NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Incell Corporation
P.O. Box 11596
Milwaukee, Wisconsin 53211

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

1600 W. Cornell St.
Milwaukee, Wisconsin
53209

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. John P. Earle

TELEPHONE NUMBER: (414) 263-4011

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: 3M
AMOUNT ENCLOSED: $ $700

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
P.D. Bayne	Peter D. Bayne	President	1/31/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

RECEIVED
FEB 7 1985

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
appl	2/4	3M	8508120670 850731 REG3 LIC30 48-24455-01 PDR	III
AMOUNT RECEIVED	CHECK NUMBER		CONTROL NO. 78331	DATE
$700	7264			2/28/85

PRIVACY ACT STATEMENT ON THE REVERSE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

ITEM #5: TYPES AND AMOUNTS OF RADIOISOTOPES REQUESTED

Element/Mass Number	Maximum Amount On Hand At Once (millicuries)	Chemical/Physical Form
Phosphorous-32	50	Any chemical or physical form, especially all nucleotides and deoxynucleotides. Also inorganic phosphate as orthophosphate or pyrophosphate.
Sulfur-35	50	As various amino acids, proteins, nucleotides, and inorganic sulfate.
Hydrogen-3	50	Any chemical and physical from. Especially nucleotides, amino acids and other bioorganics such as proteins, peptides, hormones and neurotransmitters.
Carbon-14	50	Various amino acids, lipids, sugars, and other low molecular weight organics.
Iodine-125	1	As iodide and/or iodinated proteins, peptides, hormones, and antibodies.

CONTROL NO. 78334

ITEM #6: PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

The material requested in this license will be used for research in molecular biology and biochemistry. More specificly, the isotopes will be used for *in vitro* and *in vivo* labeling of biomolecules and microorganisms; Initially this will involve bacteria and yeast, but it is possible that other microorganisms of economic interest to INCELL will be studied in the future. No whole animal studies will be done under this license.

Most of the work to be done will be *in vitro* labeling of biomolecules, mainly DNA. This will involve labeling the molecules with microcurie amounts of ^{32}P or ^{35}S for various experiments involving cloning and DNA sequencing. Tritium may also be used for isotopic labeling of DNA. ^{125}I may be used as inorganic iodide for labeling proteins, polypeptides, hormones and other small biomolecules of interest to INCELL. ^{125}I may also be purchased as iodinated proteins or antibodies for use in radioimmune assays, receptor assays and other types of binding assays.

^{32}P, ^{35}S, ^{3}H, and ^{14}C will be used in *in vivo* studies on microorganisms. These studies will involve the uptake/labeling of DNA, proteins, lipids, polysaccharides, and other biomolecules. Iodinated biomolecules as well as molecules labeled with other isotopes may be used for binding, transport and kinetic studies.

In short, the isotopes requested will be used for all facets of biochemical and molecular biological research on microorganisms.

ITEM 7: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

RESUME

John Philip Earle, Ph.D.
Radiation Safety Officer

Date of Birth

May 14, 1953

Education

B.A., Biology; Western State College of Colorado; 9/71-9/75
Post Baccalaureate Training, Chemistry; University of Illinois at Chicago;9/76-9/78
Ph.D., Biology; University of Illinois at Chicago; 9/78-10/84

Awards

Member, Phi Kappa Phi Honor Society, 1981-1984

Honorable Mention, Illinois Institute for the Study of Developmental Disabilities Fellowship Competition, 1981

Teaching Assistant, University of Illinois at Chicago, 1978-1984

Research Assistant, University of Illinois at Chicago, 1978-1984

Research and Professional Experience

Senior Staff Scientist, Incell Corporation, Milwaukee, Wisconsin, 11/84 - present

Teaching Assistant, Department of Biological Sciences, University of Illinois at Chicago, 9/78 - 10/84

Research Assistant, University of Illinois at Chicago, Laboratory of S.L. Barclay, 9/78 - 10/84

Graduate Student, Department of Biological Sciences, University of Illinois at Chicago, 9/78 - 10/84

Post Baccalaureate Training, Department of Chemistry, University of Illinois at Chicago, 9/76 - 9/78

Undergraduate Student, Western State College of Colorado, 9/71 - 6/75

Teaching

Biology 101, Cell Biology

Biology 276, Comparative Animal Physiology

Biology 250, General Microbiology

Biology 240, Genetics

Biology 262, Cell Physiology

Formal Training in Radiation Safety

Six hours of lectures on principles and practices of radiation safety received as an graduate student in Biological Sciences at the University of Illinois at Chicago. Two hours of additional lecture on the theory and use of portable and liquid scintillation counting devices in the biological research laboratory.

