John H. Engelmann
Assistant Counsel

Miles Laboratories, Inc.
P. O. Box 40
Elkhart, IN 46515
(219) 262-7482

June 11, 1985

Director of Licensing
License Management Branch
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Miles Laboratories, Inc., Elkhart, IN
Byproduct Material License #13-02249-01
Mail Control #16507

Gentlemen:

Miles Laboratories, Inc. applied for renewal of Byproduct Material License #13-02249-01 on November 29, 1983. We are now submitting further information after consultation with G. Mike McCann on April 10 and 11, 1985.

We amend our request for a license renewal of our broadscope license under the Type A requirements of 10 CFR 33.13 to a request for a broadscope license under the Type B requirements of 10 CFR 33.14. It is our understanding that a Type A license requires supervisory control by a Radiation Safety Committee, whereas a Type B license requires control by a Radiation Safety Officer. The Radiological Control Officer of the program will continue to be Kenyon D. Yoder (Refer to Chapter I and attached Statement of Training & Education). His position as Supervisor, Chemical and Radiation Safety reports to the Manager, Corporate Safety and Health within the Corporate Engineering Department which reports to the President of Miles.

PLACES OF USE

Byproduct material will be used principally at 1127 Myrtle Street, Elkhart, Indiana. Additional facility locations that may store or use byproduct material exist at 3400 Middlebury Street, Elkhart, IN; 1301 N. Nappanee Court, Elkhart, IN; 430 South Beiger, Mishawaka, IN; 4315 S. Lafayette, South Bend, IN; and 4718 Vender Ave., Lisle, IL.

MATERIAL AND USES

We are seeking authority to possess any isotope listed in 10 CFR 33.11(b) up to the limits set forth in that section. Uses include (1) as tracers in studying the disposition of organic drug molecules in animals; as tracers in various clinical chemical procedures, (2) as tracers in various in vitro biochemical systems for resale; e.g., immunological, enzymatic, (3) for incorporation into complex organic molecules for use in various research and development projects, (4) for incorporation into complex organic molecules to be sold for eventual tracer use, (5) in calibration of all instrumentation. Intended uses will not include field studies, nor testing in humans.

Additional authority is requested to possess and use sealed sources and gauges that have been evaluated and registered with the NRC or an Agreement State. Also, permission is sought to conduct leak-testing of these units and to relocate these items within our plant site. Leak-testing will be performed at 6 month intervals or at the interval specified by the manufacturer as an acceptable interval by the NRC or Agreement State. These units may contain H-3, Ni-63, Kr-85, and Cs-137. The limit for the Cesium -137 sources would be 1 Curie.

PERSONNEL

Personnel classification is outlined in the attached Chapter II. Background review and designation will be made by the R.C.O. The selection of the A.R.C.S. will be made by the R.C.O. in consultation with the laboratory director. The A.R.C.S., who is generally a research scientist, functions as the liaison between the R.C.O. and the user groups. As such, he performs the service of providing supervision of the radiation safety program for the assigned laboratory location. His duties are outlined in the attached Chapter III. Company policies are outlined to each user in the attached Chapter IV. Common practices in good handling techniques are outlined in Chapter V, and some acceptable decontamination procedures in Chapter VI.

LABORATORY USE AREAS

Laboratories are approved for use of isotopes according to the classification in Tables I & II, attached as Chapter VIII. Audit frequencies, survey frequencies, and any special additional equipment needs are outlined in Table III. Survey monitoring that show levels of contamination above the guides presented in NRC Reg. Guide 8.23 will be decontaminated.

LABORATORY MONITORING & BIOASSAYS

See the attached Chapter X on "Laboratory Monitoring"

The air flow rates through chemical fume hoods are tested on an annual bases through a preventive maintenance program by our Engineering Department. When handling Iodine -125, the sampling of breathing zone exposure of employees and thyroid intake measurements follow the guidelines set out in NRC Reg. Guide 8.20. The use of tritium follows the guidelines set out in the NRC Guideline for Bioassay Requirements for Tritium. When working in amounts greater than 100 millicuries, urinalysis is performed daily on projects of short duration and weekly if the project is extended. Other isotopes used will be evaluated for bioassay under ICRP guidelines. Bioassays will be performed when ingestion may exceed 10% of the MPBB of the material.

Film badges are supplied monthly by R. S. Landauer, Jr. & Co. They are assigned to personnel on long term projects when working with the following: 1 MeV or greater beta emitters, all low-energy gamma emitters used in quantities greater than 1.0 millicurie, all gamma emitters over 200 KeV and x-ray producing equipment. Ring badges and/or wrist badges are furnished when working with Iodine -125 and phosphorus -32 above 10 millicurie quantities.

INSTRUMENTS

Radiation Safety Instrumentation Available

Type of Inst.	#	Radiation Detected	Sensitivity Range	Window Thickness
Victoreen GM Survey, Model 490	1	beta/gamma	0-20 mR/hr.	1.4 - 2.0 mg/cm
Victoreen GM Survey, Model 491	2	beta/gamma	0-100 mR/hr.	1.4 - 2.0 mg/cm
Baird Atomic GM, Model 420 E	1	beta/gamma	0-100 mR/hr.	1.4 - 2.0 mg/cm
Technical Associates, Model PUG-1	1	beta/gamma	0-50,000 CPM	1.5 - 2.0 mg/cm
Eberline MS-1, PG-2 probe	1	low energy gamma	0-900,000 CPM	2 in. NaI cryst

Calibration source is a 30 mCi Cesium -137, NBS traceable, certified by New England Nuclear, Model # NER-401H. On date of certification, Gamma dose rate was 9.6 mRem/hr. + 3% at 100 cm. The procedure used is

outlined in the attached. The guideline contained in NRC Reg. Guide 10.8 is followed. A check source of Cesium -137, containing approximately 10 microcuries, is available to ensure that the instrument is operational before use.

TRAINING

All laboratory personnel using isotopes receive training on the company policies and handling procedures that have been developed for the safe control of radioactive materials. The practices and procedures that comprise our radiation safety program are available to the employee in the form of a manual. Included in the manual is information on our license conditions and the federal regulations. This material is reviewed in training sessions for their education.

Authorized users receive no additional formalized training initially. From time-to-time seminars are offered on various topics to broaden their expertise in handling isotopes. Additionally, scientific seminars are conducted by inside speakers or outside lecturers from universities or consultants on projects under current interest. Many are offered on a monthly basis. Some of these will deal with isotopic material and deal with the technical nature of the subject.

Technical users that work in Level 1 or 2 radiation laboratories that desire to become "Authorized Users" (see Chapter IV, Paragraph D) are provided additional training that cover the characteristics of ionizing radiation, units of dose, health hazards associated with exposure to radioactive material, procedures and precautions to minimize exposure, contamination levels, safe methods of performing work and emergency procedures. A copy of the videotape abstracts available for use in training sessions is attached.

Support personnel, such as custodial receiving and security are provided with a training session. This session covers handling practices in-house along with appropriate videotape, such as "Radiation Safety for Support Personnel" (#1406 on attached training videotape sheet).

WASTE DISPOSAL

See the attached Chapter XIV on "Radioactive Waste Disposal"

Waste material is disposed through four alternative methods: (1) Release to sanitary sewer, (2) Decay to background level and landfill disposal, (3) Incineration, (4) Packaged for commercial burial.

1. Small quantities of low level waste may be disposed by release into our sewage system. This consists of water soluble buffers and other chemicals from in vitro, biochemical, or diagnostic test system, animal excreta, and glassware decontamination. Disposals are recorded by the isotope user with signature required to verify solubility of material, and reviewed by A.R.C.S. Our sewage system handles 2.3 million gallons of liquid sewage daily. Calculations have been done to assure that each laboratory level is minimal and the total complex does not exceed the limits of 10 CFR 20.303 and almost certainly within the 10% ALARA guidelines.

2. Waste material is segregated between long and short half-life. Permission is requested to segregate radionuclides less than 90 days for storage to background levels of measurement and disposal in local landfill. Material so handled will consist primarily of phosphorus -32, iodine -125, and sulfur -35. All such material will be held until undetectable by a GM survey meter sensitive to energy level of interest. The materials withdrawn from storage will have all labeling defaced or obliterated through compaction prior to disposal. Permits have been obtained through the Indiana State Environmental Management board and the local landfill operator.

