MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below, to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Transcell Technologies, Inc.	In accordance with the letter dated May 1, 1997,
2. 2000 Cornwall Road Monmouth Junction, New Jersey 08852	3. License Number 29-30181-01 is amended in its entirety to read as follows:
	4. Expiration Date December 31, 2004
	5. Docket or Reference No. 030-33700

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 75 millicuries
C. Phosphorus 32	C. Any	C. 50 millicuries
D. Phosphorus 33	D. Any	D. 50 millicuries
E. Sulfur 35	E. Any	E. 50 millicuries
F. Chromium 51	F. Any	F. 50 millicuries
G. Iodine 125	G. Any	G. 50 millicuries
H. Iodine 131	H. Any	H. 50 millicuries

9. Authorized use

A. through H. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 2000 Cornwall Road, Monmouth Junction, New Jersey and 8 Cedar Brook Drive, Cranbury, New Jersey.

11. A. Licensed material shall be used by, or under the supervision of, Clifford B. Longley, Helena R. Axelrod, Ph.D., Eugene R. Baizman, Ph.D., or Arthur A. Branstrom, Ph.D. Licensed material listed in Items 6.A. through 6.E. may be used by or under the supervision of Nicole Theriault Hatzenbuhler.

B. The Radiation Safety Officer for this license is Clifford B. Longley.

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 29-30181-01

Docket or Reference Number: 030-33700

Amendment No. 01

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by Teledyne Isotopes. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

15. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

17. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

19. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:

    A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

20. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's application dated October 24, 1994.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 29-30181-01

Docket or Reference Number: 030-33700

Amendment No. 01

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 24, 1994
B. Letter dated November 15, 1994
C. Letter dated May 1, 1997
D. Letter dated May 28, 1997

Date JUN -9 1997

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:
JAMES M. BONDICK

By _____

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JUN - 9 1997

License No. 29-30181-01
Docket No. 030-33700
Control No. 124531

Helena R. Axelrod, Ph.D.
Director, Biological Research
Transcell Technologies, Inc.
2000 Cornwall Road
Monmouth Junction, NJ 09952

Dear Dr. Axelrod:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Although a decommissioning plan was not required to be submitted by Transcell Technologies, Inc., we have reviewed your proposed decommissioning plan submitted with the letter dated May 12, 1997 and find that the plan will meet the requirements if executed as proposed with one exception. Please note that your consultant intends to perform wipes over an area of 200 cm^2. Although averaging is permitted in some cases over an area of 300 cm^2, the results need to be reported in dpm or microcuries per 100 cm^2. Also note that future changes to the license will require a review to determine the applicability of 10 CFR 30.35.

We understand that you intend to decontaminate the facility at Monmouth Junction and will conduct the required surveys and submit the reports for approval in the near future. We understand further that the remaining licensed material will be properly disposed, and that no licensed material will be transferred to the new facility in Cranbury, New Jersey.

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We would normally continue the review process for the release of the facility for unrestricted use under this action if closure occurs within a reasonable time period. However, if the time period for closure is protracted, or if you prefer, you may request a separate action. Please provide the dates when you expect the decontamination and surveys of the facility to be completed, and dates when the survey report will be submitted for review. Also specify if you intend to request a separate action which will require a separate fee.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
JAMES M. BONDICK

James M. Bondick
Health Physicist
Division of Nuclear Materials Safety

License No. 29-30181-01
Docket No. 030-33700
Control No. 124531

Enclosures:
1. Amendment No. 01
2. 10 CFR Part 30
3. NRC Form 314
4. Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material

DOCUMENT NAME: R:\WPS\MLTR\L2930181.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	JBondick/jmb							
DATE	06/05/97		06/ /97		06/ /97		06/ /97	

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TRANSCELL TECHNOLOGIES INC.

29-30181-01

June 5, 1997

Mr. James M. Bondick
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Mail Control Number 124531

Dear Mr. Bondick:

In response to our conversation of June 4th, regarding the additions of Drs. Eugene Baizman and Arthur Branstrom as authorized users on Transcell Technologies Material license, both individuals have handled source materials of ^{3}H, ^{14}C, and ^{32}P in millicurie amounts. Both Drs. Branstrom and Baizman, although using only tenths of millicuries per experiment, as indicated in their curriculum vitae, have handled up to 5 millicurie amounts of ^{3}H, ^{14}C, and 1 mCi amounts of ^{32}P stock source materials. Dr. Baizman in addition as experience handling ^{125}I at 5 mCi level. Likewise, while at Sterling Winthrop Pharmaceuticals, Dr. Baizman was designated an authorized user under their Materials license.

Should you have any further questions, please do not hesitate to contact me at (609) 655-6923.

Sincerely

Clifford B. Longley

Clifford B. Longley, RSO

MS16
Q-6

TRANSCELL TECHNOLOGIES INC.

May 28, 1997

Mr. James M. Bondick
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Bondick:

In response to your letter of May 19th, please find enclosed for your review our response to your questions regarding Transcell's application to amend the existing radioactive materials license (mail control number 124531).

In closing, we trust that you will find the enclosed response satisfactory and look forward to obtaining an amended license in the near future. Should you have any questions, please do not hesitate to contact me at (908) 940-6925. Your timely cooperation in this matter is greatly appreciated.

Sincerely

Clifford B Longley

Clifford B. Longley, RSO

Enclosures: Response to questions

124531

OFFICIAL RECORD COPY ML 10

MAY 29 1997

Response to NRC Questions and Addendum
to
Transcell Technologies Amendment Application
of
April 30, 1997

Q.1 Your application appears to indicate that your proposed location of use may be controlled by an entity other than yourself. If so, please provide documentation of a clear contractual agreement concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. This documentation should consists of signed certification from both parties.

A.1 For the floor space leased under the agreement, Transcell Technologies has full administrative control of these areas, including access, security, and for health and safety purposes. Access to those areas are defined by physical boundaries which prevent casual access. Therefore, Transcell Technologies has full control and supervision of all areas defined by its lease agreement. It is also clear that the other areas of the building not leased by Transcell Technologies are controlled by the owner and later by other tenants, once rented or leased. Accordingly, Transcell Technologies has no responsibilities for these areas.

Transcell is leasing the laboratory facility directly from the owner under a standard agreement, which includes provisions for access and control of the floor space, maintenance of the facility, security control, and terms and conditions regarding subletting, termination of the lease, condition of the facility at the time of lease termination, and settlement of disputes. Transcell has a 10 year lease to its leased premises. The terms of the lease contain a "Quite Enjoyment" clause that states clearly that Transcell Technologies controls access to it space. In addition Transcell Technologies, as an additional measure of codifying control over the space, has a right under the Lease to get a "Non-Disturbance" agreement with the holder of the mortgage on the building. These are fairly typical commercial arrangements that should not present obstacles to gain access to our facility.

Q.2 The Management Commitment, as discussed in Section III.A. in your application, states that management will periodically perform formal audits to assess the overall effectiveness of the radiation safety program, 10 CFR 33.13 and 33.14 require applicants to establish administrative controls and provisions relating to management review necessary to ensure safe operations. 10 CFR 20.1101(c) requires that the licensee reviews the radiation protection program content and implementation at least annually. Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005) recommends that an audit and appraisal program be part of the management review. Provide the following information regarding the management review program:

Q.2.a Describe the senior management oversight of your radiation safety program. Specify the mechanisms that will be used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

A.2.a Senior management's oversight of Transcell Technologies' radiation safety programs is multifaceted. The Director of Biology Research, Dr. Axelrod, is an active member of the Radiation Safety Committee and represents Senior Management. Dr. Axelrod, whose resume is located in Attachment 1, has 24 years experience using and supervising the use of radioisotopes. Dr. Axelrod, as "Certifying Officer" on the NRC Application for the Material License, initially receives all NRC bulletins relating to the license and forwards these documents to the RSO. In addition, an annual report, which includes an audit of the complete radiation safety program, in compliance with 10 CFR 20.1101(c), is submitted by the Radiation Safety Committee to Transcell Technologies' Management Committee for review.

Q.2.b Confirm that management will perform an audit of the overall radiation safety program, the Radiation Safety Officer performance, and the radiation staff performance at least annually.

A.2.b Transcell Technologies' management is committed to conduct annual audits for the purpose of assessing the performance of the radiation safety program, RSO, and staff authorized to use radioactive materials. Section III.A makes this commitment and Section V.E.11 specifies the schedule.

Q.2.c Specify the types and frequencies of audits that will be implemented by the Radiation Safety Officer and the staff to determine user compliance with the requirements of the NRC license, and your radiation safety program. These audits should include such topics as: reviews of users' inventory and survey records, evaluation of users' training through observation and discussion, and performance of independent work area surveys.

A.2.c The conduct of audits and routine surveillance are identified in Section III.B.1 and V.E.11. The frequencies are specified in Section V.E.11.2, routine surveillance is conducted during the conduct of routine surveys (i.e., weekly and monthly) and yearly for full audits. Finally, it should be noted that Transcell Technologies is committed to conduct such audits, which include reviews of users' inventory and survey records, evaluation of users' training through observation and discussion, and performance of independent work area surveys. These items, as well as others, are described in Section III.B.1.

Q.2.d Specify the types and frequencies of surveys and monitoring that will be performed by the Radiation Safety Officer and staff. Confirm that surveys will include both unrestricted and restricted areas. The survey frequencies may be based on a hazard scheme such as that found in Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005), Appendix J, and must be performed at least quarterly.

A.2.d The survey frequencies have been established on weekly schedule in areas where more than 200 μCi are used and at least monthly in all other areas designated as radiologically controlled areas. The 200 μCi limit is an NRC criterion. The monthly surveys also include checking uncontrolled areas that are adjacent to areas where radioactive materials are used and stored. Sections V.E.1, V.E.2, and V.E.3 of the application identify the requirements and frequencies for conducting radiation, air sampling, and surface contamination surveys.

Q.3 Section IV.A.3 in your application discusses the Ventilation Exhaust System, and states: "Outside air intakes servicing all areas of the laboratories are located on the roof, approximately 84 ft away for EF-3 82 ft away for EF-4, and 76 ft away for EF-13." Considering the maximum possession limits requested in your application, a maximum credible accident causing a release, and your statement that access to the roof will not be under the administrative control of Transcell, provide your calculations to support the statement: "Accordingly, all releases will be controlled such that the roof of the building will be considered as an unrestricted area, and non-occupational airborne concentration limits will be applied at all roof locations."

A.3 Under the requirements given in 10 CFR, Parts 30.32 (i)(1) and 30.72, Schedule C, it is our understanding that we need not address catastrophic accident scenarios since our possession limits (Section II, Table II-1) demonstrates that the total radionuclide inventory is well below Schedule C limits. An emergency preparedness plan is not required since Transcell's possession limits are not in excess of the requirements.

Accordingly, releases to the roof will consider the presence of radioactive materials associated during the routine conduct of R&D activities. As is noted in Table II-2, the amounts of radioactivity used in each experiment is typically limited from 50 to 1,000 μCi. Table 1 presents expected stack concentrations and a comparison with NRC limits of Table 2. Col. 1 of App. B to Part 20. The following assumptions were used in generating the results shown in Table 1.

a. The amounts of activity assumed to be available are those used in typical R&D activities, see 3rd column of Table II-2 of our application.
b. The amounts of radioactivity available for releases were adjusted by using the release fractions (R) given in NUREG-1400 (Table 1.1) for all nuclides, except ^{3}H and radioiodines.

Table 1 Estimated Roof Radionuclide Concentrations Based on Radionuclide Usage Presented in Table II-2 of Transcell Application

Nuclide	Activity In Use	Release Fraction	Resulting Conc. - μCi/ml	App. B Conc. Limit - μCi/ml	Ratios: Conc./Limit
H-3	50 μCi	0.1	1.3E-11	1.0E-07	1.3E-04
C-14	50 μCi	0.01	1.3E-12	3.0E-09	4.4E-04
P-32	1,000 μCi	0.01	2.6E-11	5.0E-10	5.2E-02
P-33	50 μCi	0.01	1.3E-12	4.0E-09	3.3E-04
S-35	1,000 μCi	0.01	2.6E-11	4.0E-09	6.6E-03
Cr-51	1,000 μCi	0.01	2.6E-11	3.0E-08	8.7E-04
I-125	200 μCi	0.1	5.3E-11	3.0E-10	1.8E-01
I-131	200 μCi	0.1	5.3E-11	2.0E-10	2.7E-01

See above text for details and assumptions.

c. For ^{3}H and iodines, a release fraction of 0.1 was used to account for the fact that experiments rely on the use of stabler compounds, as opposed to their elemental counterparts. For the sake of comparison, 10 CFR Part 30.72 (Schedule C), uses a release fraction of 0.5 for these nuclides.

d. The concentration limits from Table 2, Col. 1 of App. B are for the most limiting compound class.

e. The exhaust flow rate is 28,000 CFM, the full rated flow of EF-3 and -4 combined, see Table IV-2 of application.

f. The experiment is assumed to be conducted over an 8-hr time period, resulting in a total exhaust stack volume of $3.81 \times 10^{+11}$ mL.

g. It is assumed that an individual on the roof is exposed to undiluted air, discounting stack height, stack momentum, and thermal buoyancy of the exhausted air.

As can be noted from Table 1, the resulting concentrations are within the limits defined by Table 2, Col. 1 to App. B to Part 20, given these assumptions. As can be noted, radioiodines are the most limiting radionuclides.

