July 1, 1985

United States Nuclear Regulatory
Commission: Region III
ATTN: William Reichhold
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Letter Dated May 21, 1985 Concerning Application for NRC License of January 31, 1985, Control No. 78331

Dear Mr. Reichhold:

The information you requested in your letter of May 21, 1985 is contained herein. Please attach it to our license application and consider it a permanent part of that document. I hope you will find that this document contains all the additional information you require to complete the processing of our application.

ITEM #1

Element/Mass #	Average Amount Used per Experiment in vitro	in vivo
Phosphorous-32	50-100 uCi	250-500 uCi
Sulfer-35	50-150 uCi	100-500 uCi
Hydrogen-3	50-100 uCi	100-200 uCi
Carbon-14	10-50 uCi	100-200 uCi
Iodine-125	10-50 uCi	100-250 uCi

INCELL CORP. 1600 W CORNELL STREET PO. BOX 11596, MILWAUKEE, WISCONSIN 53211 414/263-4111

At the present time we do not anticipate the per study use of millicurie amounts of Phosphorous-32. If experiments are required involving the use of millicurie/per study amounts of phosphorous-32 each user will be required to adhere to the following rules.

a. Use of plexiglass or other low atomic number shielding will be required as far as reasonablly practical. Use of work shields and shielded transport containers will be required for such experiments. Every effort will be made to keep Bremsstrahlung radiation to a minimum. Please note that the use of plexiglass or other similarly effective work shields will be required by users working with any amount of phosphorous-32 or iodine-125.

b. Subsequent to the use of millicurie amounts of phosphorous-32 in a single procedure or experiment, a radiation survey and wipe test will be required for any area(s), equipment, instruments, remote pipeting devices, etc. used in the experiment. Every reasonable effort will be made to remove any detectable contamination. Contamination that is not removable will be marked and any contamination in excess of 0.005 uCi will be brought to the attention of the Radiation Safety Officer or a qualified supervisor/user as soon as is reasonably possible.

c. As stated in our Application for NRC License dated January 31, 1985 (control #78331)(refered to hereafter as "the application"), Item #10 Section III, B.1, "Users (of radioisotopes) will be required to wear ring badges when working with phosphorous-32 or iodine-125". This means any amount. Also, disposable hand protection (i.e. gloves) will be worn during all use and handling of radioactive compounds.

d. Dry runs will be required prior to the performance of unfamiliar procedures. The presence of the Radiation Safety Officer or other supervisor/user will be required during all new procedures using millicurie amounts of phosphorous-32. All new experimental procedures requiring such amounts of P-32 must be approved by the Radiation Safety Officer or other supervisor/user prior to implementation.

e. Eye protection will be required for any procedures involving the handling of 10 millicuries or more of phosphorous-32. In addition, the presence of the Radiation Safety Officer or other supervisor/user will be required at all such procedures.

ITEM #2

At the present time the only person qualified to function as a supervisor/user at INCELL is the proposed Radiation Safety Officer. Therefore, we can add no additional supervisor/users to the list at this time. We do anticipate that personnel duely

qualified to function as supervisor/users will be hired within the next several months; if it becomes necessary we will ask for our lisence to be amended to add other qualified supervisor/users at that point in time.

ITEM #3

A. Enclosed please find a letter from the University of Wisconsin at Milwaukee granting permission for us to transport radioactive samples to their facility.

B. All samples will be returned to INCELL for disposal after they have been analyzed at the University of Wisconsin at Milwaukee. Please note that this transferring of samples to and from the University of Wisconsin at Milwaukee will be a temporary procedure and will be terminated when INCELL obtains its own liquid scintillation counter.

C. Samples will be transported only by the Radiation Safety Officer or a supervisor/user listed on the application.

ITEM #4

A. This is to confirm that our survey meter will be calibrated by individuals specifically authorized by the NRC to perform such calibrations at a yearly frequency and after each repair that might affect the instrument's calibration.

B. Our liquid scintillation counter, when obtained, will be calibrated yearly and after each repair that might affect the machines calibration.

ITEM #5

Radioactive waste will be collected and stored in each lab in the same containers in which it will be stored for decay or eventual disposal to a licensed radioactive waste contractor. Isotopes of similar half-life will be stored in the same container. Dry, aqueous liquid and organic liquid waste will be stored separately. Each laboratory will have a designated area for storage of radioactive waste. These areas will be shielded as needed to protect the employees from radiation exposure.