3. Some waste material may be disposed according to 10 CFR 20.306. Some iodine -125 material is obtained as in vitro diagnostic kits and qualifies under 10 CFR 31.11 (f) as exempt from the requirements of Parts 19, 20, and 21. This exempt material may be incinerated or disposed as common laboratory waste.

4. Permission is requested to continue authorization to incinerate waste materials according to 10 CFR 20.106a. Incineration of material is performed only by the Radiological Control Officer. It has been determined that the air flow (at 600 degrees F) through our incinerator stack is 2200 cu. ft./min. (6.23×10^7 cc/min.). The incinerator is operated 7 hours/day, 5 days a week allowing a total air flow of 6.8×10^{12} cc/yr. Under these conditions the limits specified in 10 CFR 20 Appendix B, Table II, Column 1, as unrestricted area, can be met at the stack, outlet, which is 46 feet high and 12 feet above the roof. A 10% ALARA can be achieved for tritium and carbon -14, a 50% ALARA for sulfur -35 and phosphorus -32, iodine -125 at 100%, and all others at 10%.

Isotope	ALARA Level	Daily Limit	Yearly Limit
H-3	10%	448.0 µCi	112,000 µCi
C-14	10%	224.0 µCi	56,100 µCi
P-32	50%	22.4 µCi	5,600 µCi
S-35	50%	100.8 µCi	25,250 µCi
I-125	100%	1.8 µCi	449 µCi

5. Commercial radioactive waste service is provided by U.S. Ecology of Sheffield, IL. for burial in the State of Washington. We hold a valid "Site Use Permit" from the State of Washington.

   Radioactive waste is the responsibility of the A.R.C.S. until transferred to the central collection area located on the premises of 1127 Myrtle Street, Elkhart. The handling and disposition is then under the control of the R.C.O.

PURCHASING & RECEIVING PROCEDURE

All radioactive requests for incoming transfers and purchase must be approved by the RCO. The following items are needed to process an order:

1. Verify that project has an approved protocol number or submit a "Protocol for the Use of Radioactive Materials", Isotope Form #7, Miles Form P.363.

2. Complete "Application for Radioisotope Procurement", Isotope Form #1, Miles Form #4.090.

3. Complete a Miles Purchase Requisition and obtain authorized signature.

4. Forward to Radiation Control Office.

Each laboratory shall maintain procedures for safely opening all packages in which licensed material is received, and shall assure that these procedures are followed according to 10 CFR Part 20.205(d).

Certain packages, as required, under 10 CFR 20.205(b), are wipe tested for leakage within three hours of receipt in our facility. These packages will be identified to the purchaser, and Isotope Form #13 (copy attached) will be furnished for a wipe test.

Additional procedures are outlined in attached Chapter XI "Purchase and Receipt of Radioactive Material."

INVENTORY CONTROL

See the attached Chapter XII, "Isotope Inventory".

SHIPPING PROCEDURES

See the attached Chapter XIII, "Shipping Radioactive Materials".

Pursuant to the fee schedule in 10 CFR Section 170.31, we previously submitted a sum of $460 under Category 3.B.1. Under this application for a new reduced status, the category needs to be reevaluated and classified.

We trust the information in this letter and the enclosures contain the information necessary to continue processing the license renewal submission. If you have further questions you may contact Mr. Kenyon Yoder, phone (219) 262-7574, or myself at the number indicated on the letterhead.

Very truly yours,

MILES LABORATORIES, INC.

John H. Engelmann

John H. Engelmann

JHE/kab 8515601E8

Enclosures

Chapter I: RADIOLOGICAL CONTROL OFFICER

A. Serve as liaison between Miles Laboratories, Inc., and the Nuclear Regulatory Commission.

B. Prepare and maintain all Nuclear Regulatory Commission Licenses, amendments, and renewals for facilities in the state of Indiana and assist all domestic plants.

C. Establish policies, procedures, and guidelines for the control of isotopes consistent with the regulation and license conditions.

D. Review and grant permission for, or disapprove and control, the use of radioactive isotopes within the company from the standpoint of safety procedures.

E. Provide assistance and counsel in facility planning, design, and construction of all new areas or facilities using isotopes.

F. Review and approve adequacy of procedures, equipment, and facilities from a safety and health viewpoint to be employed in the use of radioactive materials. Approval of safety measures must be obtained before initiation of new projects.

G. Conduct a continuous program of radiation hazard evaluation and elimination. Each Level 1 laboratory will be audited annually: Level 2 laboratories semiannually.

H. Review and approve adequacy of training and experience of all applicants requesting permission to obtain and use radioactive materials.

I. Prepare and distribute information on radiological safety. Provide training appropriate to the needs of all isotope personnel.

J. Maintain a personnel monitoring program, including bioassay when required. Maintain personnel records and notify individuals of their exposure.

K. Maintain a continuous program of radiation surveys and monitoring of all isotope facilities, and records of same.

L. Supervise and coordinate the waste disposal program, including storage and disposal; and maintain records as specified by the applicable regulatory agency.

M. Maintain and calibrate all health physics instrumentation, materials, and supplies. Disseminate information on all aspects of radiation protection.

N. Supervise and assist with decontamination in case of accidental spills involving radioactive materials.

O. Provide counsel in the manufacture, packaging, and distribution of commercial products containing radioactive material.

P. Keep records concerning action taken regarding application for radioisotope usage and other operations submitted to the R.C.O.

Q. Overall administrative direction of the company radiation safety program to ensure compliance with state and federal regulations and license conditions.

Chapter II: AREA RADIOLOGICAL CONTROL SUPERVISOR

A. An area Radiological Control Supervisor is an individual who has been assigned by departmental or divisional management to be responsible for the administration of a safe radiation program. This person, of exempt level status, will have the training and experience of an authorized user and will have been an authorized user at Miles for at least one year.

B. Personnel

1. Responsible for the use of radioactive materials within his/her department or laboratory area.

2. Must insure that each person under his/her direction uses safe handling procedures and appropriate protective equipment to assure the safety of all personnel.

3. Request all personnel to use film badges or other personnel monitoring equipment when appropriate.

4. Restrict use of isotopes to the posted areas designated for radioactive materials.

5. Report any accidental inhalation, ingestion, or injury involving radioactive materials to the RCO and to the Medical Department.

6. Assure that all workers receive training, direct supervision and on-the-job training in the use of radioactive materials.

7. Assure that "Technical Users" work only under the supervision of an "Authorized User".

C. Area Surveys

1. Responsible to establish appropriate procedures for contamination surveys and insure that the surveys are conducted at assigned intervals.

2. Survey records must be forwarded promptly to RCO.

D. Purchase of Isotopes

1. Submit a "Protocol for the use of Radioactive Materials" for proposed projects including information on procedures, methods, and safety equipment and facilities to the RCO.

2. Send Purchase Requisition and Isotope Procurement Form #4.090, signed by ARCS, to the RCO.

3. Maintain current inventories of isotopes in his/her possession and submit a quarterly report to the RCO.

E. Waste Disposal

1. Forward all waste, accompanied by a completed Form #4.395, to the RCO.

F. Audits (in area of responsibility)

1. Review all areas according to schedule outlined in Table 3 of Chapter VIII.

2. Review active user list for proper supervisory control and training.

3. Conduct physical inventory of original material.

4. Review for adherence to approved protocol and operating procedures.

5. Inspect for use of monitoring equipment, protective equipment, and proper labeling of containers, equipment, and use areas.

6. Review area survey monitoring procedures for adequacy and appropriateness.

Chapter III: ISOTOPE PERSONNEL CLASSIFICATION

ARCS:

An Area Radiological Control Supervisor is an individual who has been assigned by Departmental or Divisional management to be responsible for the administration of a safe radiation program. Upon approval by the Radiological Control Officer, the A.R.C.S. will be responsible for the operation of a radiation safety program under the guidance of the R.C.O. This person, of exempt level status, will have the training and experience of an authorized user and will have been an authorized user at Miles for at least one year.

AUTHORIZED USER:

An individual who satisfies the general requirements of 10 CFR Part 33.15. A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and at least 40 working hours of 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 to be used. In lieu of a college degree, two years of applied laboratory experience will be equal to one year of college.

TECHNICAL USERS:

Technical support personnel who are involved in the actual use and handling of radioactive materials. These personnel usually work under the immediate supervision of Authorized Users. This level might include laboratory analysts, exempt level scientists without prior experience, and animal handlers.