For EF-13, which services the Radwaste Storage Room, all radioiodines waste will be placed in closed waste containers, thereby minimizing or eliminating all such releases.

Q.4 Section IV.B in your application discusses the Liquid Effluent System and states: "In order to assess the total radiological effluent releases and concentrations, the total effluent discharges flow rate will be monitored and determine by using water readings or water consumption rates given on invoices from the local water utility." Describe

how you will quantify the radioactivity released in liquid effluents, and how you will monitor effluent releases and concentrations other than by calculations.

A.4 As part of R&D protocols, the researchers are required to maintain inventories of radioactivity or mass balances of compounds containing radioactivity. The inventories are based on specification sheets provided by the suppliers and radioanalysis (e.g., LSC or gamma counting), where the radioactivity is tracked within the different phases, compounds, or components of the experiments. This information will be used to assign and determine the levels of radioactivity in liquid waste. In addition, the RSO will perform periodic checks by taking aliquots of the liquid waste and conducting independent analyses. The concentrations and total activity discharged in the sink will be recorded and compiled monthly to very compliance with 10 CFR Part 20.2003 and Table 3 to App. B. Only the sink in the RSO's Lab (Room 170) is designated for bulk releases of liquid waste.

Q.5 Section V.A.1.3 in your application describes your Radiation Safety Officer responsibilities. Confirm that you will revise the description of the duties of the Radiation Safety Officer (RSO) would be:

a. To assess radiological hazards and prescribe and ensure the implementation of appropriate radiation safety precautions.

b. To ensure that the use of licensed material is by or under the direct supervision of individuals specifically listed in your license.

c. To ensure that all users (where appropriate) wear personnel monitoring equipment when using licensed materials.

d. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

e. To perform routine inspections of all laboratories using or storing licensed materials.

f. To ensure that the terms and conditions of your license are met, and that all required documents are maintained.

A.5 It should be noted that Section III addresses the responsibilities and duties of the RSO. The duties noted above are included in Section III. However, Transcell Technologies confirms that the Technical Support Document will be revised to also include the above noted RSO duties in Section V.A.1.3 for the sake of completeness.

Q.6. The following questions are in regard to the statement made in Section V.B.4 in your application.

Q.6.a "Since radioiodines are volatile, experiments using I-125 more than 0.1 mCi will be performed in vented hoods or enclosures. Depending upon chemical forms, the RSO may establish alternative limits for non-volatile compounds." Discuss the volatile forms of radioiodines or process you will conduct that will release volatile forms of iodine.

A.6.a It should be noted that radioiodines were included in our license in potential anticipation that future R&D activities might require the use of iodines. Over the past two years we have not used any iodines. Accordingly, we cannot address at this time which specific types of iodine compounds might be used and their respective volatility. However, it should be noted that we do not intend to conduct iodinations, using elemental iodines. For elemental iodines, stock solutions are maintained as basic solutions to minimize their volatility. As with other radiolabeled compounds, we routinely have suppliers make custom compounds for Transcell Technologies. In all cases, the radionuclides are bound in stable molecules and compounds (e.g., proteins, sugars, etc.), thereby, minimizing or precluding the volatility of the radioactivity. It should be noted that at this time, all of our R&D activities have involved ^{3}H and ^{14}C in very small amounts, typically $< 50\mu Ci$ per experiment and ordered in increments of about 250 μCi.

Q.6.b "If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow up investigations will be performed. For thyroid scans, action levels of less than or equal to 0.06 μCi will be used, based on 75% uptake, with 30% going to the thyroid and assuming a breathing rate of 20 LPM." Confirm that you will modify your action levels to 0.04 μCi of I-131 or 0.12 μCi of I-125. Refer to Regulatory Guide Position 5 in Regulatory Guide 8.20.

A.6.b It should be noted that the action level for I-125 is based on earlier NRC guidance (letter from Mr. Steven L. Baggett, Oct. 2, 1992 to an NRC licensee on this issue) noting that the value of Regulatory Guide 8.20 for I-125 is wrong. Furthermore, we have retained the NRC revised value of 0.06 μCi to be generally consistent with Regulatory Guide 8.25 (Table 1) for confirming that airborne levels and exposures (intakes) are indeed very low, determining when additional sampling (either grab or continuous) might be required, and reassessing the R&D protocol and radiological control measures. This value corresponds to 0.1% of the ALI for I-125. The corresponding value for I-131 is 0.05 μCi. Finally, there is nothing preventing a licensee from selecting action levels that offer a higher level of resolution in evaluating working conditions, defining the scope and frequency of air sampling and monitoring, and assessing worker exposures. The concern is that by adopting the more liberal 1%

limit of Regulatory Guide 8.25 (Table 1), a situation might arise that could result in possibly elevated exposures (as DAC or ALI) that would be discovered after the fact. This more conservative approach is used to account for uncertainties involving varied types of R&D activities.

Q.7 Your application states that you will also use wrist badge to monitor personnel exposures. There can be a large differential between radiation exposure to the fingers and radiation measured at the wrist. For this reason, the NRC recommends the use of finger ring dosimeters to monitor personnel extremity exposures. If you intend to use a wrist type badge instead of ring finger dosimeters, please describe how you will determine exposure tot he fingers.

A.7 We recognize that there are differences in results between wrist badges and finger ring dosimeters. Should extremity monitoring be required, we will use only finger ring dosimeters. Accordingly, the mention of wrist badges in the Technical Support Document will be deleted.

Q.8 Your application states that the Radiation Safety Officer will make dosimetry results available to each employee when requested and when terminating employment. 10 CFR 19.13(b) requires each licensee to advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106. Confirm that you will advise each worker annually of the worker's dose.

A.8. It should be noted that we have been advising our employees of their respective exposures and doses. Also note that Section V.C.1 of our application acknowledges the requirements of 10 CFR Part 19.13. However, we will revise that Section to make sure that this point clearly stated as opposed to a simple acknowledgment of Part 19.13.

Q.9 Describe the processes you will perform that will cause the liberation of radioactive carbon-14, and provide your procedures that describe how you will perform the analysis of carbon-14 in breath samples.

A.9. It should be noted that we have included the possibility of volatile forms of ^{14}C-compounds for the sake of completeness, as not doing so might have been perceived by the NRC as an oversight on our part. Over the past two years we have not used ^{14}C in a form or manner that would generate volatile forms of ^{14}C. As with other radiolabeled compounds, we often have suppliers make custom compounds for Transcell Technologies. In all cases, the radionuclides are bound in molecules and compounds (e.g., proteins, sugars, etc.), thereby, minimizing or precluding the volatility of the radioactivity. It should be noted that at this time, all of our R&D activities have involved ^{14}C in very small amounts, typically ~50 μCi per experiment. Accordingly, we cannot address at this time which types of ^{14}C compounds might be used and their respective volatilities since the procedure would have to reflect the specifics of the

R&D protocol. At this time, we do not have a procedure that specifically addresses analysis of carbon-14 in breath samples, however, it can be noted that such a procedure would involve the following major steps.

(a) Characterization of the volatile form of the compound, e.g., $^{14}CO_2$.
(b) Defining the route of exposure and excretion patterns for the given compounds, e.g., exhalation vs. urine.
(c) Defining the appropriate bioassay procedure regarding the type of sample, sampling frequency, and analyses.
(d) If breath samples were required, breath samples will be collected periodically by having the employee exhale in balloons of known volumes.
(e) The air from the balloon will then be exhausted and slowly bubbled into a bubbler with the proper solution (e.g., NaOH).
(f) Aliquots of bubbler solution will be collected and analyzed using a liquid scintillation counter, and expressed as μCi/mL.
(g) The results will be then be compared to the limits of Table 1, App. B. to Part 20, taking into account the mode of exposures, the type of compound, duration of exposure, and intake.
(h) If urine bioassay results are also available, their results will be evaluated and integrated in assessing total intake and resulting doses.

Section V.C.3 of the application presents the elements of the bioassay program.

Q.10 The statement in Section V.D.1, Liquid Effluents: "Accordingly, the requirements given in Part 20.1302 and Table 2, Column 2 of Appendix B are not applicable in the context of routine effluent releases into sanitary sewer systems," is incorrect. 10 CFR 20.1302 requires licensees to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. The licensee shall show compliance with the annual dose limits in 10 CFR 20.1301 by either demonstrating by measurements or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from licensed operation does not exceed the annual dose limits, or demonstrating that the average concentrations of radioactive materials released in gaseous or liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of App. B to Part 20 and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem in an hour and 0.05 rem in a year. Confirm that you will perform surveys in accordance with 10 CFR Part 20.1302.

A.10 The statement of Section V.D.1 was to note that the facility does <u>not</u> release liquid

effluents in surface water bodies and streams, which are governed by the limits of App. B, Table 2, Col. 2 to Part 20. Liquid waste, in limited amounts, will be released only to the sewers and are governed by the limits of App. B, Table 3 to Part 20. Finally, this statement does not take exception to the other requirements of Parts 20.1301 and 20.1302. All associated surveys will be conducted as is required.

Q.11 The information in regard to labeling, package surface survey exposure rates, and transport index is incomplete. Please review and resubmit the table to comply with the Table in 49 CFR.

A.11 Section V.E.6 of the application identifies the allowable surface contamination limits and external radiation exposure rates at the surface and at one meter. It should be noted that the 1-metre exposure rates are equivalent to the transportation index. However, for the sake of full agreement with the definition of 49 CFR 172.403, Section V.E.6 will be updated accordingly.

Q12. The following questions are in regard to the discussion on sampling or releases in your application. It appears that your monitoring and sampling program has been written for a process monitor with particulate and iodine sampling capabilities. The discussion also includes statements that are inconsistent with other statements in your application.

Q.12.a Describe the process and specify the designated release points described in Section V.E.10.1 that you will perform that will liberate radioactive iodine emissions and radioactive particulate which would require isokinetic sampling. Item 3 in your cover letter states that iodinations will not be conducted.

A.12.a Radioiodines are not currently being utilized, and iodinations is not planned in the near future. If radioiodines were required by R&D protocols, they will be used in the RSO's Lab, Room 170. The associated release point is associated with exhaust fans and stacks EF-3 and EF-4. The sampling system described in Section V.E.10.1 was included for the sake of completeness as not doing so might have been perceived by the NRC as an oversight on our part. The system, as described, is only a "generic" description to demonstrate the various components of a sampling system. It is not a process system and it will be set up as a temporary system to support and monitor specific R&D activities over their duration. The system will be set up in the Lab and/or hood exhaust where radioactive material will be used. The make up of the system will take into account sampling location and exhaust flow rate, sampling flow rate (near-isokinetic only), sampling media (particulate or charcoal and both, when required), sampling duration, required MDC for the radionuclide(s) of interest, and types of analysis.

Q.12.b What are the predetermined/specified action levels that will be derived for gross-beta and gamma activity.

A.12.b It should be noted that radioiodines were included in our license in potential anticipation that future R&D activities might require the use of iodines. Over the past two years we have not used any radioiodines.

As is noted in Sections II and V of the application, all research activities will be initially reviewed and approved by the RSO as part of the ALARA program. Under this process, before any experiment is allowed to proceed, each phase of the planned research activity will be evaluated for radiological considerations. The necessary radiological control measures will be identified and specified in the research protocol. Accordingly, we cannot identify at this time specific numerical values for action levels other than the factors that will be considered in deriving such action levels. Section V.E.10.1 identifies the factors that will be considered in deriving specific action levels.

Q.12.c What areas will use iodines routinely that will require sampling of the effluent from these areas?

A.12.c If radioiodines were required by R&D protocols, they will be used in the RSO's Lab, Room 170.

Q.13 Please clarify whether particulate and charcoal filters will be installed in the exhaust filter train or will be used on containment structures around experiments. If particulate and charcoal filters are not installed in the exhaust filter train, what are the anticipated concentrations of particulate and iodines releases from process to support the statement that the roof areas will be considered unrestricted areas.

A.13 Section IV.A.3 of the application states that the exhaust ventilation system is not equipped with HEPA or charcoal filters. As is noted in Sections II and V of the application, all research activities will be initially evaluated and approved by the RSO as part of the ALARA program. Under this process, before any experiment is allowed to proceed, each phase of the planned research activity will be evaluated for radiological considerations. The necessary radiological control measures will be identified and specified in the research protocol. As part of this process, the RSO will determine whether the amounts of radioactivity to be used in a specific protocol need to be limited or the experiment needs to be conducted in an enclosure equipped with proper filtration, such that airborne concentrations on the roof will meet the limits for unrestricted areas, as defined in Table 2, Col.1 of App. B to Part 20.

Q.14 Describe the administrative controls to restrict access to the roof area considering that Transcell Technologies is leasing the facility.

A.14 This question was addressed, in part, by Question 3. As is noted in Question 3, Transcell Technologies does not have administrative controls to restrict access to the roof. Therefore, Transcell Technologies will limit the amounts of radioactive material in use such that all releases will be controlled and that the roof of the building will be considered an unrestricted area, and non-occupational airborne concentration limits will be applied at all roof locations.

Q.15 Describe how you will monitor liquid effluents at the time of release at designated sinks. Specific which sink will be designated as radioactive sinks at the facility.