Each time radioactive material is removed from a source container for use in an experiment or procedure, it will be recorded on a "Radioacitve Material Control Form" (a copy of this form is enclosed). Each time some or all of the material is deposited in a waste container the amount and type of waste deposited will be recorded on a "Radioactive Waste Disposal Form" (copy enclosed). When each container is full (or contains no mor than 10 mCi H-3 or C-14), A "Radioactive Waste Pickup and Storage

Form" (copy enclosed) will be filled out by a user or a supervisor and the waste will be transfered to a storage cabinet under the direct supervision of the Radiation Safety Officer or a listed supervisor/user.

At the present time janitorial services at INCELL are contracted from an outside vendor. As long as this situation remains the same, an INCELL employee, properly instructed under Item #8 of the application, will be present at all times when janitorial staff is functioning. This employee will ensure that the janitorial staff is advised concerning the location, storage and potential danger of radioactive materials and wastes, and will also ensure that such materials are not spilled, disposed of or disturbed in any manner which might result in exposure of the janitorial staff to radiation. This person will also ensure that no radioactive materials or waste are inadvertantly or purposefully removed from the premises.

If the time comes when janitorial staff is employed directly by INCELL, those employees will be properly trained, under Item #8 of the application, concerning the location, storage and potential danger of radioactive materials and wastes. They will be properly trained and informed in how they are to carry out their duties around radioactive storage and waste storage areas without increasing their exposure levels.

ITEM #6

Areas to be included in radiation surveys are:
All benches where radioisotopes are used or have been used; floor areas surrounding benches. All equipment and equipment benches used in the processing of radiolabeled samples including handles, knobs, switches, and other areas that might become contaminated through physical contact. Floor areas surrounding said equipment benches. All doors, handles and adjacent floor areas surrounding storage and waste storage refrigerators and cabinets. All sinks and adjacent floor areas where contaminated glassware, etc is washed. All floor areas adjacent to temporary and permanent waste storage areas.

ITEM #7

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIALS

A. All requests for orders of radioactive materials must be approved by the Radiation Safety Officer. In the event of an extended absence of the Radiation Safety Officer from the company a listed supervisor/user, designated by the Radiation Safety Officer, will be allowed to approve such orders in the interim. Orders may be placed by: 1. the Radiation Safety Officer, 2. a listed supervisor/user, 3. a member of the purchasing department at INCELL, designated by the Radiation Safety Officer, and specifically instructed by the Radiation Safety Officer in the procedures for ordering such compounds

and in the nomenclature used in identifying and quantitating radioisotopes (i.e. differences between beta and gamma emitters, difference between microcuries and millicuries, etc.).

B. At the time of ordering, each separate radioactive compound will be assigned a control number to aid in ordering, receipt, use, disposal, and record keeping procedures for that compound. Other procedures may be instituted by the Radiation Safety Officer as deemed prudent and appropriate to aid in the ordering, receipt, use, disposal of, and accounting for radioactive compounds.

C. It will be solely the responsibility of the Radiation Safety Officer to ensure that:
   1. proper procedures have been and are being followed for ordering radioactive compounds.
   2. The materials and quantities ordered are authorized by the license.
   3. The possession limits for any and all isotopes are not exceeded, and
   4. for keeping written records identifying the isotope compound, control number, activity levels, supplier, and all other records required by the NRC.

ITEM #8

PROCEDURES FOR RECEIVING, INSPECTION AND OPENING OF INCOMING PACKAGES CONTAINING RADIOACTIVE MATERIALS

The Radiation Safety Officer will instruct all supervisor/users and other users in procedures required for opening incoming packages. It is anticipated at this time that INCELL will receive only packages exempt from external surface monitoring as specified in Section 20.205 paragraph (b) 10CFR Part 20. However, as a precautionary measure, all radioactive materials, except for those amounts and forms for which a license is not required, will be monitored at their external surface for fixed and removable contamination. Gloves will be required for opening all packages. Each successive layer of packaging and packaging material will be monitored for contamination. The final source container shall be subjected to a wipe test for removable contamination.

It will be the responsibility of the Radiation Safety Officer to insure that the procedures described herein are maintained and followed, and that packages are safely opened in accordance with Section 20.205 10CFR Part 20.

ITEM #9

In addition to the training and examination schedule described in item #8 of the application, written safety instructions will be prepared, posted and distributed to all employees. A copy of

those written instructions is listed below. The Radiation Safety Officer will update, revise and modify these instructions as required by need or by changes in 10 CFR. In addition, copies of all licensing documents, amendments to the license, applications, amendments to applications, the safety instructions listed below, NRC form 3, 10CFR parts 19, 20 and 30, and all other memos, updates and documents deemed appropriate by the Radiation Safety Officer will be combined and included in a "Manual of Standard Operating Procedures for the Use of Radioactive Compounds at INCELL". This document will be made available to all INCELL employees.