Course work in disciplines relevant to theory and mathematics of radioactivity, and radioactivity detection include: mathematics through Differential Equations, Physical Chemistry with Quantum Mechanics, Physical Chemistry Lab, Biochemistry, and undergraduate Physics.

Experience in Use and Handling of Radioactive Isotopes

Six years experience in the use and handling of radioactive isotopes in biochemical and molecular biology research. I have used all isotopes listed in this application including millicurie amounts of ^{125}I as a graduate student at the University of Illinois at Chicago. I have also used/handled millicurie amounts of ^{32}P and ^{35}S and microcurie amounts of ^{3}H and ^{14}C. These isotopes were used in various aspects of my graduate work in biochemistry and molecular biology. Radioactively labelled biological samples I have worked with include proteins, nucleic acids, lipids, and sugars. The compounds requested in this application will be used for similar types of research in molecular biology and biochemistry.

CONTROL NO. 78334

ITEM #8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

PROPOSED COURSE OF TRAINING FOR EMPLOYEES

*** This outline describes a five hour course of ***
*** training in radiation safety. This training ***
*** will be given in five one hour lectures. ***
*** all employees will be required to attend the ***
*** first two hours of lecture. The users of ***
*** radioisotopes and non-users working in re- ***
*** stricted areas will be required to attend ***
*** the last three hours of instruction. In ***
*** addition, all users must pass an examination ***
*** at the end of the course and demonstrate ***
*** competence in the safe handling, use and ***
*** disposal of radioisotopes to the satis- ***
*** faction of the Radiation Safety Officer. ***

1. What is radioactivity? Effects of radioactivity on living organisms. Describe the types of radioactive disintegration and potential health risks from radioactive exposure. Describe employee rights and responsibilities as discussed in Parts 19 and 20 of the Federal Code.

2. General principals for safe handling and storage of radioactive chemicals.
   A. Storage of isotopes in restricted areas; what constitutes a restricted area or area where radioisotopes may be used?
   B. General rules for handling of waste and procedures to follow in case of spills.

3. Use and detection of radioisotopes.
   A. Types of detection equipment and methods of detection.
      i. Types of counters and their uses.
      ii. Theory of liquid scintillation counting.
      iii. Detection of beta and gamma rays.
   B. Uses of isotopes in biological experimentation.
      i. Isotopes used for labeling various bio-organic molecules.
      ii. In vivo vs. in vitro uses of isotopes.
      iii. Labeling techniques.

4. Methods for safe use of radioisotopes in the lab.
   A. Shielding types and needs
   B. Containment of materials and methods of minimizing contamination.
   C. Techniques for handling radioisotopes.
   D. Accounting for used isotopes.
   E. Detailed description of waste disposal methods.
   F. Survey procedures for detecting contamination in the lab.

G. Use of personal monitoring devices.
H. Methods for decontamination.

5. Theory of radioactive decay and detection.
   A. Elementary physics of radioactive decay.
   B. Energy calculation in radioactive decay.
   C. Half-life calculations.
   D. Counting efficiency calculation for various counting methods.

ITEM 9: FACILITIES AND EQUIPMENT

Facilities: See enclosed annotated blueprint, marked "ITEM #9a". Our company is in a private building with access restricted to employees. The areas where isotopes will be used and stored (see blueprint) have doors with locks to further restrict access to non-users. Our research laboratory has a Kemponent brand fume hood rated at not less than 100 CFM when fully open.

