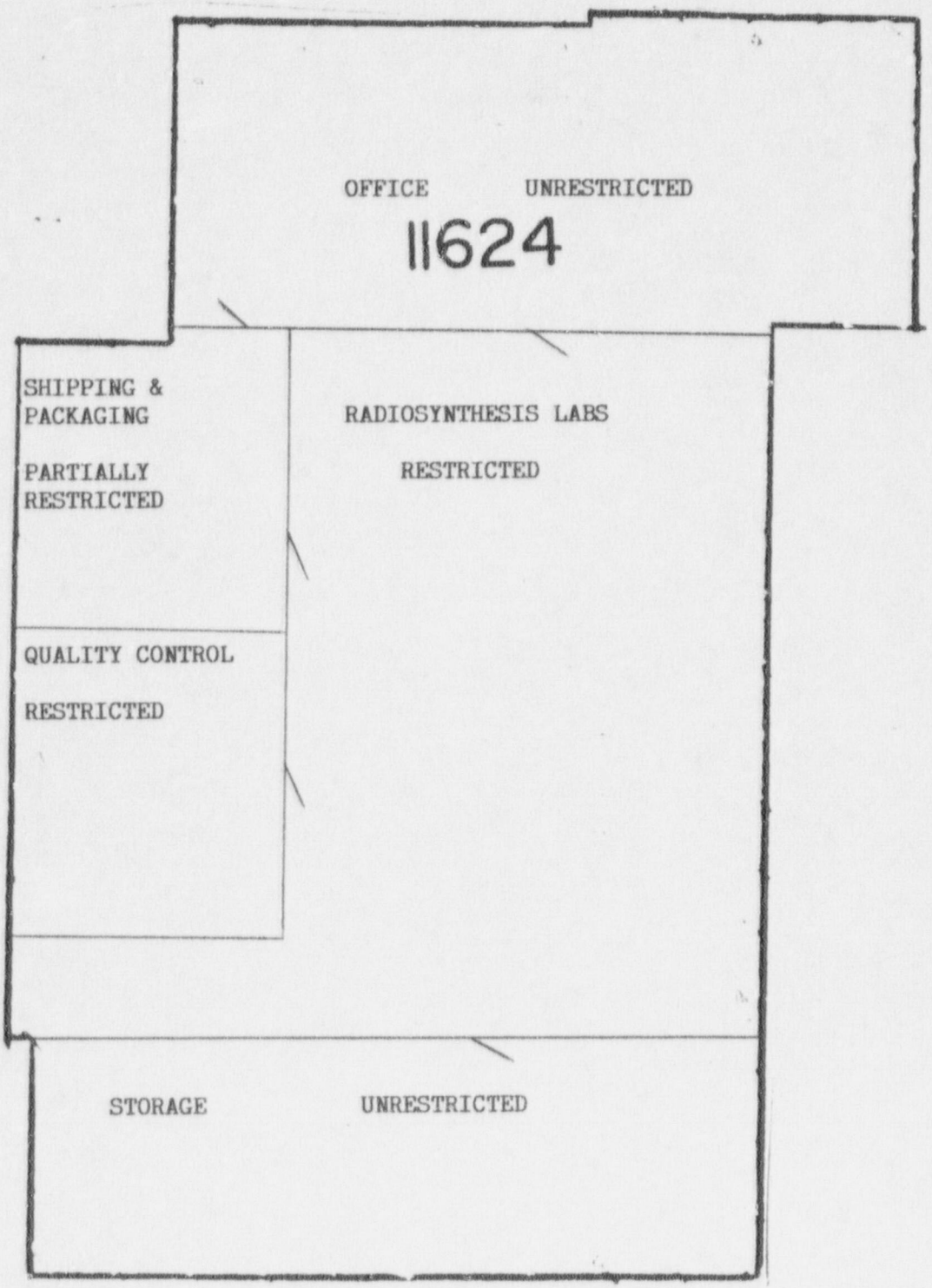
K. SECURITY

The entire facility is secured by means of electronic locks and burglar alarm system. Access to the facility is only attainable by manually entering a programmed digital electronic code. The code is known only to employees at ARC and is changed on any termination of employment.

AMERICAN RADIOLABELED CHEMICALS, INC. BUILDING 1



AMERICAN RADIOLABELED CHEMICALS, INC. BUILDING TWO



ARC STANDARD OPERATING PROCEDURE

SUBJECT: LUDLUM 2200 CALIBRATION

PURPOSE: TO DETERMINE AND VERIFY CALIBRAION FACTORS AND CONSISTANCY OF RESPONSE.

EQUIPMENT:

1. Ludlum Model 2200 with NaI detector.
2. Calibrated standards of each nuclide to be monitored (0.1 to 0.2 uCi each).

PROCEDURE:

1. Determine the proper operating voltage:

a. set "minutes" to 05
b. set switch to rate
c. set switch to x0.1
d. set window to 0.30, switch to on
e. set threshold to the peak energy of the calibration standard to be used (preferably I-131 or Cs-137).
f. set HV to 0.0

Position the calibration standard on the detector and begin increasing the HV 0.25 turns with each count. Document the results of each count and the corresponding HV setting.

Counts will show a continuous but relatively slow increase until the plateau is reached. At this point several sequential counts will yield approximately equal results. Once past the plateau, counts will rapidly increase due to noise interference. Noise can be determined very easily by removing the source (standard) from the detector and counting.

Set HV back to the setting immediately preceding the perceived plateau. Determine the optimum setting within the plateau by increasing the HV settings only slightly between counts (0.3-0.5). Determine the center of the plateau in this manner and document results. This is the optimum operating voltage.

2. Determine conversion factors in uCi/CPM for each radionuclide of interest:

a. Change "minutes" to 05
b. Change switch to x1
c. Set Threshold and Window as follows:

Iodine-125	Iodine-131
Threshold 0.20	Threshold 3.40
Window 0.40	Window 0.50

d. Count background several times, take average a divide by 5 to get CPM.

e. Count standard several times, take average and divide by 5 to get Gross CPM.

f. Subtract background CPM from Gross CPM to get Net CPM.

g. Decay standard total activity to count time. Divide uCi of standard by Net CPM to determine conversion factor in uCi/CPM.

3. Verification of response between calibrations:

a. On the day of calibration, count Cs-137 point source for one minute with threshold set at 0.25 and window switched off. Document total counts.

b. Anytime scaler is to be used, count the Cs-137 point source in the same manner and compare results. Results which deviate from expected response by more than 10% are indicative of a problem.