A.15 As part of R&D protocols, the researchers are required to maintain inventories of radioactivity or mass balances of compounds containing radioactivity. The inventories are based on specification sheets provided by the suppliers and radioanalysis (e.g., LSC or gamma counting), where the radioactivity is tracked within the different phases, compounds, or components of the experiments. This information will be used to assign and determine the levels of radioactivity in liquid waste. In addition, the RSO will perform periodic checks by taking aliquots of the liquid waste and conducting independent analyses. The concentrations and total activity discharged in the sink will be recorded and compiled monthly to very compliance with 10 CFR Part 20.2003 and Table 3 to App. B.

Only the sink in the RSO's Lab (Room 170) is designated for bulk releases of liquid waste.

Q.16 Item 2 in Section V.E.10 in your application States: " When in use, the RSO will establish specific limits for radioiodines. The amounts of radioactivity associated with liquid waste generated as dilute washes and rinses containing only very low concentrations ($< 10^{-3}$ μCi/mL) will be recorded as estimates, based on R&D protocols or process knowledge. Please be aware that for iodines, this concentration of 10^{-3} μCi/mL is two orders of magnitude higher than the concentration permitted in the regulations. Confirm that all releases to the sanitary sewer will not exceed the limits of 10 CFR Part 20, App. B and will be in accordance with 10 CFR Part 20.2003 limits.

A.16 Sections V.D.1, V.E.10.2, and VI.C.2 make several references to and acknowledge the specific requirements and limits defined in 10 CFR Part 20.2003 and Table 3 to App. B. We are aware that the limits for radioiodines are much more restrictive. It should be noted that the limit of $< 10^{-3}$ μCi/mL is not the discharge limit at the outfall of the sanitary sewer at the boundary of the leased facility, i.e., nearest accessible manhole, but rather a sink disposal limit. It should be noted that if liquid waste at this concentration were discharged in the sink, they will be diluted by other sources of water generated by Transcell activities, in addition to those generated by other tenants. A review of the data presented in Section V.D.1 indicates that there is a dilution factor of at least 10^{+5} (from Transcell alone), which would make such a release well below

the limit of Table 3, App. B to Part 20. For example, assuming that liquid waste containing I-125 at 10^{-3} μCi/mL were dumped in the sink, the resulting concentration would be 10^{-8} μCi/mL, which is a small fraction of the Table 3 limit of 2.0×10^{-5} μCi/mL. Similar case examples could be constructed for all radionuclides, but are omitted here for the sake of brevity.

As part of R&D protocols, the researchers are required to maintain inventories of radioiodines or mass balances of compounds. The inventories are based on specification sheets provided by the suppliers and radioanalysis (e.g., LSC or gamma counting), where the radioactivity is tracked within the different phases, compounds, or components of the experiments. This information will be used to assign and determine the levels of iodines present in liquid waste and discharged to the sink. In addition, the RSO will perform periodic checks by taking aliquots of the liquid waste and conducting independent analyses. The RSO will also specify discharge limits for radioiodines for the sink located in Room 170, when in use. Again, please note that at this point we are only using small amounts of ^{3}H and ^{14}C.

Q.17 In reference to analysis of liquid releases, your application states: "Other analytical techniques (e.g., gross-beta, gamma, or gamma spectroscopy) will be used as is required for specific radionuclides. Such analysis will be conducted in-house or performed by licensed commercial laboratories, and for QA/QC purposes." Table IV-3 does not list a gamma spectroscopy instrument. Please update your instrument list and provide the name of the manufacturer, model number, and frequency of the calibration of the gamma spectroscopy instrument you will use for "in-house" analysis. Provide the NRC or Agreement State license number of the commercial service you will use to perform gross-beta, gamma, and gamma spectroscopy analyses.

A.17. The purpose of referring to the use of a gamma spectroscopy system was to acknowledge the fact that in some instances such instrumentation might be required, as not doing so might have been interpreted by the NRC as an oversight by Transcell Technologies. Currently, we have no need for such instrumentation as the only radionuclide in use are ^{3}H and ^{14}C. In the event that such need would arise, it is currently anticipated that initially we would use the services of a commercial laboratory to perform such analyses and later determine whether it would be more cost-effective to purchase such an instrument, given the number of samples to be analyzed in support of R&D activities. We currently use the services of Teledyne Brown Engineering for instrumentation calibration services and we will also use this facility to perform gamma spectroscopy analyses. Section V.F.2 of the application provides more details and the NRC license number for Teledyne Brown Engineering.

Q.18 Describe the conditions or processes that will be performed where you will allow high radiation areas to be present.

A.18 As is noted in Sections II and V of the application, all research activities will be initially reviewed and approved by the RSO as part of the ALARA program. Under this process, before any experiment is allowed to proceed, each phase of the planned research activity will be evaluated for radiological considerations. The necessary radiological control measures will be identified and specified in the research protocol.

Given that our R&D program uses only limited amounts of radioactivity, we do not anticipate that such activities will result in high radiation areas. Again note that we have used only ^{3}H and ^{14}C over the past two years. However, we do expect that when using ^{32}P, ^{32}P, ^{51}Cr or iodines, elevated radiation levels could result in higher doses to extremities, skin, and lens of the eye. In such instance, we intend to use beta-blocks for stock solutions and plastic shields at all work stations using ^{32}P and ^{32}P. For gamma emitters, Pb bricks and foils will be used in a similar manner. In such instances, workers will be required to use safety glasses and wear finger ring dosimeters, in addition to the whole body badge. All such activities will be monitored by the RSO. Sections V.B.3, V.B.4, V.E.7, and V.G.3 of the application address these requirements.

Q.19 Confirm that the RSO will also conduct unannounced inspections of areas where licensed material is used or stored.

A.19. As part of his/her duties, the RSO will conduct unannounced inspections of areas where licensed radioactive materials are used and stored.

Q.20 Your application states: "Calibrations will be performed using sealed, plated, or solution sources." You application does not list any sealed sources." 10 CFR 30.32.(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or with an Agreement State; or contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed sources requested in your application.

A.20 Table II-1 does not list any sealed sources and it was never the intent to obtain any sealed sources that would be licensed under Part 30.32(g) as our program does not warrant their use. The purpose for defining "sealed, plated or solution sources" was to make sure that the possession limits also include the activity of sources and standards used to calibrate the liquid scintillation counter, gamma counter, and I-125/I-131 scaler, when needed. This distinction is being made since the NRC requires that the chemical and physical form of the radioactivity be described for all materials to be

included in the license. The sources in question are NIST traceable low specific activity sources, on the order of several to a few tens of microcuries, encased in plastic rods and buttons or electroplated on metal disks. Accordingly, there are no requirements for Transcell Technologies to obtain sources that would be licensed under 10 CFR 30.32(g). As is stated in Section V.F.2, all instrumentation used to measure radiation exposure rates (which require the use of sealed sources for their calibration) will be sent out to a third party for calibration.

Finally, the requirements identified in Section V.E.8 apply to instrumentation that contain specific sources that are integral working components. For example, some GC/MS come equipped with a Ni-63 source (~15 mCi) issued under a general license that still requires leak testing. We do not have such instrumentation in use, as is indicated by Table II-1.

Q.21 Confirm that you will change your notification to include the NRC Operations Center phone number: 301-816-5100.

A.21 The notification list (Table V-2) will be updated to include the NRC Operations Center phone number: 1-301-816-5100.

TELEPHONE CONVERSATON RECORD	Date:5/27/97	Time: 3:35 pm
Mail Control No.:124521	**License No.:** 29-30181-01	**Docket No.:** 030-33700
Person Called: Clifford Longley, RSO	**Organization:** Transcell	**Telephone Number:** 908-940-6925
Person Calling:J Bondick	**Organization:** NRC	**Telephone Number:** 6951
Subject: Additional information sent		
Summary: Spoke to Mr. Longley about the letter sent in regard to the proposed decommissioning of the facility at Monmouth Junction, NJ. Told Mr. Longley we do not review proposals, and outlined the steps required to proceed for the closure of the facility at Monmouth Junction. He stated that he had an NRC Form 314, and that they were going to dispose of the remaining radioactive waste through the waste disposal contractor. Discussed a two-part license with Mr. Longley, and noted to him that (on page V-1) they stated that they were going to inventory all radioactive materials prior to transferring this material to the Cranbury facility. Mr. Longley stated that they would not be transferring any material to the new facility and would be "starting fresh" at the new facility. He stated that he expected to send in the response to the deficiency letter within the next few days.		
Action Required/Taken: MS 15, await receipt of response to deficiency letter.		
Signature: J.Bondick *Bondick*	**Date: 5/27/97**	

MAY 19 1997

License No. 29-30181-01
Docket No. 030-33700
Control No. 124531

Helena R. Axelrod, Ph.D.
Director, Biological Research
Transcell Technologies, Inc.
2000 Cornwall Road
Monmouth Junction, NJ 08852

Dear Dr. Axelrod:

This is in reference to your application dated April 30, 1997 requesting an amendment to Nuclear Regulatory Commission License No. 29-30181-01. In order to continue our review, we need the following additional information:

1. Your application appears to indicate that your proposed location of use may be controlled by an entity other than yourself. If so, please provide documentation of a clear contractual agreement concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. This documentation should consist of signed certification from both parties.

2. The Management Commitment, as discussed in Section III.A. in your application states that management will periodically perform formal audits to assess the overall effectiveness of the radiation safety program. 10 CFR 33.13 and 33.14 require applicants to establish administrative controls and provisions relating to management review necessary to ensure safe operations. 10 CFR 20.1101(c) requires that the licensee review the radiation protection program content and implementation at least annually. Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005) recommends that an audit and appraisal program be part of the management review. Provide the following information regarding the management review program:

   a. Describe the senior management oversight of your radiation safety program. Specify the mechanisms that will be used by senior management to ensure that they are aware of the NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

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b. Confirm that management will perform an audit of the overall radiation safety program, the Radiation Safety Officer performance, and the radiation staff performance at least annually.

c. Specify the types and frequencies of audits that will be implemented by the Radiation Safety Officer and staff to determine user compliance with the requirements of the NRC license, and your radiation safety program. These audits should include such topics as: reviews of users' inventory and survey records, evaluation of users' training through observation and discussion, and performance of independent work area surveys.

d. Specify the types and frequencies of surveys and monitoring that will be performed by the Radiation Safety Officer and staff. Confirm that surveys will include both unrestricted and restricted areas. The survey frequency may be based on a hazard scheme such as that found in Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005), Appendix J, and must be performed at least quarterly.

3. Section IV.A.3 in your application discusses the Ventilation Exhaust System, and states: "Outside air intakes servicing all areas of the laboratories are located on the roof, approx. 84 ft away for EF-3, 82 Ft away for EF-4, and 76 ft away for EF-13." Considering the maximum possession limits requested in your application, a maximum credible accident causing a release, and your statement that access to the roof will not be under the direct administrative control of Transcell, provide your calculations to support the statement: "Accordingly, all releases will be controlled such that the roof of the building will be considered as an unrestricted area, and non-occupational airborne concentration limits will be applied at all roof locations."

4. Section IV.B in your application discusses the Liquid Effluent System and states: "In order to assess total radiological effluent releases and concentrations, the total effluent discharge flow rate will be monitored and determined by using water meter readings or water consumption rates given on invoices from the local water utility." Describe how you will quantify the radioactivity released in liquid effluents, and how you will monitor effluent releases and concentrations other than by calculations.

5. Section V.A.1.3 in your application describes your Radiation Safety Officer responsibilities. Confirm that you will revise the description of the duties and responsibilities of your Radiation Safety Officer. The typical duties of a Radiation Safety Officer would be:

   a. To assess radiological hazards and prescribe, and ensure the implementation of, appropriate radiation safety precautions.

   b. To ensure that the use of licensed material is by or under the direct supervision of individuals specifically listed on your license.

   c. To ensure that all users (where appropriate) wear personnel monitoring equipment when using licensed materials.

   d. To ensure that licensed materials are properly secured against unauthorized removal at all times when not in use.

   e. To perform routine inspections of all laboratories using or storing licensed materials.

   f. To ensure that the terms and conditions of your license are met, and that all required records are maintained.

6. The following questions are in regard to statements made in Section V.B.4 in your application:

   a. " Since radioiodines are volatile, experiments using I-125 more than 0.1 mCi will be performed in vented hoods or enclosures. Depending upon chemical forms, the RSO may establish alternate limits for non-volatile compounds." Discuss the volatile forms of radioactive iodine or process you will conduct that will release volatile forms of iodine.

   b. "If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow-up investigations will be performed. For thyroid scans, action levels of less than or equal to 0.06 μCi will be used, based on 75% uptake, with 30 % going to the thyroid and assuming a breathing rate of 20 LPM. Confirm that you will modify your action levels to 0.04 μCi of I-131 or 0.12 μCi of I-125. Refer to Regulatory Position 5 in Regulatory Guide 8.20.

7. Your application states that you will also use wrist badges to monitor personnel exposures. There can be a large differential between radiation exposure to the fingers and radiation measured at the wrist. For this reason, the NRC recommends the use of finger ring dosimeters to monitor personnel extremity exposure. If you intend to use a wrist type badge instead of ring finger dosimeters, please describe how you will determine exposure to the fingers.

8. Your application states that the Radiation Safety Officer will make dosimetry results available to each employee when requested and when terminating employment. 10 CFR 19.13(b) requires each licensee to advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106. Confirm that you will advise each worker annually of the worker's dose.