GENERAL SUPPORT PERSONNEL:

Individuals who do not actually use radioactive materials, but may come in contact with packages or work in areas where above exempt quantities are stored or used. This level might include receiving personnel, security, and janitorial staff.

Chapter IV: INDIVIDUAL ISOTOPE USER

A. No person shall begin working with radioactive material until such time as he/she has been approved in writing by the Radiological Control Officer. The individual shall indicate to the RCO their desire to work with radioactive materials by completing and forwarding copies of Isotope Forms 2, 4, and 6. The ARCS shall assure that each person under his/her direction has received the appropriate training and has read the Miles Radiological Control Handbook and the relevant portions of Title 10, Code of Federal Regulations, Parts 19 and 20 (see Section 4 of this manual), and the Nuclear Regulatory Commission license held by Miles Laboratories (see Section 3 of this manual).

B. The Radiological Control Officer will not approve the application from employees under 18 years of age (10 CFR 20.104).

C. An "Authorized User" as described in Chapter II will be one who has satisfied the requirements of a bachelor level degree in the sciences or engineering, and has had at least 40 working hours of training and experience in the safe handling of radioactive materials.

D. Individuals without formal training in the use of isotopes or appropriate experience will be classified as a "Technical User". They must work under the supervision of an "Authorized User". With adequate training and additional experience to obtain an adequate understanding of handling techniques, methods, equipment, and calculations unique to the use of radioactive materials they may become "Authorized Users."

E. Occasionally, the medical condition of some employees may require that exposure to hazardous materials be further minimized or eliminated. The Director of Employee Medical Affairs may recommend that such employee be assigned according to the terms described in the Personnel Practices Manual H.11.1. Medical conditions concerning work involvement should be reviewed with the Department of Occupational Health.

F. At the perogative of the Director of Employee Medical Affairs, medical evaluation may be required prior to initiation of radioisotope use or periodically thereafter.

G. Each individual user should strive to keep exposure to radiation as low as reasonably achievable. Laboratory air and water concentrations and surface contamination levels shall be kept to a minimum and, specifically, below those listed in Section 4, Appendix B, Table II of this manual.

H. The user shall wear the prescribed monitoring equipment as indicated in the project's "Protocol for Use of Radioactive Material".

I. The user shall follow all appropriate work procedures as specifically mentioned in this manual and as prescribed in the project's "Protocol for Use of Radioactive Material".

J. Each user shall restrict use of radioisotopes to those areas approved as radioactive material work areas. These areas are restricted to isotope use only to prevent the spread of contamination.

K. Assure that all equipment that comes in contact with radioactive material are labeled and isolated. Once used for radioactive substances, the equipment should not be used for other laboratory work until demonstrated to be free of contamination.

L. Report immediately accidental inhalation, ingestion, or injury to the ARCS, RCO, the Department of Occupational Health, or the designated medical representative.

M. Report immediately to the ARCS or RCO all incidents involving isotopes that might lead to the spread of contamination.

Chapter V: SAFE HANDLING PROCEDURES

A. Protection Against Personal Contamination

1. No smoking, eating, or drinking is permitted in the immediate area where radioactive material is being used.

2. The storage of food and drinks in radioisotope refrigerators, freezers, or cabinets is prohibited.

3. All radioactive solutions are to be pipetted using pipette filling devices.

4. Wear protective clothing whenever contamination is possible.

5. Wear disposable gloves to avoid contact with radioactive materials. Organic solvents will permeate through various gloves. Choose the glove material with respect to the solvent being used.

6. Extreme care must be exercised if working with open cuts below the wrist. Use appropriate glove material to protect contamination of skin.

7. Use protective shields and mechanical devices whenever their aid will assist in reducing exposure. (See Chapter IX of this section for additional information).

8. Wear the prescribed personnel monitoring device.

9. Use appropriate monitoring devices to determine the presence of contamination on hands, clothing, and work area. Each worker is personally responsible to check for contamination before leaving the area.

10. Wash hands and arms thoroughly before handling any object that goes to the mouth, nose, or eyes.

B. Protection Against Laboratory Contamination

1. Areas restricted to radioisotope use are to be kept clean, orderly, and free of unnecessary equipment and supplies.

2. All chemical procedures using radioactive materials are to be carried out on a surface that has an area large enough to accomodate the work to be performed. Congestion can lead to unsafe working conditions.

3. Contamination of the general laboratory air and ventilation system must be avoided. Where the use of isotopes may result in airborne contamination, a suitable hood or glove box must be used with the appropriate filtration system, direct exhaust, and air monitoring devices. (See Chapter IX of this section for additional information).

4. Absorbent paper, with the plastic backing down, should line the interface of work surfaces that could become contaminated.

5. Wherever practical, confine solutions to double containers. In movement about the laboratories, an outer unbreakable container should be used to prevent the possibility of spillage or breakage.

6. The transfer of solutions from one container to another, should be performed within a double container or over an absorbent lined tray or pan to limit and confine spillage and the spread of contamination.

7. Handling equipment that is not contaminated should be placed in a tray or pan located away from the actual work area.

8. A caution label (see Section 4, part 20.203f) shall be applied to all containers actually containing radioactive material; contaminated containers shall be labeled unless attended by an individual who takes precautions necessary to prevent someone else from possible contamination.

9. Contaminated equipment or that suspected of contamination shall be labeled and isolated until decontaminated.

10. Contaminated equipment, supplies, containers, etc., shall not be released from the area for general use until shown to be free of contamination.

C. Protection Against Contamination of Clothing

1. It shall be the responsibility of the designated user to see that appropriate clothing is worn whenever contamination is possible.

2. Such protective clothing shall be monitored at appropriate intervals during usage.

3. Such protective clothing is not to be worn eleswhere, especially in areas where smoking and eating are common practice.

Chapter VI: DECONTAMINATION PROCEDURES

A. Decontamination of Clothing

1. Laboratory clothing should not be released to laundries unless the contamination is below permissible levels. If contaminated with a short-lived isotope, the clothing may be stored until the contamination is reduced to a safe level.

2. Contaminated street clothing should be isolated in plastic bags until they can be laundered. Contact the RCO for assistance in determining appropriate procedures to follow. A separate washing of lightly contaminated clothing can be carried out according to certain procedures:
   a. Begin with several rinsings.
   b. Use standard detergents with longer periods of washing and repeated rinsings for heavy contamination.
   c. Cleaning efficiency of resistant contamination can be accelerated by using complexing agents such as 1% citric acid solution or 10% sodium citrate, or chelating agents such as 1-2% EDTA or 5-10% sodium carbonate in combination with the detergent.
   d. Follow with numerous rinsings and monitor for residual radioactivity. The laundry equipment should be monitored for residual contamination.

3. If neither of the above is practical, discard the clothing as radioactive waste.

B. Decontamination of the Skin

1. The immediate washing of contaminated areas with soap and water is the best general method for decontamination regardless of contaminant, subject to the following:
   a. Tepid water should be used.
   b. The soap should not be abrasive nor highly alkaline.
   c. The skin should be washed for a few minutes at a time, then dried and monitored.
   d. Washing can be repeated if necessary, provided that there is no indication of damage to the skin.

2. If this procedure fails, a commercial skin decontaminating agent can be employed.

3. Special care should be paid to proper decontamination of creases, folds, fingernails, areas between fingers, and the outer edges of the hands.

4. Care should be taken to avoid spreading contamination to uncontaminated parts of the body, and to avoid internal contamination. An open wound should be protected against any further contamination.

5. Avoid the use of organic solvents or alkaline solutions that may increase the probability of radioactive materials penetrating through the pores of the skin.

6. The cleaned area should be dried with fresh non-contaminated towels and monitored.

C. Decontamination of Equipment

1. A decision to decontaminate material must take into account the continuing value of the material compared with effort and cost of decontamination.

2. Equipment should be decontaminated as soon as possible to prevent the contaminant from becoming fixed.

3. Rinse 3 times with an appropriate solvent (aqueous or organic) and dispose of all rinse into the proper radioactive waste container. Rinsing should be performed immediately after use, before the article dries.

4. Place the rinsed equipment in one of several commercially available decontaminating solutions to soak overnight. Pour solution into waste container and mix fresh decontamination solution before scrubbing equipment and washing according to general procedures.