Equipment: INCELL currently owns a Picker hand-held labmonitor model #641065. We have both a thin end-window standard mica, halogen quenched geiger probe and a gamma probe with 1 1/2" X 1" crystal in integral photomultiplier tube assembly. This counter operates as a bench top unit using line voltage or as a portable unit operating from a rechargable battery pack. The day to day functioning of this instrument will be checked with disc sources. When we begin to use ^{125}I the instrument will be calibrated yearly for detection of gamma radiation. We also anticipate the purchase of a liquid scintillation counter within the next 1 to 2 years. Until that time we have access to a liquid scintillation counter at the University of Wisconsin at Milwaukee, a 10 minute drive from our research lab.

CONTROL NO. 78331

ITEM #10: RADIATION SAFETY PROGRAM

I. Duties and Responsibilities of the Radiation Safety Officer.

A. Responsible for all aspects of safe receiving, storage, use, and disposal of radioactive compounds.

1. Will be responsible for receipt and inspection for contamination of radioactive material per 10CFR 20.205.
2. Will assume responsibility for safe storage and use of radioactive compounds by laboratory personnel.
3. Will be responsible for proper storage and disposal of radioactive waste generated.
4. Will inspect and maintain records and documents required by law in association with items A1 through A3 above.

B. Responsible for instruction and oversight of all company employees with access to areas where radioisotopes are used; Responsible for instruction and supervision of users of radioactive compounds. (See attachment for outline of employee training program for use and handling of radioactive material.)

C. Responsible for assuring that receiving, inspection, decontamination of packages, disposal, lab surveys, and personnel monitoring are carried out and documented.

II. Control Measures.

A. All isotopes will be stored in one of four refrigerators/freezers in two locked rooms that will be classified as Restricted Areas.

B. All waste will be stored in bottles (liquid) or drums (dry). Partially filled containers will be stored behind a 1/4 inch plexiglass or wood shield. Full containers will be stored in locked wooden cabinets with access limited to isotope users.

C. All short-lived aqueous liquid waste (^{32}P, ^{125}I, ^{35}S) will be stored for a time, then disposed of to city sewers in accord-

CONTROL NO. 7983

ance with 10CFR 20.203. Other liquid waste will be stored until it decays to background then disposed of in accordance with appropriate Federal, State and Municipal Regulations. Dry solid waste will be stored until it decays to background. Prior to disposal as non-radioactive solid waste, a thin-end window geiger probe will be used to confirm that the levels of radiation are at background. We have no present plans to use longer lived isotopes (^{14}C, ^{3}H) until 1987. If the need for use of these isotopes arises before that time they will be stored in separate containers as described above. When disposal becomes necessary it will be contracted through a licensed radioactive disposal service company. In such case it will be the responsibility of the Radiation Safety Officer to prepare and maintain all shipping manifests in accordance with the Federal Code.

D. For tritium, only quantities less than 10 mCi will be purchased, handled or accumulated as waste in individual containers.

III. Day to Day General Safety and Instruction.

A. Instruction.

1. An outline of the proposed instruction program for employees is included. This program consists of five one-hour lectures by the Radiation Safety Officer.
2. All company employees, whether users or not, will be required to attend lectures 1 and 2. The users and personnel working in areas where isotopes are used will be required to attend lectures 3 through 5.
3. Users will have to pass a written test at the end of the lecture series and will also have to demonstrate proper care in use and disposal of radioactive compounds to the satisfaction of the Radiation Safety Officer.
4. The following books will be available for all employees who wish to further study about the principles and practice of safe use of radioisotopes.

   a. "Radiation Protection, A Guide for Scientists and

Physicians." by Jacob Shapiro. Harvard University Press, 1981.

b. "Radioactive Methodology in the Biological, Environmental and Physical Sciences." by C.H. Wang, D.L. Willis and W.D. Loveland. Prentice Hall, 1975.

B. Safety.

1. Employees who work in areas where radioisotopes are used will be required to wear body badges. Users will also be required to wear ring badges when working with ^{32}P or ^{125}I. These detection devices will be exchanged quarterly.
2. Weekly laboratory surveys using hand held counting devices will be made and documented for all areas in which isotopes are used. Monthly wipe surveys will be done and documented.
3. All radioactive contamination will be clearly marked with tape and every reasonable effort will be made to remove such contamination as soon as possible after detection.
4. All employees will be instructed in proper procedures for receiving radioactive compounds. Newly received isotopes will be placed in a designated storage area within the defined restricted area and notification will be given, as soon as possible, to the Radiation Safety Officer (preferablly) or an isotope user that an isotope has been received. The Radiation Safety Officer or a trained user will inspect the package for contamination as soon as possible after receipt.
5. For the duration of this license, an outside consultant with advanced training in Radiation Safety and Health Physics will be retained as a source of help and advice should any unforeseen problems arise.