9. Describe the processes you will perform that will cause the liberation of radioactive carbon-14, and provide your procedures that describe how you will perform the analysis of carbon-14 in breath samples.

10. The statement in Section V.D.1, Liquid Effluents: " Accordingly, the requirements given in Part 20.1302 and Table 2, Column 2 of Appendix B are not applicable in the context of routine effluent releases into the sanitary sewer systems," is incorrect. 10 CFR 20.1302 requires licensees to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 10.1301. The licensee shall show compliance with the annual dose limits in 10 CFR 20.1301 by either demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from licensed operation does not exceed the annual dose limit, or demonstrating that the average concentrations of radioactive material released in gaseous or liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of appendix B to Part 20 and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year. Confirm that you will perform surveys in accordance with 10 CFR 20.1302.

11. The information in regard to labeling, package surface exposure rates, and transport index is incomplete. Please revise and resubmit the table to comply with the table in 49 CFR.

12. The following questions are in regard to the discussion on sampling of releases in your application. It appears that your monitoring and sampling program have been written for a process monitor with particulate and iodine sampling capabilities. The discussion also includes statements that are inconsistent with other statements in your application.

    a. Describe the processes and specify the designated release points described in Section V.E.10.1 that you will perform that will liberate radioactive iodine emissions and radioactive particulates which would require isokinetic sampling. Item 3 in your cover letter states that iodinations will not be conducted.

    b. What are the predetermined/specified action levels that will be derived for gross-beta or gamma activity?

    c. What areas will use iodines routinely that will require sampling of the effluents from these areas?

13. Please clarify whether particulate and charcoal filters will be installed in the exhaust filter train or will be used on containment structures around experiments. If particulate and charcoal filters are not installed in the exhaust filter train, what are the anticipated concentrations of particulate and iodine releases from processes to support the statement that the roof areas will be considered unrestricted areas.

14. Describe the administrative controls to restrict access to the roof area considering that Transcell is leasing the facility.

15. Describe how you will monitor liquid effluents at the time release at designated sinks. Specify which sinks will be designated as radioactive sinks at the facility.

16. Item 2 in Section V.E.10 in your application states: "When in use, the RSO will establish specific limits for radioiodines. The amounts of radioactivity associated with liquid waste generated as dilute washes and rinses containing only very low concentration ($< 10^{-3}$ μCi/ml) will recorded as estimates, based on R&D protocol or process knowledge. Please be aware that for radioiodines, this concentration of 10^{-3} μCi/ml is two orders of magnitude higher than concentrations permitted in the regulations. Confirm that all releases to the sanitary sewer will not exceed limits in 10 CFR 20, Appendix B, and will be in accordance with 10 CFR 20.2003 limits.

17. In reference to analysis of liquid releases, your application states: "Other analytical techniques (e.g. gross-beta, gamma counting, or gamma spectroscopy) will be used as is required for specific radionuclides. Such analyses will be conducted in-house or performed by licensed commercial laboratories, and for QA/QC purposes." Table IV-3 the description of radiation detection equipment does not list a gamma spectroscopy instrument. Please update you instrument list and provide the name of the manufacturer, model number, and frequency of calibration of the gamma spectroscopy instrument you will use for "in-house" analyses. Provide the NRC or Agreement state license number of the commercial service you will use to perform gross-beta, gamma counting and gamma spectroscopy analyses.

18. Describe the conditions or processes that will be performed where you will allow high radiation areas to be present.

19. Confirm that the RSO will also conduct unannounced inspections of areas where licensed material is used or stored.

20. Your application states: " Calibrations will be performed using sealed, plated, or solution sources." Your application does not list any sealed sources. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or with an Agreement State; **or** contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed source(s) requested in your application.

21. Confirm that you will change your notification to include the NRC Operations Center phone number: 301-816-5100.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 124531. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-6951.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,
ORIGINAL SIGNED BY:
JAMES M. BONDICK

James M. Bondick
Health Physicist
Division of Nuclear Materials Safety

License No. 29-30181-01
Docket No. 030-33700
Control No. 124531

Enclosures:
1. 10 CFR Parts 20, 30 and 71
2. Regulatory Guides 8.20 and 10.5, Revision 2
3. Information Notice 94-07

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TRANSCELL TECHNOLOGIES INC.

030-33700
29-30181-01
Q6

May 12, 1997

Mr. John Kinneman
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Kinneman:

Please find enclosed a proposed decommissioning plan for Transcell Technologies, Inc current facilities. Transcell Technologies has filed, as a separate action (Mail Control Number 124531), an application to amend its existing radioactive materials license with a change of address. Transcell is completely moving its current facilities from 2000 Cornwall Road, Monmouth Junction, New Jersey to 8 Cedar Brook Drive, Cranbury, New Jersey. The new facility should be completed the early part of June 1997. At that time all operations will cease at the Monmouth Junction facility and be reinitiated at the Cranbury facility.

Transcell Technologies is a small discovery research company which conducts a wide variety of activities to support the research and development of new drugs. As a small company with limited resources, it is our desire to most efficiently decommission our current leased facilities for unrestricted use. I have examined the regulatory guide 3.65, " Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Parts 30, 40, and 70," and have generated the attached proposal. Could you please review the enclosed decommissioning plan and indicate any further additions you feel necessary.

In closing, I trust that you will find the enclosed proposal satisfactory and look forward to obtaining your approval in the near future. Should you have any questions, please do not hesitate to contact me at (908) 940-6925. Your timely cooperation in this matter is greatly appreciated.

Sincerely

Clifford B. Longley

Clifford B. Longley, RSO

Enclosures: Transcell Technologies Decommissioning Plan.

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Proposed Decommissioning Plan for Transcell Technologies Inc.

Located at

2000 Cornwall Road
Monmouth Junction, NJ. 08852

License # 29-30181-01 Docket # 030-33700

May 1, 1997

Table of Contents

I. Objective

The Transcell Technologies, Inc. (Transcell) conducts a wide variety of activities to support the research and development of new drugs. In support of such activities, several radionuclides are used in a limited number of experiments per month. Transcell Technologies has recently submitted an amendment to its Byproducts license to indicated a change in address (Mail Control Number 124531). Transcell will be vacating it current facilities in Monmouth Junction New Jersey and moving its operations to 8 Cedar Brook Drive, Cranbury, New Jersey, 08512. The new facility should be completed the early part of June 1997. At that time all operations will cease at the Monmouth Junction facility and be reinitiated at the Cranbury facility. The objective of this decommissioning plan is to return the current areas at Transcell where radionuclides are used to unrestricted use. This Objective will be accomplished by decontaminating and extensively surveying areas by swab testing where radioactivity was used.

Since initiation of our Byproducts license approximately two years ago, Transcell has purchased only ^{14}C and ^{3}H labeled compounds (Table 1). The other radionuclides permitted on our license have not been purchased. Since inception of Transcell's radioisotope programs approximately 1.3 mCi of ^{14}C labeled compounds and 7.4 mCi of ^{3}H label compounds have been purchased and 0.6 mCi ^{14}C and 1.8 mCi ^{3}H of these labeled compounds have been used.

Table 1. Quantities of Radionuclide purchased Since Initiation of Byproducts License (March 24, 1995)

Licensed Radionuclide	Possession Limit	Total Amount Purchase (mCi)	Total Amount Used* (mCi)	Total Amount Disposed (mCi)	Total Amount On Hand (mCi)
^{14}C	75	1.25	0.60	0.53	0.72
^{3}H	100	7.38	1.75	1.61	5.77
^{32}P	50	0	--	--	--
^{33}P	50	0	--	--	--
^{35}S	50	0	--	--	--
^{51}Cr	50	0	--	--	--
^{125}I	50	0	--	--	--
^{131}I	50	0	--	--	--

* as of 4/28/97

The radioactive waste generated in Transcells radioisotope programs entered three waste streams: solid, scintillation vials, and sink (Table 2). The total volume of solid and

scintillation vial waste generated since the beginning of our radioisotope programs has amounted to four 55 gallon drums of waste, two 55 gallon drums for each waste stream. The combined radioactivity in these two waste streams was approximately 0.06 mCi ^{14}C and 0.15 mCi ^{3}H. Dilute aqueous ^{3}H and ^{14}C wastes generated were disposed of in accordance with 10 CFR, Parts 20.2003, 20.2005, 20.2007, and 20.2108, Appendix B, Table 3 limits. These dilute solutions contained compounds that were completely miscible and biodegradable. The total radioactivity disposed of by this route since inception of Transcell's radioisotope programs was 0.53 mCi ^{14}C and 1.61 mCi ^{3}H with a average daily laboratory sewer effluent discharge volume ranging from 3,000 to 8,200 gallons per day.

Table 2. Quantities of Radioactive Waste Generated (From 3/25/95 to 4/28/97)

Radionuclide	**Waste Stream**		
	Solid (mCi)	Scintillation Vials (mCi)	Sink (mCi)
^{14}C	0.033	0.030	0.532
^{3}H	0.027	0.119	1.607

The decontamination of the laboratory and waste storage areas will be performed as described in Transcell Technologies Technical support document submitted with its Byproducts license application and Transcell's Radiation safety manual. All procedures for decontamination have been reviewed and approved by Transcell's Radiation Safety Committee and are part of Transcell standard operating procedures. Following decontamination of the laboratory and radioactive waste storage area the final decommissioning survey will be performed.

Teledyne Brown Engineering (TBE-ES) has been contracted to perform the final decommissioning survey of the four areas within Transcell Technologies that radioisotopes have been used or stored. These areas encompass less than 2000 square feet of laboratory and waste storage space. The final decommissioning survey will be performed by TBE-ES using their protocols (Attachment I). The decommissioning survey will be performed in accordance to NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination." They will also prepare a report pursuant to NRC "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of License for Byproduct, Source or Special Nuclear Material Licenses." TBE-ES has projected that 200 swab samples will be collected during the decommissioning survey and this should take a minimum of four hours to perform.

Transcell's RSO will be responsible for general oversight of the decontamination and decommissioning and will ensure compliance with operational safety, auditing of the swab data, and addressing issues resulting from the decontamination and decommissioning.

II. Methods used for protection of occupational and public health and safety.

The use of radioactive materials was limited to three laboratories: rooms 169, 175, and 180A; and the radioactive waste storeroom 136A (Figure 1). Source materials of ^{14}C and ^{3}H labeled compounds were stored in room 175. Microcurie aliquots of these compounds were dispensed in room 175 for use in trace label radioisotopic studies performed in the three laboratories. Waste materials generated during these studies were removed and stored in the radioactive waste storeroom. Work areas with in these laboratories were monitored for possible contamination by performing swab tests.

Typically no contamination was detected during monitoring. No spills greater than 50,000 DPM have ever been recorded. Any contamination detected was removable. Sink effluents from these laboratories, as part of Transcell's standard Radiation Safety program, were also regularly monitored from the facilities chemical waste pre-treatment tank. The diluted ^{14}C and ^{3}H radioactive washes disposed of by this route were completely biodegradable and free from particulate and colloids. Monthly surveys of this effluent, prior to disposal to the sanitary sewer, has never shown any detectable ^{14}C or ^{3}H counts above background levels.

The decommissioning of laboratory will be performed under the ALARA program described in Transcell Technologies Technical support document. The goal of Transcell's ALARA Program is to maintain all personnel radiation exposures and radioactive releases to the environment at levels which are as low as is reasonable achievable and to ensure compliance with all pertinent Federal and State and local regulations. The success of Transcell's ALARA program is dependent upon the shared responsibilities and combined efforts of the Radiation Safety Officer, R&D and support staff, and the Radiation Safety Committee. The following tabulation presents the relationships between regulatory exposure and ALARA limits

	Dose Equivalent Limits		
Exposure	Annual Regulatory Limits (Part 20)	Monitoring Required	ALARA Limits
Whole body	5 rem/yr	0.5 rem/yr	0.25 rem/yr
Extremities	50 rem/yr	5.0 rem/yr	2.5 rem/yr
Skin	50 rem/yr	5.0 rem/yr	2.5 rem/yr
Lens of eye	15 rem/yr	1.5 rem/yr	0.75 rem/yr
Pregnant worker	0.5 rem per gestation	0.05 rem per gestation	lowest possible dose
Uncontrolled areas	100 mrem/yr 2 mrem/hr	-- --	lowest possible dose or rate

Transcell Technologies RSO, in conjunction with TBE-ES health physics, will manage and audit the decontamination and decommissioning process. Instruments and equipment used during the decontamination and decommissioning survey will be commensurate to removal and detection of low level contamination of ^{14}C and ^{3}H. All radioactive wastes held by Transcell as a result of their radioisotopic studies and those wastes generated during the final decontamination will be disposed of by TBE-ES prior to the final decommissioning survey. The volume of waste generated during decontamination should be less than two cubic feet and contain less than 5 microcuries of ^{14}C or ^{3}H labeled compounds. Any radioactive wastes generated during the final decommissioning survey will also be disposed of by TBE-ES.

III. Planned final radiation survey.

The laboratory spaces will be released for unrestricted use only after all equipment, systems and structures that are part of the three laboratories and radioactive waste storage are shown to comply with "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of License for Byproduct, Source or Special Nuclear Material Licenses." TBE-ES will perform the final decommissioning survey for Transcell Technologies. The swabs obtained from the survey with be scintillation counted using the analytical facilities of TBE-ES. The data obtained will be reviewed and audited by both Transcell Technologies and TBE-ES health physicists. Any residual contamination observed will be removed and the area re-surveyed. The final decommissioning survey report will be prepared by TBE-ES for submission to the NRC. Form 314, "Certificate of Disposition of Materials" will be filled out by Transcell Technologies and the results from the TBE-ES final decommissioning survey attached.