5. Equipment should be monitored and where contamination of more than 3 times above background exists, the equipment should be resoaked or disposed of as radioactive waste.

6. All decontaminating solutions should be monitored for radioactivity before proper disposal.

7. Decontaminated equipment may then be washed according to general cleaning procedures.

8. Alternative cleaning agents for glassware are chromic acid solution, concentrated nitric acid, ammonium citrate, and other chelating agents such as EDTA.

9. Alternatives for metal tools include dilute nitric acid, a 10% solution of sodium citrate, and other chelating agents. Stainless steel could be treated with dilute sulphuric acid or a suitable polish. Cleaning agents should be chosen taking into account the material of which the equipment is made and the likely chemical nature of the contaminant.

10. If the decontamination causes any corrosion of the metal, any future contamination will be more difficult to remove. A new coat of paint may be desirable.

11. Surfaces of paintwork can be cleaned with soap or detergent and water, commercial preparations, or in extreme cases removed with paint renover and repainted.

12. Floor surfaces can be cleaned with detergent and water, commercial preparations, or in extreme cases the wax polish may need to be removed and rewaxed. Floor tile can be removed and replaced if defaced by solvent spills.

Chapter VII: PERSONNEL MONITORING

A. Prior to the start of initial work, all personnel who will work with radioactive material must first complete Isotope Personnel forms 2, 4, and 6.

B. Film badges will be assigned to personnel employed on long-term projects when working with the following: 1 MeV or greater beta emitters, all low energy gamma emitters used in quantities greater than 1.0 millicurie, all gamma emitters over 200 KeV, x-ray producing equipment, or at the discretion of the RCO. Film badges need not be worn when it has definitely been established by the RCO that exposures will not exceed the limits specified in Section 4, part 10 CFR 20.202. When not in use film badges must be stored in a location away from radiation, excessive heat, or moisture.

C. Pocket dosimeters may be assigned for short term projects subject to all of the above. A record of exposure recorded by each dosimeter will be maintained by the RCO.

D. Records of personnel monitoring shall be maintained by the RCO (see Section 4, part 10 CFR 20.401 a and c) and are available upon request subject to 10 CFR 19.13 (see Section 4).

E. Bioassays

1. Urinalysis may be required whenever tritiated water could arise during the use of the material.

2. Projects involving tritium in amounts greater than 100 millicuries will require daily urinalysis during short-term projects and weekly on long-term projects (Form #4.922).

3. Thyroid scans will be required of personnel involved directly in Iodine-125 tagging operations in excess of 10 millicuries. A pre-operational baseline measurement shall be taken within 2 weeks prior to beginning work and again within 72 hours following subsequent use of Iodine-125. Long term use may vary this procedure. (Form #4.990)

4. Bioassays with other isotopes and at lower amounts may be prescribed at the discretion of the RCO.

F. Limits of exposure of individuals to radiation in restricted areas are defined in 10 CFR 20.101 and 20.103 (see Section 4).

Chapter VIII: ISOTOPE USE AREAS*

A. No radioactive material shall be used or stored in any Level 1 or Level 2 Isotope Lab area until the ARCS has provided the RCO with a line drawing of the area, and this area has been approved by the RCO.

B. Each Level 1 or Level 2 Isotope Lab area in which licensed material is used and/or stored shall be conspicuously posted with the conventional radiation caution colors (magenta on yellow background) and bear the conventional radiation symbol and the words: "Caution Radioactive Materials". Only those personnel immediately concerned with the isotope work shall be permitted to use the restricted area.

C. Areas possessing higher levels of radiation exposure, such that an individual could receive a dose in excess of 5 millirem/hour or in any 5 days a dose in excess of 100 millirem, would be posted as: "Caution Radiation Area".

D. A room or area is not required to be posted with a caution sign when the total amount of activity used at any time does not exceed the value given as Exempt A in Table 3 (See Section 4, 10 CFR 20, Appendix C).

E. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level 12 inches from the surface does not exceed 5 millirem/hour.

F. Any room or enclosure in which airborne radioactive material meets the criteria stated in 10 CFR 20.203 d (see Section 4) shall be posted: "Caution Airborne Radioactivity Area".

G. Caution signs are not required to be posted at areas containing radioactive materials for periods less than 8 hours provided such materials are constantly attended by an individual who will prevent unnecessary exposure during such periods.

H. Caution signs are not required to be posted at areas containing radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.

I. Any area deleted from restricted isotope use must be reported to the RCO. The area must be monitored and recorded as being free of contamination, with all caution signs removed before it can be released for common use.

* Refer to Isotope Lab Classification Chart in Table 2

ISOTOPE TABLE 1

CLASSIFICATION OF RADIONUCLUDES ACCORDING TO RELATIVE RADIOACTIVITY PER UNIT ACTIVITY
(Based on Published data and NIH Sources)

Class 1 (very high toxicity)
SR-90 + Y-90, *Pb-210 + Bi-210(ra D + E), Po-210, At-211, *Ra-226 + 55% *daughter products, Ac-227, *U-233, Pu-239, *Am-241, Cm-242, plus other transuranium isotopes.

Class 2 (high toxicity)
Ca-45, *Ca-47, *Fe-59, *Sr-85, Sr-89, Y-91, *Ru-106 + Rh-106, *I-125, *I-131, *Ba-140 + *La-140, Ce-144 + *Pr-144, Sm-151, *Eu-154, *Tm-170, *Hg-203, *Th-234 + *Pa-234, *natural uranium.

Class 3 (moderate toxicity)
*Na-22, *Na-24, P-32, P-33, S-35, Cl-36, *K-42, *Sc-46, *Sc-47, *Sc-48, *V-48, *Mn-52, *Mn-54, *Mn-56, Fe-55, *Co-57, *Co-58, *Co-60, Ni-59, *Cu-64, *Cu-67, *Zn-65, *Ga-67, *Ga-72, *As-74, *As-76, *Br-82, *Kr-85, *Rb-84, *Rb-86, *Zr-95 + *Nb-95, *Nb-95, *Mo-99, Tc-98, *Rh-105, Pd-103 + Rh-103, *Ag-105, *Ag-111, Cd-109 + *Ag-109, *Sn-113, *Te-127, *Te-129, *I-132, *Xe-133, *Cs-137 + *Bs-137, *La-140, Pr-143, Pm-147, *Ho-166, *Lu-177, *Ta-182, *W-181, *Re-183, Ir-190, *Ir-192, Pt-191, *Pt-193, *Au-196, *Au-198, *Au-199, Tl-200, Tl-202, Tl-204, *Pb-203, *Hg-197.

Class 4 (slight toxicity)
H-3, Be-7, C-14, *F-18, *Cr-51, Ge-71, *Sr-87m, *Tx-99m, *Tl-201.

*Gamma emitter and/or associated photon emitter.

Boxed isotopes are those which Miles has regularly used over the years.

ISOTOPE LABORATORY CLASSIFICATION
(Refer to Isotope Table 1)

ISOTOPE TABLE 2

GUIDELINES FOR MAXIMUM ACTIVITIES IN MILES LABORATORIES

Class (Radiotoxicity) of Radionuclides	Exempt Level Lab	Maximum Use In (2) Typical Miles Laboratory Level 1 lab.	Radionuclide Laboratory (2) Level 2 lab.
1 (Very high)	0.1 µCi	10 µCi or less	10 µCi-10 mCi
2 (High)	1.0 µCi	100 µCi or less	100 µCi-100 mCi
3 (Moderate)	10 µCi	1 mCi or less	1 mCi-1 Ci
4 (Slight)	100 µCi	10 mci or less	10 mCi-10 Ci
Exempt QT.	See (1)	None	None

Level 1 and Level 2 have the meanings normally used in the classification of laboratories for handling radioactive materials. Level 1 is a good quality chemical laboratory. Level 2 is a specially designed radioisotope laboratory. In the case of a conventional modern chemical laboratory with adequate ventilation and fume hoods, as well as polished, easily cleaned, non-absorbing surfaces, etc., it would be possible to increase the upper limits of activity for Level 1 laboratories towards the limits for Level 2 laboratories for toxicity groups slight and moderate.

Modifying factors should be applied to the quantities indicated in the last 2 columns of the above table, according to the complexity of the procedures to be followed. The following factors are suggested but due regard should be paid to the circumstances affecting individual cases.