ITEM #11: WASTE MANAGEMENT.

DESCRIPTION OF WASTE DISPOSAL METHODS TO BE USED AT INCELL

All waste being stored will be kept in a locked wooden cabinet. This cabinet will be kept in the research laboratory with access limited to the Radiation Safety Officer and other isotope users.

INCELL plans to store all aqueous waste on premises until such time as the isotopes decay to levels that are allowable in municipal sewerage. Only isotopes with similar half lives will be combined (^{32}P, stored alone; ^{125}I and ^{35}S, combined; ^{3}H and ^{14}C, combined). At present INCELL has no immediate plans for the use of ^{3}H, ^{14}C or ^{125}I; we don't anticipate any use for these compounds for the next two to three years. Over the next two years we anticipate the use of no more than 20 millicuries of ^{32}P and 10 millicuries of ^{35}S per year. The waste from these two compounds will be stored separately. Liquid waste will be stored in 1 gallon glass bottles or 5 gallon plastic carbouys. Dry waste will be stored in fiberboard drums lined with plastic. Each container will be numbered and have affixed to it the type and amount of material and the date added. Each numbered waste container will, when full, be registered by the Radiation Safety Officer as to total amount of isotope and date. A separate record of all drums and bottles in storage and disposed of will be kept by the Radiation Safety Officer.

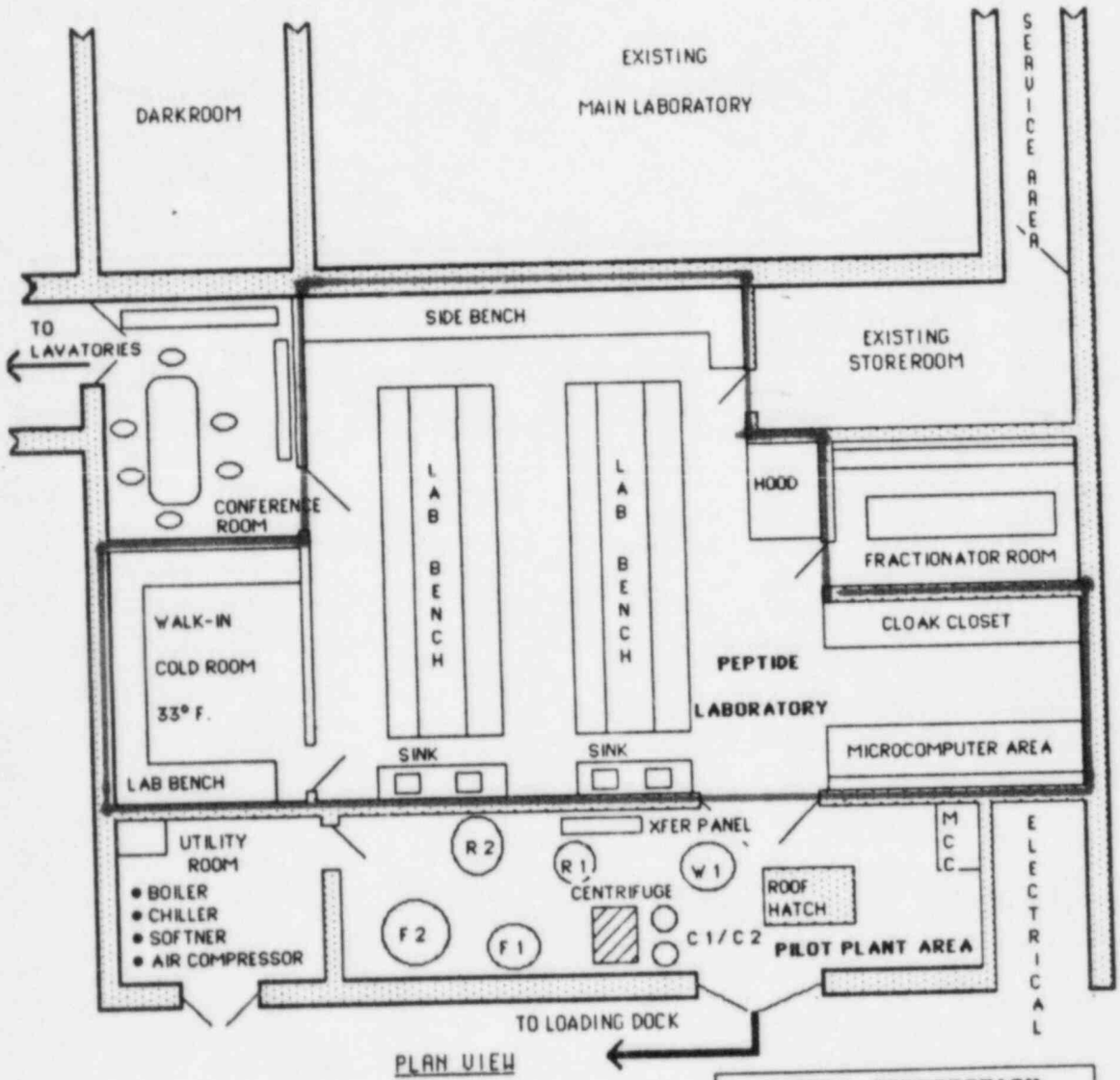
All short-lived aqueous liquid waste (^{32}P, ^{125}I, ^{35}S) will be stored for a time, then disposed of to city sewers in accordance with 10CFR 20.203. Other liquid waste will be stored until it decays to background then disposed of in accordance with appropriate Federal,