IV. Funding

The cost of decontaminating and decommissioning Transcell Technologies laboratory and waste storage facilities are estimated to be less than $2500. The quantities of radioisotopes permitted under Transcell Technologies Byproduct license allows Transcell to be exempt from posting financial assurances. The costs for decontamination and decommissioning of the laboratories and radioactive waste storeroom are contained within Transcell Technologies normal operating budget, accordingly no special funding is necessary.

V. Security and Accounting

An inventory of all radioactive materials will be performed prior to transferring this materials to Transcell Technologies Cranbury facility. The less than 0.7 mCi ^{14}C and 5.6 mCi ^{3}H compounds remaining after the final waste disposal will be secured by the RSO and transferred to the Cranbury facility.

Figure 1

Transcell Technologies
Facility Site Plan

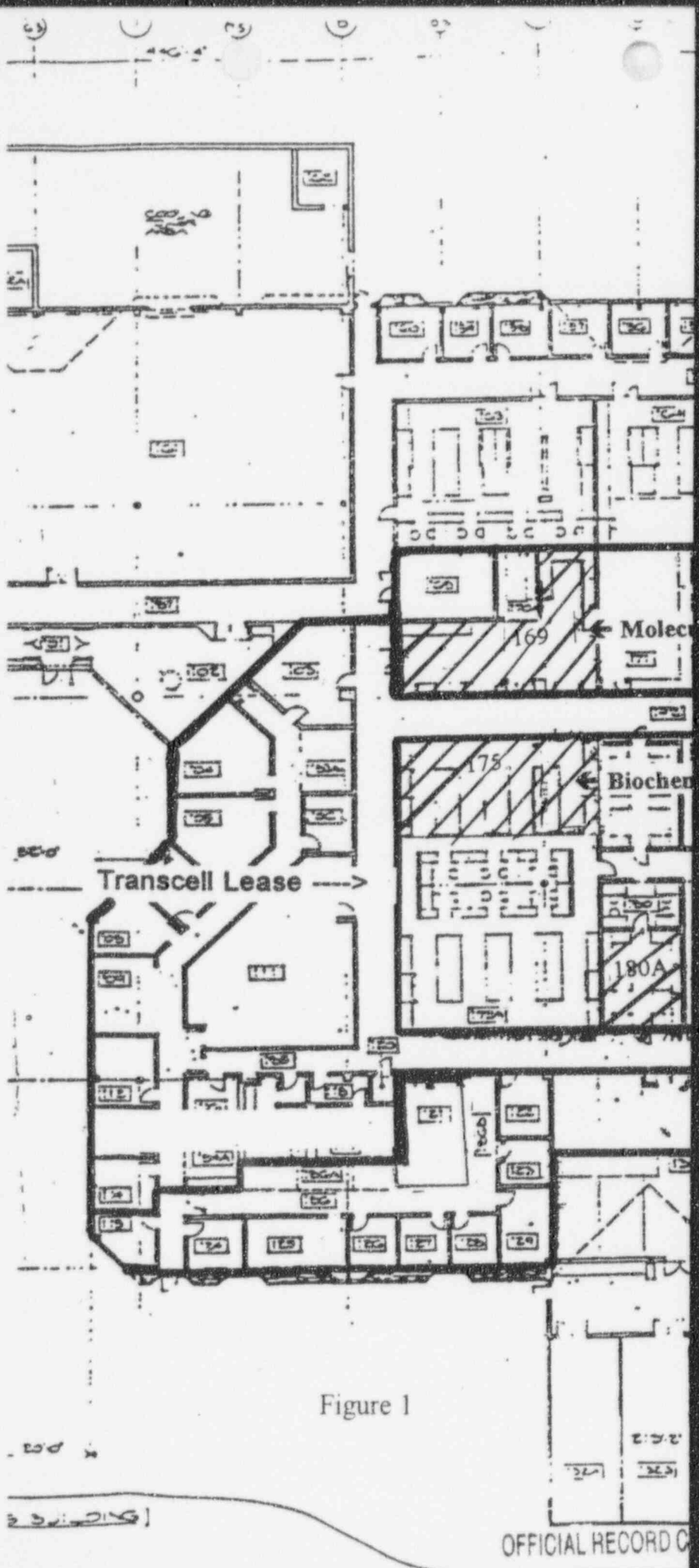
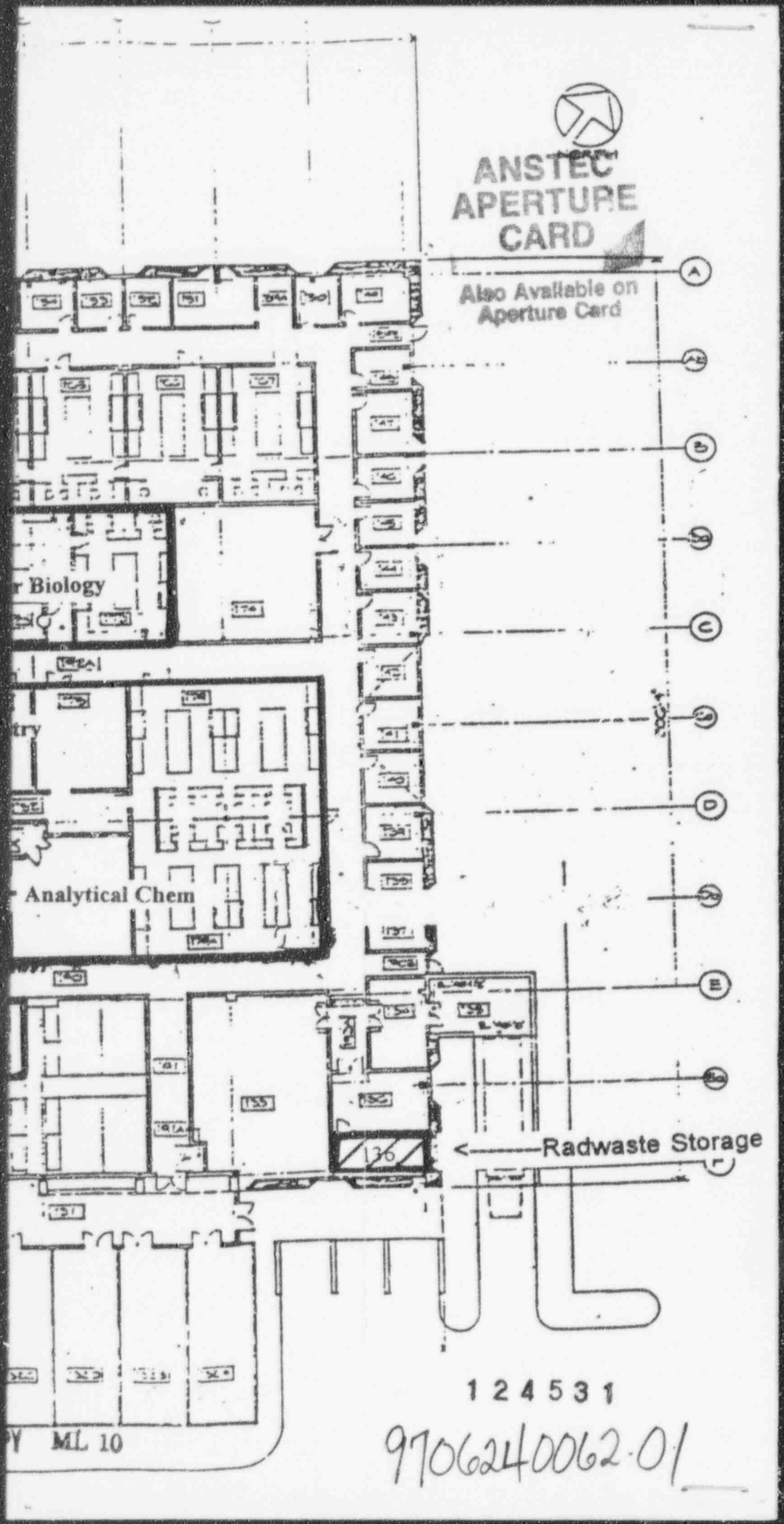

169
Molec
178
Biochem
Transcell Lease
180A
OFFICIAL RECORD C

Figure 1


ANSTEC
APERTURE
CARD
Also Available on
Aperture Card
Biology
Analytical Chem
136
Radwaste Storage
ML 10
124531
9706240062-01

APPENDEX 1

Teledyne Brown Engineering Environmental Services
Health Physic Procedures

HPP-5 SMEAR ANALYSIS BY LIQUID SCINTILLATION COUNTING

Purpose: To determine the level of removable radioactive contamination on laboratory and other surfaces.

Discussion: All samples are compared to a set of reference standards that are traceable to the National Institute of Standards and Technology which are counted with each set of samples. The counting efficiency is determined by these standards.

Equipment: Liquid Scintillation Counter, Opti-flour liquid scintillation fluid or equivalent, absorbant filter papers (Whatman No. 4 or equivalent), and liquid scintillation vial standards.

Procedure:

1. Prior to arriving at the area prepare smears for each room to be surveyed by numbering an absorbant filter paper with consecutive numbers and placing into a plastic bag with the room number and total number of smears indicated on the white area of the bag.

2. Determine from the diagram of the area to be surveyed, the exact location of the smear sample.

3. Using moderate pressure, wipe approximately 200 cm^2 of surface area with the absorbant filter paper.

4. Place sample within the plastic bag for the room being surveyed. See Additional Information below.

5. Transport sample to Teledyne Brown Engineering.

6. Log in sample in Sample Receipt log.

7. Complete a Liquid Scintillation Sample Receipt Form (IWL-HP-10) with all the requested information.

8. The first sample of every batch of samples is to be a background sample.

9. Place the smear in the bottom of a scintillation vial with the "dirty" side facing up.

10. Add 15 milliliters of prepared scintillation cocktail to each liquid scintillation vial.

11. Secure the cap and number each vial cap with the corresponding Sample ID from the Sample Receipt Form. Shake vigorously.

12. Load vials into the Liquid Scintillation Counter.

13. Allow samples to cool 1 to 2 hours before starting the counting cycle.

14. Enter the appropriate information (Batch #, Customer, etc.) into the printout header and initiate counting cycle per procedure HPP-012, Operation of Packard Model 1900 CA or 1600TR Liquid Scintillation Counter.

15. Analyze data and prepare a report.

16. All samples are to be retained for a minimum of one month in case further evaluation is requested.

17. Liquid scintillation vials are to be disposed by transfer to a licensed facility for incineration.

Safety Items:

1. When dispensing scintillation cocktail, goggles, gloves and lab coats must be worn and the work is to be conducted within a fume hood.

Additional Information:

When a survey is being performed of an area where known contamination is expected to exceed 500 dpm per sample for beta-gamma emitting radionuclides each smear sample should be placed into its own plastic bag to prevent cross-contamination between samples.

Forms Used:

FORM TITLE	ID. NUMBER
Liquid Scintillation Sample Receipt	Form IWL-HP-10

HPP-16 EQUIPMENT AND AREA DECONTAMINATION

Purpose: To clean equipment or areas contaminated with radioactivity to levels suitable for their intended use or release from regulatory control.

Discussion: When working with loose radioactive material, a small quantity may become deposited on surfaces other than those in the designated area. Often, this can be cleaned using moistened towels and a cleaning agent. Remember, even if a surface 'looks clean' there may be contamination present. Only proper monitoring equipment and techniques can detect contamination.

Equipment: Absorbant cloth or paper towel, Radiacwash, Noxon, survey meter, smears, radwaste container, PPE appropriate to the situation, warning signs.

Procedure:

1. Assemble the necessary materials and equipment prior to the start of the decontamination.
2. Restrict access to the area to prevent the spread of contamination.
3. Survey the area with a meter and/or smears to obtain an estimate of the levels of contamination.
4. Don the proper personal protective equipment (PPE) based on the survey results and the Health Physicists' direction.
5. Start in the least contaminated area and work towards the more contaminated area. Make only one pass with the cleaning cloth, then fold it over and use the other side or place it in the contaminated trash bag.
6. Clean using straight, even passes of the cloth. Avoid circular motion, as this will only spread the contamination around.
7. Upon completion of the decontamination, re-survey the area for both fixed and removable radioactivity. Record the results and submit the data to the Health Physicist for approval and authorization to release the area.

Safety Items: Any technician without prior experience in decontamination must be supervised by an experienced individual.

Additional Information:

Ensure that the proper survey meter is used for the radionuclides suspected in the contamination. Refer to appropriate regulatory guidelines for release limits.

Forms Used: None.

030-33700

May 1, 1997

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Sir/Madam:

29-30181-01

Please find enclosed an application to amend our existing radioactive materials license. The package contains a completed NRC Form 313 and an updated Technical Support Document describing the radiation safety program. The check for the license amendment fee is also enclosed. In reviewing the enclosed amendment please note:

1. The amendment is filed in response to a relocation from South Brunswick, NJ, to Cranbury, NJ.

2. We are deleting Cl-36 and Rb-86 from our license and there are no changes to the possession limits for the remaining radionuclides.