Procedure	Modifying Factor
Storage (stock solutions)	x 100
Very simple wet operations	x 10
Normal chemical operations	x 1
Complex wet operations with risk of spills	x 0.1
Simple dry operations	x 0.1
Dry and dusty operations	x 0.01

(1) Exempt quantities

All generally licensed items at quantities approved by the regulations. All items generally licensed according to 10 CFR 31.11 at quantities approved by the regulation. All exempt quantity items at quantity specified in Part 30.71 Schedule B, or Appendix C.

(2) With proper documentation of experimental protocol and with approval of the R.C.O., investigators may be permitted to exceed these quantities in specifically approved laboratories.

TABLE 3

SPECIAL REQUIREMENTS

	Survey Frequency	ARCS Audit Frequency	RCO Audit	Spec. Equipment	Training & Experience
Exempt A (Less than 10x Table 2 used monthly)	At end of project or annually	Not required	Annually or end of project	No additional requirements	None required
Exempt B (More than 10x Table 2)	Quarterly	Annually	Annually	No additional requirements	Personnel should have access to Authorized User or ARCS
Level 1	Quarterly	Semi-Annually	Annually	. May use shielding . Cont. monitor or wipe testing . Liq. Scint. counter	Meet requirement of Authorized or Technical User
Level 2	Monthly	Quarterly	Semi-Annually	. Appropriate shielding . GM survey meter . LSC . May require suitable fume hood	Meet requirement of Authorized or Technical User

Chapter X: LABORATORY MONITORING

A. All isotope work areas or restricted areas, as discussed in Chapter VIII previously, are required to be surveyed.

1. It shall be the responsibility of the ARCS to establish appropriate procedures for such surveys and to insure that the surveys are conducted as outlined in Table 3 to Chapter VIII, per NRC license conditions.

2. A wipe test appropriate to the isotopes used shall be made of all work areas. Two examples are included in the isotope forms section 5 of this manual, i.e. isotope forms #18 and #20.
   a. Select filter paper of a size appropriate to the vial or counting tube used.
   b. Soak in solvent that will remove contaminant (50% ethanol or 0.9% sodium chloride).
   c. Wipe paper over a sampling area of 100 cm^2.
   d. Count sample three times, for a minimum of 5 minutes each, to obtain a statistical accuracy.
   e. Record on survey report form.
   f. Consult Table 4 - "Table of Contamination Levels" for further action required.
   g. An observed count rate more than three times the background count rate will require decontamination of work area: scrub with soap and water, commercial decontamination preparations, 50% ethanol, or solvent appropriate to contaminant; take precautions to avoid spreading the contamination to adjacent areas; then rinse area with water and recount.
   h. Record all information, retain a copy, and send original to the Radiation Control Office.

B. Areas possessing high level gamma emitters, high level beta emitters, finished products, sealed sources, and storage areas of same will require routine monitoring of radiation levels with a portable survey meter. An example of G-M survey reading is included in the isotope forms section 5 of this manual, i.e. isotope form #19.

1. Areas with radiation levels below 5 millirem/hour are to be posted "Caution Radioactive Materials".

2. Areas where radiation levels may expose individuals to 5 millirem in any one hour; or in any five consecutive days, a dose in excess of 100 millirem, shall be posted "Caution Radiation Area".

C. Formal records of the results of all surveys shall be maintained by, and copies of the survey records must be promptly forwarded to, the RCO. Such records must be retained until the NRC authorizes disposition (see Section 4, part 20.401 c).

TABLE 4

Table of Contamination Levels
(Beta-Gamma)

LABORATORY AREAS

Smear Results	Action
250 dpm/100 cm^2	No action required
250-1000/100 cm^2	Area or surface cleaned as soon as possible. Custodial personnel may be used.
1000-2000/100 cm^2	Areas or surfaces cleaned as soon as possible by the investigator or supervised assistant.
2000/100 cm^2	Immediate action shall be taken to prevent spreading. Immediate clean-up should be performed by the investigator or supervised assistants. A determination should be made of caustive factor and corrective measures instituted.

SKIN, CLOTHING & EQUIPMENT

250 DPM/100 cm^2	Decontaminate skin or clothing worn outside laboratory areas.
2000 DPM/100 cm^2	Decontaminate clothing room only in laboratory area.
1000 DPM/100 cm^2	Removable contamination should be reduced below the level.
5000-15000 DPM/100 cm^2	Average to maximum allowable of fixed, non-removable contamination permitted on equipment transferred for uncontrolled release.

Note - Depending on the isotope and the counting efficiency, the relation between CPM and DPM will be different, but in general the 3 x BKG is similar to the 250 DPM action level.

Chapter XI: PURCHASE AND RECEIPT OF RADIOACTIVE MATERIAL

A. Reference is made to Corporate Procedure No. 6120089 entitled "Radioactive Substances--Ordering, Receiving, and Delivering Process--Elkhart Complex".

B. All vendors of radioactive material are required to possess and read a copy of the purchaser's NRC license before any transfer can be made (10 CFR 30.41). We have furnished most major vendors a copy of our NRC license.

C. All radioactive requests for incoming transfers and purchase must be approved by the RCO. The following items are needed to process an order:

1. Verify that project has an approved protocol number or submit a "Protocol for the Use of Radioactive Materials", isotope form #7, Miles form P.363.

2. Complete "Application for Radioisotope Procurement", isotope form #1, Miles form #4.090.

3. Complete a Miles Purchase Requisition and obtain authorized signature.

4. Obtain Division cost accountant signature.

5. Forward to Radiation Control Office.

D. Each laboratory shall maintain procedures for safely opening all packages in which licensed material is received, and shall assure that these procedures are followed (see Section 4, part 20.205 d).

1. Dependent upon quantity, form, and type of isotope, the following general procedure should be followed:
   a. Since our receiving department is not permitted to open radioactive material packages, it is important to open all packages immediately to verify contents and possible damage.
   b. Place package in vented hood.
   c. Open outer package and remove packing slip. Open inner package and verify that the contents agree in name and quantity with the packing slip.
   d. Check for possible breakage of seals or containers, loss of liquid or change in color of absorbing material.
   e. Wipe test isotope container for possible surface contamination.
   f. Compare or record type of activity, quantity present, and location of storage on isotope inventory form #4.196. This form will be provided by the RCO after processing the purchase requisition.
   g. Deliver processed package to requisitioner. If delivery is delayed, notify requisitioner of its arrival and clearance.

h. If material has been packaged in dry ice, refrigerate or deliver immediately to ultimate user.

i. If contamination, leakage, or shortages are observed, notify the RCO and the vendor's Customer Service Department immediately by collect telephone call.

2. Any specific instructions included with the package must be followed.

E. Prior to disposal, reuse, or transfer of an empty radioactive material container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material (see Section 4, part 20.203 f.4).

Chapter XII: ISOTOPE INVENTORY

A. The Radiation Control Office will issue an inventory number to each container of radioactive material.

B. A continuous record of each item is to be maintained from receipt to its final disposition. This can conveniently be done by the consistent use of form #4.196, which is mailed to the requisitioner by the Radiation Control Office.

C. It shall be the responsibility of the ARCS to audit inventories of isotopes in his/her possession at frequency specified in Table 3 of Chapter VIII. Inventory adjustments include uses of material, radioactive decay, transfers, and final waste disposition.

D. When original material is used to synthesize other usable material, this should be shown as deleted from the original inventory. A new inventory record (Form 4.196) should be initiated for the new material, including the original inventory lot number from which it was synthesized.

E. Except during periods of use, all isotopes shall be stored in specified central locations within using areas; employing all appropriate shielding and under the control of the ARCS. Note that storage of radioactive material in unrestricted areas is subject to conditions stated in Section 4, parts 20.105 b and 20.207.

F. All isotopes released to personnel shall be protected to prevent spillage of material or unnecessary exposure to all personnel. Any theft or loss of large quantities of radioactive materials are to be reported immediately.

G. Notify the RCO of any inventory transfers between using laboratories within the company to facilitate inventory control of the item.

1. Delete from original isotope inventory form #4.196.

2. Prepare a new form #4.196 including all available information for the receiving laboratory and attach to the material being transferred.