INSTRUCTIONS FOR THE USE AND SAFE HANDLING OF RADIOACTIVE COMPOUNDS IN THE LABORATORY

1. Permission to use radioactive compounds shall be granted by the Radiation Safety Officer only. All users must complete a course of instruction given by the Radiation Safety Officer and pass a written examination covering basic theory and safe laboratory use of radioactive compounds. Users must also demonstrate skill in the proper use, handling and disposal of radioactive materials in the lab to the satisfaction of the Radiation Safety Officer.

   Some new employees, judged by the Radiation Safety Officer to have adequate training and experience, may be allowed to use radioisotopes prior to completion of the above described course, provided that they demonstrate proper technique and care in the use of these compounds. This privilege will be granted solely at the discretion of the Radiation Safety Officer and does not release these employees from the course and examination requirement described above. These employees must complete this course at its earliest offering. In any event, no new employee with less than a Master of Science degree in the physical, biological, or engineering sciences, or less than three years experience in a laboratory where radioisotopes are used will be allowed to use such compounds prior to the satisfactory completion of the training course.

2. Experiments requiring the use of >1 millicurie of any isotope must be approved by the Radiation Safety Officer or a listed supervisor/user.

3. Use of protective apparel, at a minimum laboratory coats and gloves, is required when performing any procedure using radioactive compounds.

4. Mouth pipeting is forbidden in any laboratory where radioisotopes are used, whether or not you are using them. Remote pipeting and transfer devices (preferably disposable) must be used at all times.

5. Eating, drinking and smoking are forbidden in areas where radioactive compounds are used or stored.

6. Every effort should be made to keep the spread of radioactive materials and contamination to a minimum.
   a. Confine your work to as small an area as possible.
   b. Work on absorbent paper; enough to absorb any spill.
   c. Carry out dry runs before attempting any new procedures using radioisotopes.
   d. When transporting radioactive compounds between rooms or through halls and corridors, samples should be in a secondary container adequate for holding the entire contents of the radioactive source container. Whenever possible the secondary container should have enough absorbent material to absorb the entire contents of the sample, should a spill occur.
   e. Spills must be attended to immediately, even if it means interrupting an experiment in progress.
   f. All equipment and work areas should be monitored for contamination both during and after the completion of the experiment. Don't forget to check your hands, clothes, and body also.

7. Materials, experiments, samples, isotopic compounds, and containers which may produce aerosols, mists, positive vapor pressures, or vapors of radioactive compounds should be confined to the fume hood. Examples are:
   a. A sealed frozen container that has been thawed may have a positive vapor pressure when opened. Open in the hood.
   b. volatile radioactive compounds such as acetate and ammonia should be opened and used in the fume hood.
   c. Aspirations, vacuum filtrations or distillations are examples of procedures that should be carried out in the fume hood.
   d. Procedures utilizing Iodine-125 (especially elemental iodine) should be carried out in the fume hood.
   e. A good rule to follow is "If you are uncertain, do it in the hood".

   This list is by no means exhaustive. If you have questions direct them to the Radiation Safety Officer.

8. Weekly surveys using a hand held counting device, as well as monthly wipe tests, will be made and documented. These contamination surveys will be carried out in all areas where radioisotopes are used and stored. These surveys will be carried out by the Radiation Safety Officer or by an individual familiar with these surveys, appointed by and under the supervision of the Radiation Safety Officer.

   In addition it is suggested that each worker survey his or her own work area at least weekly, and perhaps more frequently, <u>especially</u> before, during and after procedures involving the use of radionuclides.

9. All rooms where radioactive chemicals are stored or used, or where radioactive waste is stored, will be marked at each entrance, as required by law (Section 20.203 10CFR Part 20; a copy of which is available to all employees) by a sign

bearing the conventional three-bladed radiation caution symbol in magenta or purple with a yellow background and the words "Caution (or Warning) Radiation Area". A second sign will be present at the entrance to each room or area where radioactive material is used or stored bearing the radiation caution symbol and the words "Caution (or Warning) Radioactive Material(s)". In addition, other signs may be posted on or near these areas which may aid employees in minimizing exposure to radiation or radioactive materials.