3. The scope of our R&D program, as described in our earlier submittal and here again, remains unchanged. Iodinations will not be conducted since iodinated compounds will be obtained from vendors and/or collaborating R&D laboratories.

4. The changes to the Technical Support Document include the following updates:

   a. Section I identifies the new location and address of the Transcell facilities.

   b Section II has been revised since Cl-36 and Rb-86 are being dropped from our license. Note: we are also dropping the use of Na-22, which is being regulated by NJDEPE. This aspect is being addressed separately with the State.

   c. Section III, a change to the organizational chart has been made to reflect a new position title and two resumes have been added for new Senior Research Scientists.

   d. Section IV has been revised to reflect the configuration of the new facility located in Cranbury, NJ. Attachment 2 presents new facility drawings. Table IV-3 has been updated to reflect current and future inventories of radiation detection equipment.

e. A few changes were made in Section V. They include: the risk assessment addressing Rb-86 has been deleted; shifting the exchange schedule of film badges/TLDs to a quarterly cycle, instead of monthly; an action level of 0.06 μCi for thyroid monitoring has been added to reflect NRC guidance; the dosimetry processor has been changed from Landauer to ICN; the evaluation process of sewer releases has been updated to reflect the new facility and new sanitary discharge rates; the requirement for conducting surveys was updated to reflect the NRC criterion of 200 μCi as a threshold for weekly surveys; the removable surface contamination limits were updated to include the NRC criterion 20 dpm/100 cm^2 for I-125; and the portable instrumentation calibration schedule was changed to a yearly schedule, instead of semi-annual.

f. Section VI has been updated to reflect the new sanitary system and the expected waste generation rates and volumes have been revised downward in light of historical data since the license was issued. Section VI also provides a description of the new radioactive waste storage area.

g. The attachments section contains new facility and systems drawings.

5. As before, a financial assurance and funding plan is not required given the current possession limits for radionuclides with half-lives greater than 120 days. The sum of the ratios is ≤ 1 for 10^3 times the quantities given in Appendix B of 10 CFR, Part 30. A spreadsheet presents the results of the calculation using the methodology given in 10 CFR, Part 30.35.

6. We intend to transfer the R&D program relying on radioactive materials in one step, i.e., R&D activities taking place at the South Brunswick facility will be totally terminated and then moved to the new facility once this amendment has been approved. With this approach, radioactive materials will be used only at one facility at the time.

7. We intend to decontaminate the South Brunswick facility after all R&D activities have been transferred to the Cranbury, NJ, location. We will address the survey, decontamination, and release of the South Brunswick facility in a separate licensing action, to be addressed in the near future. Accordingly, we anticipate to keep the license for the South Brunswick facility only for custodial care and monitoring of residual levels of radioactivity until the facility is released for unrestricted use by the NRC. In addressing these issues, it is our intention to meet with the NRC staff in the near future to identify specific requirements and define a schedule for the timely release of the South Brunswick facility.

In closing, we trust that you will find the enclosed application package satisfactory and look forward to obtaining an amended license in the near future. Should you have any questions, please do not hesitate to contact me at (908) 940-6925. Your timely cooperation in this matter is greatly appreciated.

Sincerely

Clifford B. Longley, RSO

Enclosures: Form 313, Technical Support Document, Check

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.

030-33700

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)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 29-30181-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Transcell Technologies, Inc.
2000 Cornwall Road
Monmouth Junction, NJ 08852

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

8 Cedar Brook Drive
Cranbury, NJ 08512

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mr. Clifford Longley, RSO

TELEPHONE NUMBER

908-940-6925

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.

ATTACHED

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

ATTACHED

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

ATTACHED

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

ATTACHED

9. FACILITIES AND EQUIPMENT.

Attached

10. RADIATION SAFETY PROGRAM.

ATTACHED

11. WASTE MANAGEMENT.

Attached

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY 3M

AMOUNT ENCLOSED $640.00

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
Helena R. Axelrod	Helena Axelrod, Ph.D.,	Director Biological Research	4/30/97

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

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

MAY - 1 1997

OFFICIAL RECORD COPY ML 10

124531

TECHNICAL SUPPORT DOCUMENT
RADIOACTIVE MATERIALS LICENSE AMENDMENT

TRANSCELL TECHNOLOGIES, INC.

located at

8 Cedar Brook Drive
Cranbury, NJ 08512

prepared by

Jean-Claude F. Dehmel, CHP
S. Cohen & Associates, Inc.
McLean, VA 22101

for

Clifford Longley
Radiation Safety Officer

April 15, 1997

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List of Figures

List of Tables

List of Attachments

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TECHNICAL SUPPORT DOCUMENT
TRANSCELL TECHNOLOGIES, INC.
RADIOACTIVE MATERIALS LICENSE APPLICATION

I. INTRODUCTION

This technical document supports an amendment to Transcell Technologies, Inc. (Transcell) current license to possess and use radioactive materials at the following new facility:

8 Cedar Brook Drive
Cranbury, NJ 08512

The NRC License No. is 29-30181-01 and the Docket No. is 030-33700.

Figure I-1 presents the location of the facility within the Cranbury area and Figure I-2 presents the site plan. The office and laboratory floor spaces are leased from Cedar Brook Corporate Center, LP, Cranbury, NJ.

The application amendment has been prepared in response to Regulatory Guide 10.7 (Guide for the Preparation of Applications for Licenses for Laboratories and industrial Uses of Small Quantities of Byproduct Material, Rev. 1, 8/1979 and errata of 7/1984). The application has been filed using NRC Form 313, Application for Materials License.

The technical support document references the items required by NRC Form 313. For example:

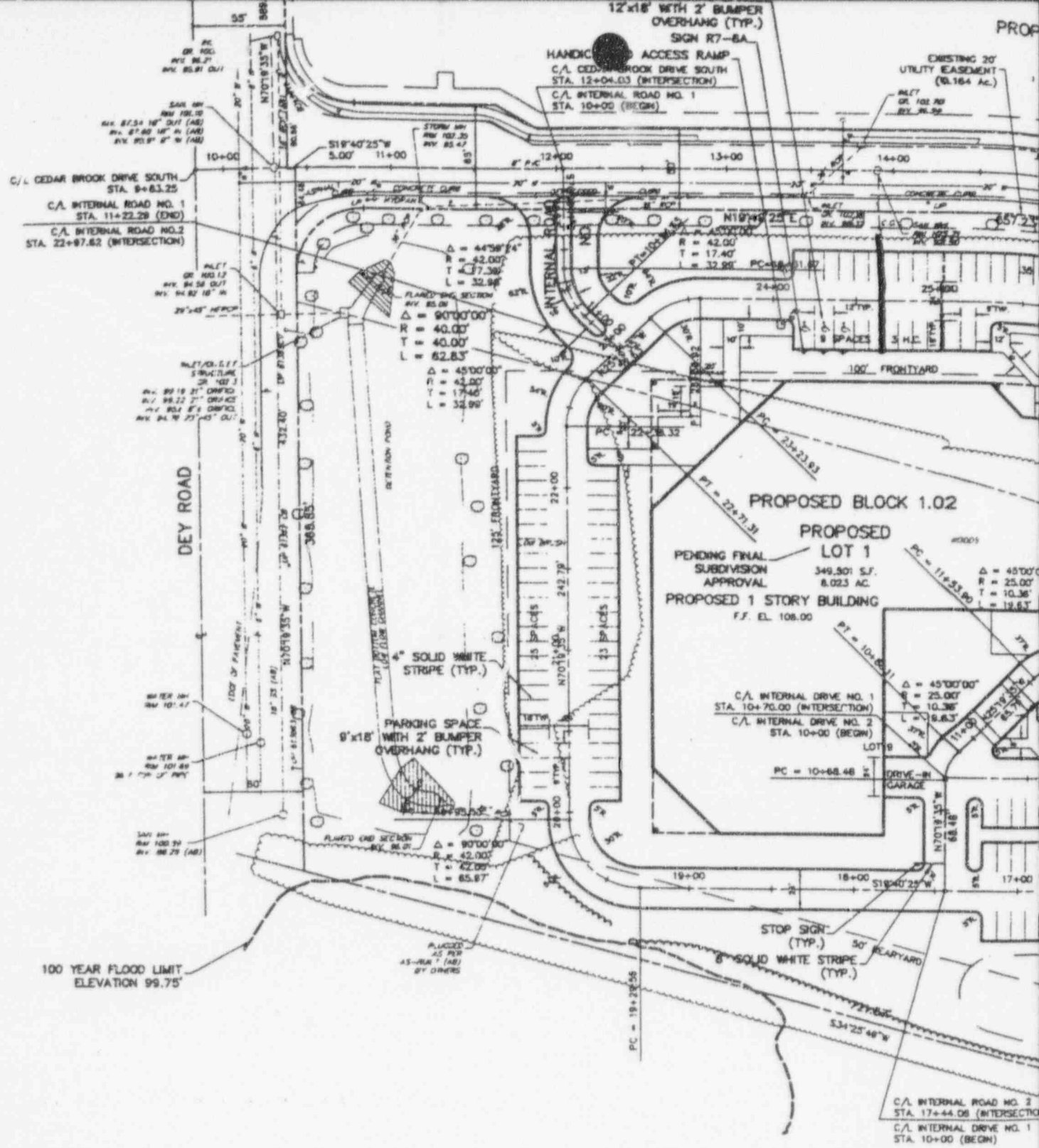
A. Radioactive Materials (Item 5)

The item referenced as "Item 5" refers to the corresponding entry in NRC Form 313.

A completed NJDEPE's Radioactive Materials Registration form has been submitted separately.

Mr. Clifford Longley will perform the functions of the Radiation Safety Officer. Currently, the RSO's office is located at the Monmouth Junction facility. Mr. Clifford Longley is reachable at (908) 940-6925.

Figure I-1 Transcell Facility Location in Cranbury, NJ.

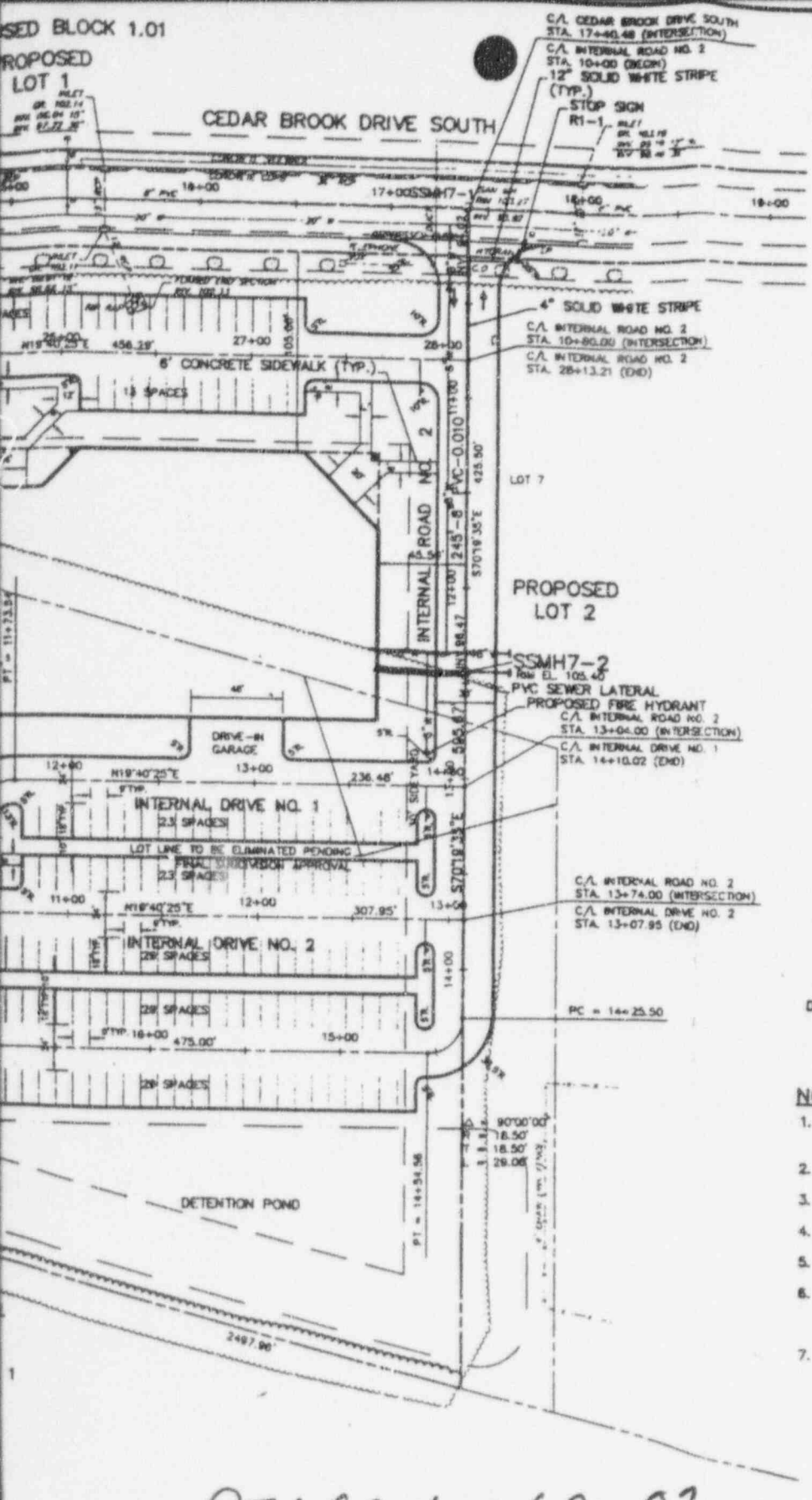


NO.	DATE	DESCRIPTION	CHKD.	APPRD.
1	6/96	PLANNING BOARD COMMENTS		

REVISIONS

DESIGNED:
DRAWN: R.L.
OFFICE CHECKED: D.G.D.