H. The total complex inventory will be adjusted quarterly on the basis of an inventory of research and development isotopes performed by authorized users and the ARCS and reported to the RCO using form #4.398. A similar inventory is conducted quarterly of finished goods distributed by Miles. This total inventory is essential to assure full compliance with the license possession limits.

Chapter XIII: SHIPPING RADIOACTIVE MATERIALS

A. The shipping of radioactive material as either a transfer or for sale must receive prior approval of the Radiation Control Office.

1. Routine shipments must be approved for methods and packaging employed.

2. Non-routine shipments - the shipper will receive assistance from the Radiation Control Office.

B. The recipient of any radioactive material to be shipped from Miles must provide evidence of an NRC (or Agreement State) license by furnishing a copy of his license to the Miles Radiation Control Office before shipment can be made. Non-compliance with this requirement is a violation of the Atomic Energy Act and is subject to criminal prosecution. If a valid license is not already in our possession, request a copy from the recipient in order to fulfill this requirement and speed processing of the shipment.

C. Radioactive material leaving the company must be packaged, labeled, and shipped in accordance with the applicable regulations governing the mode of transportation, as regulated by the Materials Transportation Bureau of the Department of Transportation. The Radiation Control Office works in cooperation with the Miles Traffic Department to assure compliance with these ever changing regulations.

D. Radioactive material leaving the company must be deleted from the inventory of the shipper (research laboratories use inventory form #4.196)

Chapter XIV: RADIOACTIVE WASTE DISPOSAL

A. Disposal Factors

The accumulation of radioactive waste must be collected in containers separate from conventional waste in order to maintain inventory control and to insure proper disposition of the material. Due to the increasing difficulties associated with waste disposal, a number of specific points need to be emphasized:

1. Care must be exercised to separate radioactive waste from non-radioactive waste. Non-radioactive waste is an expensive burden.

2. Work planning should include thought in minimizing the generation of waste.

3. The segregation of material according to burnable and non-burnable is important in the final disposition. Only the generator can conveniently separate such material.

4. Segregation of short half-life material is of primary importance to disposal options.

5. Follow any additional procedures provided by the RCO to facilitate waste handling operations.

B. Basic Types of Radioactive Waste

1. Segregation by half-life:

Short Half-life (less than 90 days)		Long Half-life (greater than 90 days)	
P-32	14.28 d	H-3	12.26 y
S-35	87.9 d	C-14	5730 y
Cr-51	27.8 d	Na-22	2.62 y
Fe-59	45.6 d	Ca-45	165 d
I-125	60.2 d	Co-57	270 d
I-131	8.05 d	Co-60	5.26 y
		Cs-137	30 y

2. Segregation by physical form:

a. SOLID FORM

dry waste - Burnable materials - low activity bench top liners, pipettes, test tubes, etc.
- non-burnable materials - glass, metal, unused product
absorbed waste - Liquid absorbed in sawdust, vermiculite, etc.
animal carcasses - soiled bedding, etc.

b. LIQUID FORM

aqueous (water soluble) - may be sewered
organic solvents - may NOT be sewered

c. LIQUID IN VIALS

capped liquid scintillation vials - see (3a) below

d. GASEOUS FORM

volatilized I-125, H-3, Kr-85

3. Segregation as exempt from disposal rules:

a. LESS THAN 0.05 uCi/gram H-3 or C-14, and P-32 after decay

Liquid scintillation media
Animal carcasses

C. Methods of Waste Disposal

1. Decay to background level (about 10 half-lives).

2. Release to sanitary sewer (water soluable) according to MPCw.

3. Package for commercial burial.

4. Incinerate (requires NRC permit).

5. Vent to atmosphere according to MPC air.

WASTE HANDLING PROCEDURE

Waste accumulated by individual users must be prepared for transfer to the central collection center in the proper containers, accompanied by a completed form #4.395 (Kankakee facility uses form #7.595) and in accordance with the following:

A. Solid Waste - special plastic-lined waste containers are available from the Radiation Control Office for disposal of dry contaminated waste. These are to be located in all laboratories using radioisotopes.

1. All such containers must be conspicuously labeled with radioactive material caution signs.

2. A container for burnables shall be maintained separate from non-burnables and labeled appropriately.

3. Separate material that will incinerate at temperatures up to 1400°F (760°C) from non-burnable material.

4. Burnable material should be relatively low in activity in order to meet the MPC emission guidelines.

5. The contaminated waste shall be sealed in the plastic bag for disposal by the RCO.

B. Liquid Waste - Organic solvents should be separated from aqueous liquids. An appropriate safety can should be used for storage of flammable solvents. Aqueous materials should be retained in non-breakable plastic or coated containers.

1. Organic solvents will be disposed by approved methods.

2. Aqueous liquids may be discarded via the sewer system if the total discharged per day does not exceed the maximum permissible limits (see Section 4, 10 CFR 20.303, Appendix B, Table I, Column 2).
   a. liquid must be water soluble
   b. each lab may not exceed 1,000 microcuries of H-3, C-14, P-32, S-35, or I-125 per day
   c. may only be discarded in approved designated sinks
   d. records maintained and submitted quarterly.

3. All such containers must be conspicuously labeled with radioactive material caution signs.

4. Containers of volatile liquid waste shall contain appropriate additives to prevent volitilization of the radioactive material.

5. All strong acid or base liquid waste must be neutralized before disposal.

6. Each bottle shall contain no more than one isotope and no immiscible liquids shall be contained together.

7. Incompatible chemicals shall be called to the attention of the RCO.

C. Liquid Scintillation Vials

1. Scintillation vials containing scintillator should be replaced in their original trays for transfer to the collection center.

2. Trays containing Sulfur - 35 or Phosporus 32 must be identified.

3. Solvent-free scintillation fluids and vials should be segregated for a less expensive disposal method.

D. Animal Carcasses and Animal Wastes

1. All radioactive animal carcasses and tissues must be placed in plastic bags, conspicuously labeled with radioactive material caution tape, isotope and activity, then frozen.

2. Animal urine may be handled as liquid waste.

3. Animal feces will need to be dried, absorbed, or solidified for disposal as solid waste.

4. Animal tissue should be placed in a container. All liquid must be absorbed with vermiculite or similar absorbent for disposal as solid waste.

E. Airborne Radioactive Emission

1. Airborne emissions are subject to concentration limits as specified by the NRC in Appendix B of 10 CFR 20 for each isotope. Consult with the RCO for monitoring techniques.

F. Records

1. Records of disposal by isotope, activity, and form are required at time of transfer to the collection center.

2. In addition to all containers bearing the caution tape, each container should be identified with the appropriate disposal records form #4.395 (Kankakee facility uses form #7.595).

3. The following information should be supplied on the form:
   a. date
   b. isotope
   c. user's name and department
   d. type of waste (liquid, combustible, or non-combustible solid)
   e. description of contents (nature of material in exact terms)
   f. chemical contents (principal solvent, reagent, or most toxic form)
   g. activity (show determination)

4. Records of aqueous liquid should be completed and initialed by individual who disposes into the sanitary sewer. At the end of each quarter, the Area Radiological Control Officer needs to sign and forward to the Radiation Control Office.
   a. Isotope Form #34 - Elkhart, Indiana
   b. Isotope Form #34a - South Bend, Indiana
   c. Isotope Form #34b - Lisle, Illinois

Calibration of Survey Instruments

Background information and procedural details are located in the Bureau of Radiological Health Training Publication -260. (TP-260 is contained in section X of the Basic Radiological Health Manual in the course conducted by the U.S. Environmental Protection Agency.)

All portable survey instruments of Geiger-Mueller and ionization chamber type instruments are to be calibrated every six months. An amendment to our license permits the calibration to be performed annually. All records are maintained in the notebook titled "Calibration Schedule and Curves - Survey Instruments".

Equipment needed:

Survey instruments
Meter stick
Chalk
Certified sealed source - 30 mCi ^{137}Cs
Source handling tool
Ring stand with clamp
Small screw driver
Clipboard - data sheets
Film Badge
Keys - Cabinet & Source

Procedure:

1. Annually change batteries to prevent failures and corrosion.
2. Set up source in outdoor area or if indoors in an open area to prevent backscatter. Surrounding area is barracaded.
3. Mark off distances in chalk.
4. Measure radiation intensity by noting average reading at each distance marked.
5. Move toward source. At each distance marking record scale reading, range, and distance on data sheet.
6. DO NOT LINGER NEAR SOURCE NOR ALLOW OTHERS TO APPROACH SOURCE.
7. Calculate true exposure rates for the same distances. (Gamma radiation levels are listed on page 131 of 1970 edition of the U.S. HEW Radiological Health Handbook). Recalculate for decay.