10. Each container of licensed radioactive material shall bear a durable and clearly visible label identifying the radioactive contents and bearing the words "Caution (or Danger) Radioactive Material", unless the amount of material is less than that listed in Appendix C Part 20 10CFR (<100 uCi for C-14, <1 mCi for Tritium, <1 uCi for I-125, <10 uCi for P-32, and <100 uCi for S-35). All radioactive waste containers will be similarly labeled. All refrigerators, freezers and other storage compartments will be labeled with a sign bearing the radiation caution symbol and the words "Caution (or Danger) Radioactive Materials".

11. Contaminated materials should, whenever possible, be discarded to radioactive waste. Lab coats and other clothing, as well as non-disposable lab ware and equipment should be hand washed (wear gloves) with soap and water or other cleaning solvents, treated with an ultrasonic cleaner, soaked in aqua regia or cleaned in other ways deemed prudent and approved by the Radiation Safety Officer. Non-disposable items from which contamination can not be removed must be stored in shielded containers or waste cabinets, away from areas where personnel might receive radiation exposure from the contaminated items, until such time as the contamination has reached undetectable or background levels when checked with a hand held monitoring device with suitable probe and the scale set to the most sensitive level.

12. All employees routinely working in areas where radioisotopes are used or stored are required to wear personal monitoring devices known as "body badges". These devices will be returned to the Radiation Safety Officer or an individual designated by him(her) on a quarterly basis (every three months). These badges will be exchanged for new badges and the used badges will be analyzed to access employee exposure to radiation. Reports will be posted for the previous quarter showing how much radiation each employee has been exposed to. Subsequently, these reports will be on file at INCELL and available for inspection by employees at all reasonable times. In addition, users of radioactive materials will be required to wear ring badges (finger detection devices) when working with any amount of I-125 or P-32. Any other employee who is concerned about personal exposure to radiation may request a body badge for themselves; see the Radiation Safety Officer for details.

13 All users will dispose of waste in appropriate containers in each room where radionuclides are used. Aqueous and organic liquid waste must be placed in separate containers. Separate containers will be used for P-32, I-125 and S-35, and tritium and C-14. Amount of isotope and date should be recorded on the Radioactive Waste Disposal form for that radioactive waste container. Dry waste must be placed in separate containers for different isotopes of similar half-life (i.e. P-32 alone, I-125 and S-35 together, C-14 and tritium together). When a waste container is full a Radioactive Waste Pickup and Storage form must be filled out and submitted to the Radiation Safety Officer before transferring the container to the waste storage cabinet. Quantities of isotopes disposed of to municipal sewerage must not exceed amounts listed in appendicies B and C 10CFR Part 20 as specified in Section 20.303 of that document.

14. All users of radioisotopes must document the use and disposal of radioisotopes. This will be done on the Radioactive Material Control Form provided with each radioactive compound received at INCELL. Each time an aliquot of a radioactive compound is removed from a source container it must be marked on the appropriate control form. When less than 1% of the original activity of that isotope remains, this form will be returned to the Radiation Safety Officer and become a part of INCELL's permanent records.

THESE RULES ARE FOR YOUR OWN PERSONAL SAFETY. THEY MUST BE FOLLOWED AT ALL TIMES. FAILURE TO DO SO WILL RESULT IN SUSPENSION OR REVOCATION OF THE PRIVILEGE OF USE OF RADIONUCLIDES.

ITEM #10

We will use thermoluminescent dosimeters as our personnel monitoring devices. The exchange frequency will be monthly for the ring badges and quarterly for the body badges. Initially we plan to use R.S. Landauer or Siemens as our supplier; however, should a similarly experienced and accredited company offer us similar service at a lower price, we may change suppliers during the term of this application.

ITEM #11

As stated in the application Item #8, "All employees will be required to attend the first two hours of lecture" (of the proposed course of training for employees outlined in that item of the application). All employees will be instructed in 1) the nature of radioactivity and its effects on living organisms. 2) Types of radioactive disintegration and potential health risks from radioactive exposure. 3) Employee rights and responsibilities discussed in Parts 19 & 20 10CFR. 4) General

principles for safe handling of radioactive materials; storage of isotopes in restricted areas and what constitutes a restricted area or an area where radioisotopes may be used. 5) General rules for handling waste and procedures to be followed in case of a radioactive spill.

The course of training outlined in item #8 of the application will be offered, at a minimum, on a yearly basis and all employees will be required to attend a refresher at least once a year. Ancillary personnel will be required to attend the first two hours of lecture and employees working in areas where radioactive isotopes are used or stored will be required to attend all five hours of lecture.