LICENSE NO. 14263
NEW JERSEY PROFESSIONAL ENGINEER
JOHN L. BUZZI
7/3/96
DATE



ZONING COMPLIANCE CHART

(ALLOWED BASED ON RO/LI ZONE—PLANNED INDUSTRIAL PARK)

DESCRIPTION	ALLOWED	PROPOSED
LOT AREA	5.00 Ac.	8.023 Ac. (349,501 S.F.)
FRONTAGE	250'	897.23'
FRONT YARD	100/125'	100/125'
SIDE YARD	30'	30'
REAR YARD	50'	50'
F.A.R.	0.30	0.215
BUILDING AREA	104,804 S.F.	75,200 S.F.
BUILDING HEIGHT	65' MAX.	26'±
TOTAL COVERAGE	55%	54%
PARKING SPACES	241	238+3 H.C.
PARKING SPACES IN FRONT YARD SETBACK	(60)25%	60(25%)
PARKING SPACES IN SIDE YARD	(0)0%	48(20%)
PARKING SPACES IN REAR YARD	(180)75%	133(55%)

DESIGN WAIVER REQUIRED - DRIVEWAY SETBACK

NOTES:

1. PROPOSED USE - OFFICE(15,000 S.F.)/RESEARCH(45,300 S.F.)/ WAREHOUSE(14,900 S.F.).
2. PARKING FOR OFFICE REQUIRES 1 SPACE PER 250 S.F.
3. PARKING FOR RESEARCH REQUIRES 1 SPACE PER 300 S.F.
4. PARKING FOR WAREHOUSE REQUIRES 1 SPACE PER 500 S.F.
5. SEE ARCHITECTURAL PLANS FOR BUILDING FLOOR PLAN DETAILS.
6. DEPRESSED CURBS AND HANDICAP RAMPS SHALL BE CONSTRUCTED AT ALL DRIVEWAY AND ROADWAY CROSSINGS WHERE SIDEWALKS ARE SHOWN.
7. ADDITIONAL REGULATORY APPROVALS REQUIRED INCLUDE:
   MIDDLESEX COUNTY PLANNING BOARD
   FREEHOLD SOIL CONSERVATION DISTRICT

I-3

9706240062-02

Figure I-2 Site Plan

124531

KUPPER ASSOCIATES 15 STELTON ROAD, PISCATAWAY, N.J. 08854	APPLICANT/OWNER: CEDAR BROOK CORPORATE CENTER, L.P. 1000 EAST PARK BOULEVARD CRANBURY, N.J 08512	PRELIMINARY/FINAL SITE PLAN BLOCK 1.02 LOT 1 SITE PLAN TOWNSHIP OF CRANBURY TAX MAP SHEET #1 COUNTY OF MIDDLESEX NEW JERSEY SCALE: 1"=40' DATE: 6/96	3 of 13 175-012 CONTRACT NO.

II. DESCRIPTION OF RESEARCH ACTIVITIES (Item 9)

The Transcell Technologies, Inc. (Transcell) facility will be conducting a wide variety of activities to support the research and development of new drug delivery systems. In support of such activities, several radionuclides will be used in a limited number of experiments per month. These experiments will primarily involve two broad categories of research activities. The first category includes research activities which will be conducted most frequently using, for example, H-3 and C-14. The second category includes infrequent research activities using P-32, P-33, S-35, Cr-51, I-125, and I-131. Iodinations will not be conducted since iodinated compounds will be obtained from vendors and/or collaborating R&D laboratories. Research activities will not involve:

1) human applications or use,
2) animal applications or use,
3) introduction of materials in food, beverages, cosmetics, drugs, or other products designed for ingestion or inhalation,
4) commercial production or distribution of by-product materials,
5) environmental tracer studies, and
6) materials irradiation.

The description and requirements under which such research activities will be conducted are discussed separately below.

II.A. Radioactive Materials (Item 5)

Table II-1 presents the radionuclides, chemical and physical form, maximum amounts which will be possessed at any one time. The research activities noted below include the use of solutions and sealed or plated sources for the purpose of calibrating and checking bench top and portable radiation detection equipment.

Finally, the possession limits also include the anticipated amount of activity that will be contained in stored radioactive waste. For short-lived radionuclides, radioactive waste will be stored onsite for decay and long-lived radionuclides will be held until a low-level waste disposal facility becomes operational in the Northeast Compact or shipped to an approved LLW disposal facility that will accept waste from the Compact. Transcell will also make use of offsite waste treatment services as part of its overall waste management program. Section VI provides specific details of the waste management program.

Table II-1 NRC RADIONUCLIDES AND POSSESSION LIMITS

Byproduct, Source, and/or Special Nuclear Material	Chemical and/or Physical Form	Maximum Possession Limit at Any One Time
A. H-3	A. Any	A. 100 millicuries
B. C-14	B. Any	B. 75 millicuries
C. P-32	C. Any	C. 50 millicuries
D. P-33	D. Any	D. 50 millicuries
E. S-35	E. Any	E. 50 millicuries
F. Cr-51	F. Any	F. [illegible] millicuries
G. I-125	I. Any	I. [illegible] millicuries
H. I-131	J. Any	J. 50 millicuries

Authorized Use:

A - H. Research and development as defined in 10 CFR, Part 30.4. Also includes waste, sources, and calibration standards for use in radiation protection applications.

II.B. Purposes for Which Materials Will be Used (Item 6)

II.B.1 Routine Research Activities

Routine research activities involve about ten experiments per month using such radionuclides as H-3, C-14, P-32, Cr-51, and I-125. These experiments include, but are not limited to:

o Membrane Transport

Radiolabeled drugs or other radioisotope solutions will be introduced onto synthetic membranes or tissues (in-vitro).

o Synthesis

Radiolabeled compounds are reacted with other compounds to form a new radiolabeled compound. The material formed is separated via different physical or chemical techniques, stored and analyzed.

- Cytotoxic Assays

  Radiolabeled compounds will be mixed with biological materials to assess the cytotoxic effects of different compounds.

- Metabolic Labeling

  Radiolabeled compounds will be administered into tissues (in vitro) via a variety of methods for the purpose of studying DNA kinetics.

- Iodinated Probes

  Radioiodinated compounds will be obtained from vendors and collaborating laboratories and administered into tissues (in vitro) via a variety of methods for the purpose of studying compound kinetics.

The various chemical and physical operations will typically include filtration, centrifugation, electrophoresis, GC/MS, solvent extraction, evaporation, freezing, heating, incubation, homogenization, high pressure liquid chromatography, dialysis, liquid and gas chromatography, and thermal oxidation. The various handling methods include injection, pipetting, and permeation.

The measurement techniques will typically include liquid scintillation detection (LSC), HPLC, gamma counter, and auto-radiography.

Wastes generated include LSC fluids, organic solvents, paper, cloth, miscellaneous labware, gloves, labcoats, and tissues.

Table II-2 presents a summary of the radionuclides, approximate number of experiments, and total monthly activity throughput.

II.B.2 Infrequent Research Activities

Infrequent research activities are those that are not conducted routinely, although in many respects the methods used will not differ markedly from those noted above. This category, however, is comprised primarily of research activities:

- which include radionuclides that may necessitate special radiological considerations, or

- for which a radiological evaluation has never been performed before, or

Table II-2 SUMMARY OF MONTHLY EXPERIMENTS AND NUCLIDE USES[a]

Nuclide	Approximate No. of Experiments/year & Activity/Experiment		Estimated Total Activity per Month (mCi)
H-3	100	35 uCi	0.29
C-14	500	5 uCi	0.21
P-32	12	1,000 uCi	1.00
P-33	4	50 uCi	0.02
S-35	2	1,000 uCi	0.20
Cr-51	12	1,000 uCi	1.00
I-125	12	200 uCi	0.20
I-131	2	200 uCi	0.03

(a) See text for details.

- for which the use of experimentation equipment and methods which have never been assessed before, and
- for which the research staff has had no previous experience.

Under these conditions, each type of experiment will be jointly evaluated by the research staff and the RSO or his/her designee.

The necessary requirements, guidelines, and radiological controls will thus be established.

II.B.3 Long-Term Radioactive Waste Storage

Since radioactive waste may be stored for a protracted time period, a low-level waste management program has been instituted to:

1) minimize waste generation rates,
2) segregate various waste forms at the point of generation,
3) store waste with short-lived radionuclides separately for decay-in-storage,
4) appropriately package all waste destined for long-term storage, and
5) monitor the long-term stability of all stored waste.

Dry solid waste may also be shipped out, as needed, for processing (e.g., compaction, supercompaction, etc.) to commercial facilities and returned to Transcell for storage.

II.B.4 Research Protocols and Requirements

In order to safely conduct all research activities, a research protocol, evaluation, and approval process has been instituted. Under this process, before any type of experiment is allowed to proceed, each phase of the research activities will be evaluated for radiological considerations. Such considerations will include the following:

- Overview of experiment method, equipment, frequency, physical processes, handling, measurement techniques, and waste generation, etc.

- Radionuclide(s), activity per test, activity throughput, activity recovery, initial and final forms of radiolabeled compounds, volatility, waste specific activity, etc.

- Radiological considerations such as potential for inhalation or ingestion; personal or equipment contamination; airborne and liquid effluent releases; exposure rates and doses to fingers, hands or whole body; need for bioassay; use of ventilated enclosure; special dosimetry; ALARA considerations; additional radiological controls such as surveys, posting, material accountability, protective equipment and clothing; etc.

- Need to conduct "cold-runs, using established research procedures, to conduct preliminary tests to assess potential radiological conditions such as fate of radionuclide, need for special equipment and prototype testing, etc.

- Personnel training including research staff, technicians, RSO staff, materials management, janitors, security, and maintenance staff whenever access is required during off-hours, special instructions for equipment operations and/or shutdown of ventilation exhaust fans, etc.

- Waste generation including interim storage and packaging; segregation of liquids; mixed wastes, waste classification, solid wastes, and labeling; posting, pickup requirements and instruction to waste broker and processors; methods to minimize waste generation; disposition of biological tissues; releases to sewer; etc.

- Impacts on long-term waste storage needs address waste streams and forms as to their compatibility, stability, containerization, interim monitoring, and shipping and disposal requirements.

- Radioactive material procurement arrangements for receipt, inspection, delivery to end-user, inter departmental transfers, dispensing, handling, monitoring, logging, inventory, ultimate disposition in air, water, solid or liquid waste, etc.

- Needs and requirements for specific radiological surveys, hold points, equipment tests and checks, verification of filter collection efficiency, effluent release and/or dilution rates, interferences with other facility operations or research activities, administrative approvals for industrial H&S, ALARA goals, offsite releases, QA/QC, etc.

- Emergency and contingency plans including first aid, emergency kits, emergency shower and eye wash, radiological spill kit, access to outside support services, such as hospital, fire police, consultants, etc.

These requirements will be established once for each type of research activity. Unless it is shown that there is a need to modify an experiment out of the pre-established set of controls, all experiments will be conducted under the umbrella of the routine radiological surveillance program.

If the research activities are modified such that there could be an increase in occupational exposures beyond ALARA goals or result in new radiological conditions (e.g., other radionuclides, unusual waste forms or potential stack releases), the deficient conditions will be corrected and additional controls will be instated to correct the situation.

Whenever such situations occur, a review and evaluation will be jointly conducted with representatives of the responsible research division(s) and RSO or his/her designee. The outcome of such reviews and evaluations will identify the following:

- Causes of the problem, e.g., equipment failure, inadequate personnel training, failure to follow procedures, etc.

- Consequence to personnel safety, including both radiological and non-radiological considerations. The radiological impacts will be reviewed against established ALARA objectives.

- Impact to facility or environment including spill, contamination, airborne or sewer releases, etc.

- Proposed recommendations to remedy deficient conditions including added administrative controls, purchase and installation of new equipment, modification of research activi ies/protocol, submission of a new protocol package, need for additional training, greater staffing, etc.

The summary of each critique will be maintained in the RSO's permanent files. The findings and recommendations, depending upon the severity of the event, will also be placed on the agenda of the next Radiation Safety Committee meeting. For incidents involving personnel exposures, contamination, inhalation, etc., records will be retained indefinitely or until the NRC authorizes their disposition.

II.B.5 Decommissioning Funding Plan Exemption

A financial assurance and funding plan is not required given the possession limits presented in Table II-1 for radionuclides with half-lives greater than 120 days. The sum of the ratios is ≤ 1 for 10^3 times the quantities given in Appendix B to 10 CFR, Part 30.35. The attached spreadsheet presents the results of the calculations using the methodology given in 10 CFR, Part 30.35.