Data Sheet

Distance (Feet or Yards)	Range Selector Setting	Dial Reading (mR/hr)	True mR/hr (Calculated)

Date of Calibration _____ Source _____

Manufacturer _____ Model No. _____

Serial No. _____ Signature _____

1400 RADIATION SAFETY

1401. RADIATION SAFETY: INTRODUCTION
Indiana University

Videotape
16 minutes

A very good review of low energy β, hard β, x-ray and gamma emitters. Reviews safe handling procedures and techniques for lowering exposure levels, introducing the concept of radiation protection. It is ideal for scientists who have not handled isotopes and for those who need a review. This is an up-to-date film that discusses all the isotopes we are currently using in research at Miles. This film can be used to provide training to all laboratory workers on the basic concepts and precautions to be observed in the isotope areas of our chemical laboratories.

1402. RADIATION SAFETY: LABORATORY TECHNIQUES
Indiana University

Videotape
16 minutes

A very good program for lab personnel who need to learn or review good handling techniques for the safe use of radioactive material. It presents a program illustrating laboratory safety techniques when working with isotopes. Such a program involves careful planning, safe working habits, routine monitoring, regular inventory maintenance, proper disposal of waste, and utilization of the expertise of radiation safety personnel. This film is applicable to many of the techniques and handling procedures used in research at Miles. It can be used to train scientists who have not handled isotopes before, as well as providing a good informative review for the more experienced personnel.

1403. RADIATION SAFETY: EMERGENCY PROCEDURES
Indiana University

Videotape
11 minutes

This film should be viewed with the knowledge that a number of accident situations are illustrated in this short film. It is beyond reality in that regard, but the incidences that arise illustrate to the viewer what should be done when specific types of accidents occur; whether that may be a small accident in an RIA clinical laboratory, or a larger spill accompanied by personnel injury. The re-enactments emphasize the four basic principles for coping with an emergency situation: assist people first, monitor personnel, control the area, and call radiation safety. Also shown are monitoring techniques and decontamination procedures. This film is recommended primarily for experienced isotope laboratory personnel.

1404. RADIATION PROTECTION (slide series)
Training Resources

100 slides

Very attractive visuals to use as support material in developing your subject on the use and handling of radioactive materials. These slides are produced by Training Resources, Nuclear Support Services. 44 slides are on radiation terms and definitions, 39 on basic concepts, and 17 on signs and labels. A teacher guide is included, providing background information for each slide. An excellent opportunity to develop a topic that is suitable for your group and will draw audience attention to your talk.

1405. WORKING WITH RADIATION...AND PROTECTING THE UNBORN — Videotape
Radiation Management Corporation — 30 min.

This film is intended for laboratory personnel who are concerned about genetic effects from radiation exposure. It is equally appropriate to other scientists or support personnel expressing concern on this subject. This film presents the fundamental information needed by an occupational radiation worker on the subjects of genetic, prenatal, and low-level somatic effects of radiation exposure. The first portion deals with the properties of radiation and some basics of radiation protection. The second portion answers a number of questions on the effects of radiation on the unborn child, with discussions by medical personnel and radiation safety experts. This program is very well done with good visual effects, lively discussions that move rapidly, and a topic that is of interest to both female and male employees.

1406. RADIATION SAFETY FOR SUPPORT PERSONNEL — Videotape
NUS Corporation — 20 minutes

Filmed in a small hospital, it follows the daily routine of several personnel and how their jobs interact with either handling radioactive material or working briefly in the area. It introduces the audience to the various levels of radioactive material caution signs and what to be aware of when entering a laboratory using radioactive material. Suitable for showing to security, maintenance, custodial, and other personnel that may enter laboratories using radioactive materials. The acting in this film is somewhat artificial, but it provides a means for discussing isotope laboratories wich support personnel. It outlines the procedures various support personnel should remember to follow when working or visiting in the area. This tape should be followed with information specific to the type of radioactive material used, exposure levels, and the types of projects that the audience may encounter.

1407. INTRODUCTION TO RADIATION SAFETY — Videotape
Miles — 25 minutes

This is a video taping of a seminar given in Elkhart in June 1983. Kenyon Yoder, Corporate Radiation Safety Officer, presents a program on the utilizations of isotopes in research laboratories. Among the topics covered are the basic types of radioactivity; means of identifying radionuclides by their three properties, which are discussed in detail with a number of examples; some of the isotopes used at Miles, and their typical uses; activity determinations and calculations are explained. This film is appropriate for introducing the detailed concepts of radioactive materials to personnel who will be active isotope workers.

1408. RADIATION PROTECTION AND HANDLING TECHNIQUES — Videotape
Miles — 25 minutes

This is a continuation of the radiation safety seminar described in #1407. In this portion, the concepts of radiation protection are described. Among the topics covered are: directly ionizing vs. indirectly ionizing particles; external vs. internal radiation hazards; exposure protection measures; and several principles of contamination control. The final portion describes briefly the licensing requirements at Miles, Elkhart, along with some general procedures to be followed in setting up a new area for isotope use. This videotape is appropriate for laboratory personnel needing to learn or review protective measures and safe handling techniques.

1409. LIQUID SCINTILLATION COUNTING TECHNIQUES
Miles

2 Videotapes (3/4")
Part 1 59 min.
Part 2 50 min.

Dr. Wayne Wilms, Application Group, Beckman Instruments, conducted a seminar in Elkhart in June 1983. This is a videotape of that session in which Dr. Welms presented a very lively discussion, as he is an interesting speaker and presents many insights on the subject matter. He basically presented three major topics: sample preparation, liquid scintillation counter set-up, and optional features available on counters to speed up output and data manipulation.

The sample preparation section was the major portion of the talk. Some of the topics discussed in depth included: types of isotopes that can be detected; chemistry of LSC and the scintillation process; counting medias; quenching problems; chemiluminescence, photoluminescence, and static electricity problems; problems with phase counting; label counting methods, sample preparation, and counter set-up; sample channel ratio (SCR) counting; external standardization and its use in external quench monitoring; counting vials, different filters, and counting medias; tissue solubilizers, etc. Statistical treatment of counting, preparation, window settings and spectrum search methods; calculation modes; the quench compensation factor (QCF); and the use of the counters computer calulator to aid in data manipulation to save you time.

These tapes are intended for scientists with some experience in LSC as the subject is covered in depth. The beginner could learn from the first portion of the tape, but is especially suited for the isotope workers who wants to gain additional perspective in counting methods. Also suitable for someone seeking help in identifying problems with their current counting methods. An accompanying liquid scintillation handbook and selection guide is available with the tapes upon request.

External Monitoring of Radioactive Packages

Each package containing radioactive material in excess of exempt status stated in 10CFR20.205 must be monitored. The monitoring shall be performed no later than three hours after receipt at licensee's facility, or eighteen hours if received after normal working hours.

If removable radioactive contamination in excess of 0.01 µCi (22,000 DPM) per 100 square centimeters of package surface is found on the external surface of the package, immediately notify the R.C.O.