I hope the above information is sufficient for completing the processing of our application. If you have any further questions please do not hesitate to call me at (414) 263-4011. Thank you for your patience and consideration in our application procedure.

Sincerely,

John P Earle

John P. Earle Ph.D.
INCELL Corporation

enclosures

THE UNIVERSITY OF WISCONSIN—MILWAUKEE/ P.O. Box 413, Milwaukee, Wisconsin 53201

COLLEGE OF LETTERS AND SCIENCE
DEPARTMENT OF BIOLOGICAL SCIENCES

(414) 963-4214

Incell Corporation
Attention: John Earle, Ph.D.
P.O. Box 11596
Milwaukee, Wisconsin 53211

Dear Dr. Earle:

This is to inform you that Incell may measure samples for levels of radioactivity in liquid scintillation vials at the University of Wisconisn-Milwaukee. Mr. A. Thomson, Chemistry Department, will work out the operational details with you. Scintillation vials containing H-3 or C-14 must not exceed the activity concentrations as listed in 10 CFR 20.306(a). These vials must be returned to Incell for disposal.

It will be the responsibility of Incell to comply with regulations that may apply to the use and transportation of radioactive materials to and from UW-Milwaukee.

Sincerely yours,

Ralph Grunewald

Ralph Grunewald
Associate Professor and
Radiation Safety Officer,
UW-Milwaukee

RADIOACTIVE MATERIAL CONTROL FORM

CONTROL NO.:_____ DATE RECEIVED:__/__/__ P.O. NO.:_____

RECEIVED BY:_____ STORAGE LOCATION:_____

ISOTOPE:_____ ACTIVITY:_____ FORM:_____

LOT NO.:_____ DATE:__/__/__ COMPANY:_____

CONTAMINATION INSPECTION:_____ BY:_____

DATE	AMOUNT REMOVED (mCi)	REDUCTION BY DECAY OR DISPOSAL (mCi)	FINAL DISPOSITION		
			SOLID WASTE	LIQUID WASTE ORG.	LIQUID WASTE AQU.

NOTES

PLEASE RETURN THIS FORM TO THE RADIATION SAFETY OFFICER WHEN LESS THAN 1 % OF THE ORIGINAL ACTIVITY REMAINS.

DATE RETURNED:__/__/__

Incell Corp. 5/85

RADIOACTIVE WASTE DISPOSAL FORM

WASTE CONTAINER NO.:_____ TYPE OF WASTE:_____

A) ADDITION OF ISOTOPES TO WASTE CONTAINERS (to be filled out by user when adding isotopes to waste containers. Use reverse side if necessary.)

	DATE	ISOTOPE	AMT ADDED (mCi)	CONTROL NO.	FORM	ACTIVITY WHEN REMOVED TO STORAGE
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
					TOTAL (mCi)	

B) TO BE FILLED OUT AND ATTACHED TO "RADIOACTIVE WASTE PICK UP AND STORAGE FORM" AT TIME OF TRANSFER TO PERMANENT STORAGE.

TOTAL ESTIMATED ACTIVITY(mCi):_____

AS OF (DATE):__/__/__ BY:_____

Incell Corp. 5/85

RADIOACTIVE WASTE PICKUP AND STORAGE FORM

NO._____

DATE:__/__/__ COMPLETED BY:_____ DEPARTMENT:_____

TYPE OF MATERIAL: ☐ SOLID ☐ LIQUID ☐ AQUEOUS ☐ ORGANIC

TYPE AND SIZE OF CONTAINER:_____
(Glass, plastic, scintillation vials, etc.)

RADIONUCLIDES: ☐ 32-P ☐ 125-I and 35-S ☐ 3-H and 14-C (Must be less than 10 mCi each)

APPROXIMATE TOTAL ACTIVITY (mCi):_____

IF LIQUIDS SPECIFY:

Solutes (gm) and type	Solvents (% v/v) (organic only)

IF SOLIDS SPECIFY: Approx. % Glass and Metal _____
Approx. % Paper and Plastic _____.

IF SCINTILLATION VIALS SPECIFY COCKTAIL: _____

_____

_____

RECEIVED, RECORDED AND TAGGED BY: _____ __/__/__ (date)

FINAL DISPOSITION: TO _____ BY _____

DATE: __/__/__

LEVEL OF ACTIVITY AT DISPOSITION: _____

SIGNED:_____ DATE:__/__/__

Incell Corp. 5/85