CONTROL NO. 78331

State and Municipal regulations. Dry solid waste will be stored until it decays to background. Prior to disposal as non-radioactive solid waste, a thin end-window geiger probe will be used to confirm that the levels of radiation are at background. We have no present plans to use longer lived isotopes (^{3}H, ^{14}C) until 1987. If the need for the use of these isotopes arises before that time, they will be stored in seperate containers as described above. Should such amounts of long lived isotopes (^{3}H, ^{14}C) be accumulated that disposal becomes necessary or if short lived isotopes accumulate more rapidly than can safely be disposed of in this way, then a contract with a licensed radioactive waste disposal service will be executed.

CONTROL NO. 7833

ITEM 9A: PROPOSED FUTURE EXPANSION
(TENTATIVE LAYOUT)



PLAN VIEW

NEW PILOT PLANT & PEPTIDE LABORATORY

1/8 IN = 1.0 FT.

INCELL CORPORATION 1400 N. GRANDE A. ST. MILWAUKEE, WISCONSIN
FACILITY EXPANSION PHASE II
SCALE = 1/8 in. = 1.0 ft. September 25, 1984
DWG 45A

THIS IS A TENTATIVE PLAN FOR EXPANSION TO BE INITIATED THIS YEAR. THE WALK-IN COLD ROOM AND PEPTIDE LABORATORY WILL BE DESIGNATED AS USER AREAS.

DOCUMENT/ PAGE PULLED

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LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES
CHECK LIST
(REGULATORY GUIDE 10.7)

DEF	ACC	
		ITEMS 2 AND 4
_____	_____	1. Name and address? (principal location)
		ITEM 5. PLACE OF USE
_____	_____	1. Places of use . . other than principal address in ITEM 4?
		ITEM 6., ITEM 7. USERS AND RSO. (ITEMS 16 and 17)
_____	_____	1 Individual users trained with materials they wish to work?
_____	_____	2. RSO - Designated? Properly trained? DUTIES? (Should be trained as in App. A. Medical Guide 10.8; authorize in categories - Low β's, high β's, γ's, Iodine).
		ITEM 8. MATERIAL
_____	_____	1. List of radionuclides . . . chemical/ physical forms, activity desired?
_____	_____	2. Sealed sources . . manufacturer . . . model number?
_____	_____	3. If gauges or G.C. . . . model no./ manufacturer of device
_____	_____	4. Intended use of each radionuclide or source listed?
		ITEMS 10. AND 11.
_____	_____	1 List of RS Instruments?
		a. manufacturer's name, model no., number of each type, type radiation detected . . . proper window?