Date & Time Received: _____ P.O.# _____

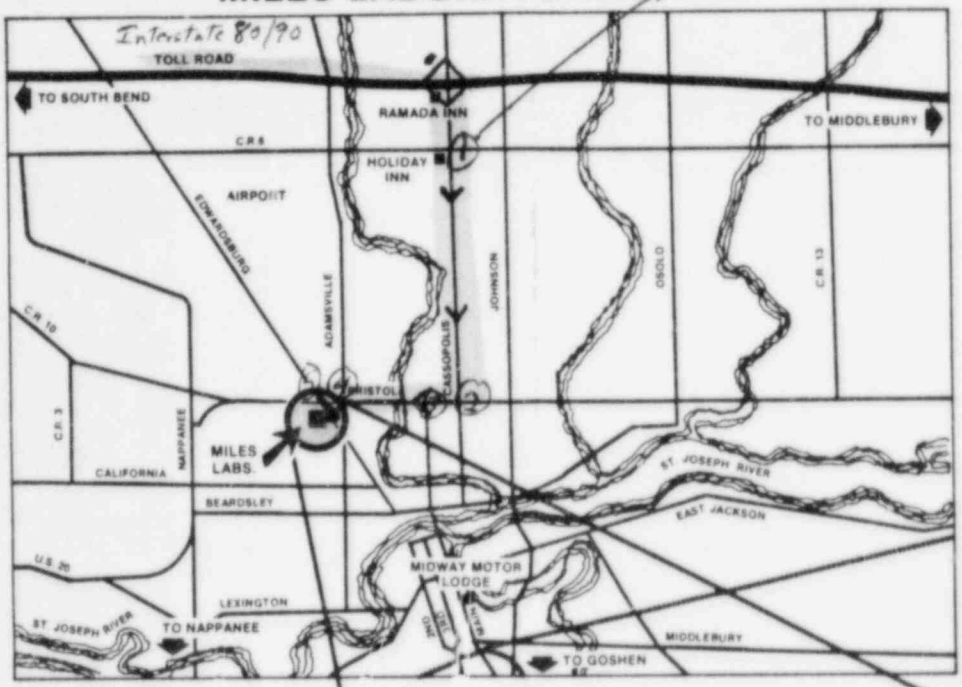
Isotope: _____ Activity: _____

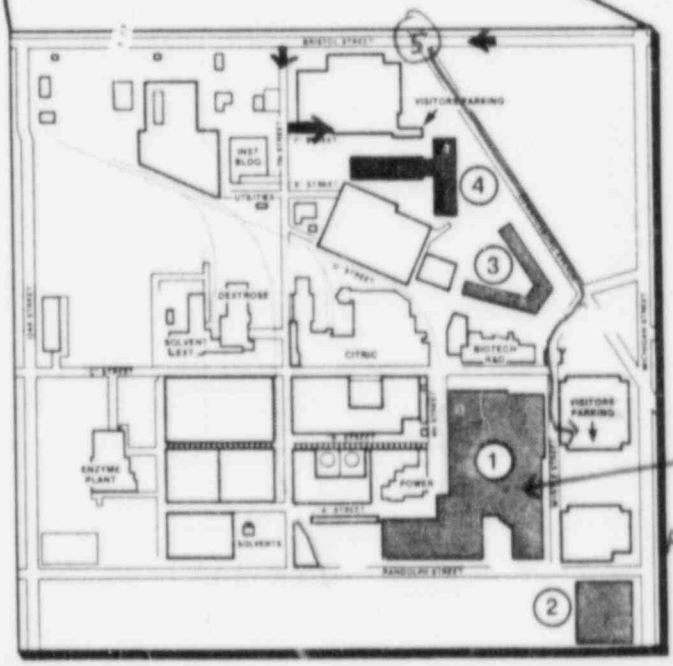
	CPM	DPM
Background		
Outside Carton, wipe # 1		
Outside Carton, wipe # 2		

Signature: _____ Date: _____

Stop lights

MILES LABORATORIES, INC.





(1) Miles Laboratories, Inc. Main Building

(2) Centennial Center

(3) Research Building

(4) [illegible]es Building

W—N—E

entrance

RECEIVED
MAR 18 1985
REGION III

MAR 18 1985

From the desk of
Kenyon D. Yoder

3-14-85

MILES

Mike McGann,

I am enclosing a map to aid in your travel to Elkhart.

I will plan on April 10 + 11 unless I hear differently.

Ken Yoder

MAR 18 1985

CONVERSATION RECORD

TIME: 8:40 am | DATE: 13 March 85

TYPE: ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Ken Yoder	Miles Lab	

SUBJECT: C/N 16507

ROUTING	
NAME/SYMBOL	INT

SUMMARY: Rescheduled site visit to 10-11 April, due to program review

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Mike McC	Mike McC	03/13/85

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME: 12:05 pm
DATE: 8 February 1985

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE (☐ INCOMING ☒ OUTGOING)

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU: Kenyon D. Yoder

ORGANIZATION (Office, dept., bureau, etc.): Miles Labs, Inc Elkart, Ind

TELEPHONE NO: (219) 262 7482

SUBJECT:
C/N 16507
L/N 13-02249-01

SUMMARY

Called and schedule site visit for Thursday March 14, 1985. Advised Mr Yoder that we will need additional information and as clarification of the following: H[3] ~~No use~~ No field uses

1) Possession limits and intended uses.
2) Need training and experience for each committee member
3) Clarification of quorum appears as if only (2) persons needed to approve policies and/or changes to licensed uses (see B.1 page 1 Chap 1)
4) Need to clarify extent of authority grant RCO between meetings of committee as infered in Item B.2. Page 1 Chap 1 of Rad. Saf Manual
5) Does committee perform annual program review?

ACTION REQUIRED: Part 33, Regulatory 8.23, 10.5, Incineration Guide
New H^3 guide {8.20} 10.8

NAME OF PERSON DOCUMENTING CONVERSATION:

SIGNATURE:

DATE:

ACTION TAKEN:

SIGNATURE:

TITLE:

DATE:

CONVERSATION RECORD

TIME | DATE

TYPE: ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
	Miles Lab Elkhart, Ind	

ROUTING

NAME/SYMBOL	INT

SUBJECT: C/N 16507 (Page 2)

SUMMARY (RSO)

6) frequency of and on-site surveys and audits conducted by RSO or his staff

7) Clarify Item B 7 on page 3 of Chap 1 RSO should already have listing of users

8) describe radiation safety personnel staff available to assist RSO

9) Training - need

i) minimum commitment 33.15(b) in addition to present commitments for authorized users

ii) for all, need description of 10.12 training, also if in-house instruction for didactic given, need topics, length of instruction trainer and description of records

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

CONVERSATION RECORD

TIME | DATE

TYPE
☐ VISIT ☐ CONFERENCE ☐ TELEPHONE
☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
	miles Lab Elkhart, Ind	

SUBJECT
C/N 16507
(Page 3)

ROUTING	
NAME/SYMBOL	INT

SUMMARY
10) for monitoring of rad. waste in decay-in-storage need assurance that instrument appropriate to measure radiation of interest available e.g. for I^{125}
11) need better description of decon. action point, eg table 2 of Reg Guide 8.23
12) also need criteria used for release of facilities and equipment, e.g. NRC decon guide
13) commitment for 12 volatile release
14) need criteria for survey frequencies (US) type and quantity used in labs.
15) need to discuss assignment of ring badges.
16) if direct read dosimeter used will need calibration info

ACTION REQUIRED
17) bioassay need actinpunts e.g. 10 CFR 20 NRC Reg Guide 8.20 & HHS guidelines

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME

DATE

TYPE

☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
	miles, Lab Elkhart, Indiana	

ROUTING

NAME/SYMBOL	INT

SUBJECT

C/N 16507

(Page 4)

SUMMARY

18) Incineration - will need to submit information as outlined in incineration guide

19) Will need to describe how monitor liquid releases in accordance with 20.303.

20) Will need to describe instrumentation and/or instrumentation available to RSO and users

21) discussed modifying license from Type A to Type B, or modified R&D license

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Mike McCann	George M. McCann	8 February 1985

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME: 1300 | DATE: 31 Jan 1985

TYPE: [X] VISIT [ ] CONFERENCE [ ] TELEPHONE [ ] INCOMING [ ] OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Stanley Kawecki	Victoreen Inc Cleveland, Ohio	

ROUTING	
NAME/SYMBOL	INT

SUBJECT: C/N 77657

SUMMARY

1) 878-10 ~~cable~~ high range containment monitor - need registration no
2) Need license to distribute exempt grantee
   a) send information for E & G licenses

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME: 10:00am | DATE: 30 Jan 85

TYPE: ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Victoreen, Inc Stanley Kawecki		

ROUTING

NAME/SYMBOL	INT

SUBJECT: Directions from airport to Victoreen

SUMMARY

Leave airport and take Interstate 71 (N) to downtown Cleveland. Take 1st Exit downtown Cleveland (Label as Orange and/or Broadway Street). Get into middle lane of Orange Street, will travel approximately ¼-½ mile, road will curve to the left and will need to get on Woodland Ave. Stay on Woodland Ave approx 10 minutes. Will see Victoreen 4 story building with large black water towers (Victoreen written on it) on top of building

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
mike mc C	Mike M. Mc C	01/30/85

ACTION TAKEN

SIGNATURE	TITLE	DATE