DEF ACC

2. Proper calibration? (Require same as in Reg. Guide 10.8)

   a. Frequency - annually?
   b. Two points on each scale?
   c. Action levels: ± 10%, ± 20%?
   d. Daily check?

3. If calibration by manufacturer or consultant . . . name, location, procedures, frequency as in Appendix D, Reg. Guide 10.8

4. If calibration by licensee,

   a. proper source - activity high enough?
   b. Traceable to NBS?
   c. manufacturer's name, model number, accuracy?
   d. step-by-step procedures?

ITEM 12. - PERSONNEL MONITORING

1. If required - name and frequency of service?

   a. Appropriate badges - ring, whole-body?

2. If pocket dosimeters,

   a. manufacturer's name and model number?
   b. range?
   c. frequency and method of calibration?
   d. frequency of recording or reading?

3. Bioassays - proper? If not - description of consideration?

ITEM 13. FACILITIES AND EQUIPMENT

1. If small - diagram of each lab?
   If large - diagram of typical lab?

2. Does diagram show proper shielding, etc.?

   a. adjacent areas?
   b. receipt areas?
   c. waste?
   d. ventilation systems, if airborne materials?
   e. fumehood, glove boxes, etc. if required?
   f. storage areas?

DEF	ACC	
		ITEM 14 WASTE DISPOSAL
		1. Are name and License number of commercial waste disposal service listed? (not mandatory)
		2. Liquid waste in accordance with 20.303?
		3. Air release in accordance with 20.106?
		4. If approved, proper incineration?
		5. Solid waste - by decay? proper disposal?
		6. Transfer from users to disposal area?
		ITEM 15. RAD. SAFETY PROGRAM
		1. Proper area surveys?
		a. wipe b. GM c. air sampling d. effluent sampling
		2. Area surveys of all areas? e.g. waste disposal, where airborne, etc.?
		3. Proper action levels for area surveys?
		4. Proper frequency of area surveys? (Individual - RSO should do one specifically at least quarterly).
		a. as minimum - after exp't b. low - monthly med-wkly; hazardous-daily
		5. Proper records of area surveys maintained?
		6. Sealed source leak tests?
		a. If by commercial leak test kit, is name of supplier and model number of kit supplied?

ACC

b. If performing their own:
   (1) Name and qualifications of individual performing?
   (2) Type, name of manufacturer, and model number of measuring instrument used to analyze samples?
   (3) Procedures for calibration of measuring instrument Stds listed? Method including sample calculation showing how results converted to activity units (e.g. uCi?)

7. Personnel training - as minimum equivalent to 19.12? Frequency? include lab rules (see Guide 10.7 for topics that should be covered)

8. Proper ordering procedures? (should only have one person ordering).
   a. check possession limits.

9. Proper receipt procedures?
   a. during regular hours?
   b. during off-duty hours?
   c if damaged - notify RSO?
   d. one receiving area?

10. Package opening; proper procedures?
   a min. - equivalent to App F, Reg. Guide 10.8.
   b. leakage . . . contamination.
   c. monitoring - surface . . . 3 feet.
   d. monitor - packing materials.
   e. wear gloves
   f. transfering to users.

11. General lab safety instructions
   a. copy posted
   b. procedures for users obtaining and using materials.

ACC

c. supervision
d. lab coats
e. instructions wearing monitoring equipment
f. surveys
g. waste disposal
h. mouth pipeting
i. smoking, eating, drinking in areas of use or storage

ITEM 15. ANIMAL USE?

1. Is there a description of facilities?
2. Is copy of instructions to caretakers?
3. Is there a description of handling of animals, waste, and cages?
4. Is there a procedure for insuring that cages and rooms are secure?

ITEM 18. CERTIFICATION

1. Proper signature and date?

ITEM 15. P-32 (OR OTHER HIGH ENERGY β'S) (STD. PARAGRAPH L-40)

1. Finger badge?
2. Appropriate shielding; (10 mCi) eye protection?
3. Survey?