10 CFR PART 30.35 DECOMMISSIONING FUNDING CRITERIA EVALUATION

Half-Lif (days)	License Limits (mCi)	App. B (mCi)	-- Part 30 Appendix B Limits (mCi) and Ratios x10^3	Ratio	x10^4	Ratio	x10^5	Ratio
4.48E+03	1.00E+02	1.00E+00	1.00E+03	1.00E-01	1.00E+04	1.00E-02	1.00E+05	1.00E-03
2.09E+06	7.50E+01	1.00E-01	1.00E+02	7.50E-01	1.00E+03	7.50E-02	1.00E+04	7.50E-03
	175.00			0.8500		0.0850		0.0085

III. ADMINISTRATIVE MANAGEMENT AND RESPONSIBILITIES (Item 10)

The Transcell Technologies, Inc. (Transcell) organizational chart describing the administrative management and responsibilities is shown in Figure III-1. The relationship between management, research staff, Radiation Safety Officer (RSO), and the Radiation Safety Committee are described below.

III.A. MANAGEMENT COMMITMENT

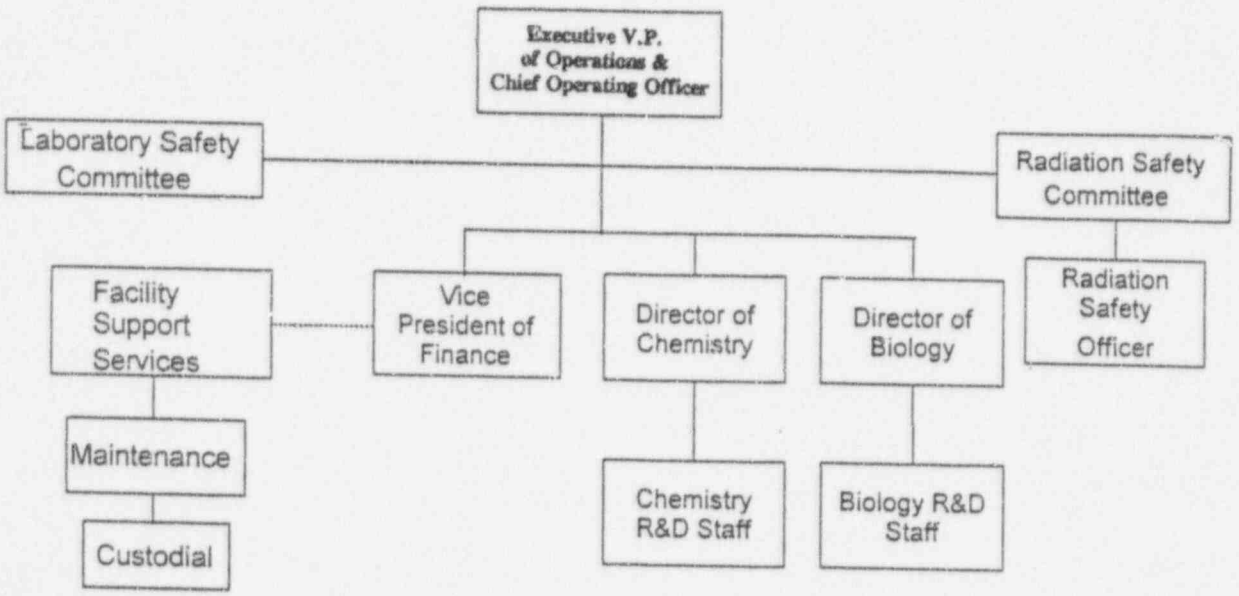
Transcell's management is committed to implement and manage the radiation safety program in accordance with all Nuclear Regulatory Commission regulations and requirements. In addition, the ALARA program's goals and objectives are to minimize all exposures, provide clearly defined radiation protection responsibilities, and provide an environment in which the radiation protection staff can do its job properly. The following elements describe the corporate commitment and objectives of the ALARA program.

- Facility personnel will be made aware of management's commitment to keep occupational and all other exposures as low as is reasonably achievable (ALARA). The commitment will appear in company practice manuals, procedures, and in instructions posted or issued to personnel.

- Management will periodically perform formal audits to assess the overall effectiveness of the radiation safety program. This will include reviewing operating procedures, past exposure records, conducting lab inspections, and consulting with the RSO and outside consultants. As a minimum, management will ensure that all operating procedures are reviewed, that working conditions of personnel receiving the highest exposures are evaluated, and that the radiation protection staff has access to outside technical consultants or expertise.

- Management will ensure that there is a well-supervised radiation protection capability with well-defined responsibilities. The qualifications of the RSO will be commensurate with the licensing requirements, scope of R&D activities, and range of potential or anticipated events that may be encountered in this type of research environment.

Figure III-1 Transcell Technologies, Inc. Organizational Chart



- Management will see that the research staff receives sufficient training so that radiation workers understand how radiation protection relates to his/her job. He/she will have adequate opportunities to discuss any radiation safety issues with the RSO. Proper training will be provided to ensure that all workers have a thorough understanding of their radiation protection responsibilities.

- The RSO or his/her designee will be given the authority to enforce the safe conduct of all research activities. This authority will include the administrative means to stop and prevent unsafe practices and to promptly communicate such concerns to the appropriate level of management. All radiation safety or research procedures will be reviewed and approved by the RSO or designated representative. This authority will be defined in company manuals and procedures.

- Modifications to lab operating and maintenance procedures and to equipment and facilities will be made where they will substantially reduce exposures at a justifiable cost. Management will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented wherever practicable and cost-effective.

- It is the responsibility of the RSO to conduct surveillance activities and investigations to ensure that occupational exposures are as well below the specified limits as is reasonably achievable. Additionally, the RSO or designated representative will be vigilant in identifying new and more effective methods to conduct research activities, while minimizing occupational exposures.

- The RSO and his/her designee will be familiar with the origins of radiation exposures at the facility. They will know these by locations, operations, and by types of research activities. Once research protocol authorizations have been issued, exposures will be reviewed and monitored for the purpose of identifying trends and degrading conditions. The RSO will also be familiar with operations and R&D activities that have the potential for higher exposures and releases to the environment.

- The RSO will identify methods and procedures with which to reduce exposures. When unusual exposures have occurred, the RSO will direct an investigation of the circumstances of such exposures to determine the causes and take steps to reduce the likelihood of future occurrences. In such instances, the RSO will demonstrate that such investigations have been carried out, that conclusions were reached as a result of the investigation, and that corrective actions have been identified and implemented.

- The RSO will periodically review operating procedures that may affect radiation safety and survey facility operations to identify situations in which exposures can be reduced. Required changes will be promptly implemented. The RSO will be receptive to employee suggestions relating to radiation protection issues.

- Necessary equipment and supplies for all radiation protection activities will be provided to the RSO and research staff. The RSO will be responsible for ensuring that proper equipment and supplies are available, are maintained in good working order, and are used properly.

The RSO is delegated the responsibility for compliance with Federal, State, and local requirements regarding radiation safety, LLW waste disposal, and sewer and gaseous effluent releases. Transcell's management will provide all corporate resources needed to effectively manage and implement the radiation safety program.

III.B. RADIATION SAFETY OFFICER

The Radiation Safety officer (RSO) will be a full time Transcell employee who will oversee research activities at all facilities required to maintain the by-product materials license issued by NRC. Minimum qualifications for the RSO include a four-year college-level education with emphasis in the natural and physical sciences, and two years of experience in radiation protection involving similar isotopes, quantities, and forms of radioactive materials to those that will be used under this license. Attachment 1 presents the resume of the RSO.

The Radiation Safety Officer has the overall responsibility for developing, implementing, and maintaining the radiation protection program as described in the license application/amendment in accordance with all applicable regulations and license conditions.

In meeting these responsibilities, the RSO will fulfill the following three primary roles:

1. Conduct/oversee the routine activities required by the radiation protection program.

2. Interact with Transcell's management as the focal point for all radiation-related issues.

3. Serve as the primary contact for State or Federal regulatory agencies in the course of correspondence or inspection.

Each of these roles is more clearly defined in the following subsections.

III.B.1 Radiation Safety Protection Program Activities

In implementing the radiation safety protection program, the RSO will be responsible for ensuring compliance with the operational Radiation Safety Program as described in Section V of this document as well as meeting the applicable regulations and license conditions. Because of the limited number of experiments conducted, the number of employees involved with those applications, the RSO or designated representative may selectively oversee some of the tasks as they are performed. The major duties of the RSO are listed below:

1. General oversight of all activities involving radioactive materials including, but not limited to, the various components of the radiation protection program.

2. Actively identify conditions and issues involving the possession and use of radioactive materials that may affect the health and safety of Transcell employees, visitors, or the general public. Identify conditions that may affect Transcell's ability to comply with any of the license conditions and NRC regulations.

3. Ensure that all radiation protection program components are effective in maintaining exposures to radioactive materials at levels that are as low as is reasonably achievable (ALARA).

4. Review and approve all requests and orders for radioactive materials.

5. Manage and coordinate the receipt and handling of radioactive materials.

6. Maintain an inventory of all radionuclides at all R&D labs. The inventory system will track radioactive materials from receipt, storage, to disposal, documenting possession or control, locations of radioactive materials, and methods and dates of disposal. The RSO will use the inventory system to ensure that possession limits are not exceeded.

7. Ensure that by-product materials are properly stored and secured to minimize inadvertent exposures to employees, visitors or the general public, and to avoid unauthorized handling or removal.

8. Conduct oversight activities of the radioactive waste storage and disposal program and approve disposal and/or treatment methods for specific waste streams. The RSO will evaluate packaging and shipping methods for any radioactive materials.

9. Oversee and review the maintenance and calibration radiation detection instruments according to procedures, protocols, and schedules.

10. Arrange the conduct of airflow tests for lab hoods and ventilated enclosures and, when required, monitor HEPA and charcoal filtration systems collection efficiencies.

11. Supervise the cleanup and decontamination activities in the event of D&D, accidents, or contamination incidents.

12. Conducting leak tests of all sealed sources, when required.

13. Issue and retrieve personnel radiation dosimetry devices and arrange for their processing. This activity includes reviewing exposure results and notifying individuals whenever exposures are reaching or exceeding administrative and/or regulatory limits. The RSO will investigate such events and propose the necessary corrective action.

14. Conduct initial and periodic re-qualification training sessions for employees requiring the use or handling of radioactive materials, or access into radiologically controlled areas.

15. Maintain corporate records that document the results of activities stipulated by regulatory requirements and license conditions. Records will document the following activities:

- Employee monitoring results including bioassay, external dosimetry, and contamination monitoring.
- Environmental monitoring data from measurements of radionuclide concentrations in air or sewerage.
- Employee initial and re-qualification training.
- Routine work area monitoring including external exposure rate and contamination surveys, and air sampling.
- Receipt, storage, inventories, and disposal of all radionuclides, including waste.
- Maintenance and calibration of all radiation detection instrumentation and survey meters.
- Leak tests of all sealed sources, when used.
- Airflow tests of hoods and/or any other types of ventilated enclosures, when used.

III.B.2 Interaction with Management

The RSO will have direct access to management as shown in the organizational chart (Figure III-1). The interaction between the RSO and management will serve two purposes.

a) First, the RSO's function is independent of the research staff, minimizing potential interference with the radiation protection program. The RSO has the authority to terminate any work utilizing radioactive materials, and to delay any planned activities if radiation protection issues are not adequately addressed.

b) Second, the interaction of the RSO with management will ensure that management is informed of the status of the radiation protection program, and that it is involved in its development.

III.B.3 Interaction with Regulatory Agencies

The RSO will serve as the corporate focus with representatives of State or Federal regulatory agencies. Correspondence regarding by-product or accelerator-produced materials licenses will be directed and handled by the RSO. The RSO will review all correspondence, request clarification as necessary to determine a course of action, and respond to all regulatory agencies.

The RSO will participate in inspections and audits conducted by regulatory agencies, and will address issues that result from inspections. Responses to inspection findings will be developed by the RSO and finalized by the RSO before submittal to the inspecting agency.

III.C. RESEARCH STAFF

The research staff will be responsible for ensuring that all research activities involving radioactive materials are conducted in accordance with established regulatory requirements and administrative procedures and programs. The research staff will assign for its division a Senior Research Scientist (SRS) and Radiation Safety Supervisor (RSS) responsible for all radioactive material uses. The selection of such individuals will be approved by the RSO and Radiation Safety Committee.

The background, training, and education of the SRS will be commensurate with the assigned uses of radioactive materials and associated radiation protection responsibilities. Each research division will ensure that the assigned SRS are provided with the time and material resources with which to conduct these activities. The SRS will be free to communicate with the RSO or designated representatives on any radiation safety issues.

III.C.1 Senior Research Scientist

A Senior Research Scientist (SRS) with the appropriate background, training, and experience will be assigned to each research division or lab area. The SRS will be responsible for managing and overall supervision of all R&D activities involving the use of radioactive materials. The SRS will develop the necessary research activity protocols and procedures. The SRS and RSO will jointly develop and establish the necessary radiological controls commensurate with each type of research activity. The SRS also provides the RSO necessary information and technical data with which to evaluate the potential radiological hazards. Once the necessary radiological measures have been established, it will be the responsibility of the SRS to ensure

that such requirements are properly implemented. The SRS may delegate some of these responsibilities to qualified R&D staff members at his/her discretion (e.g., Radiation Safety Supervisor). Attachment 1 presents the resumes of the designated SRS.

III.C.2 Radiation Safety Supervisor

A Radiation Safety Supervisor (RSS) is appointed by the SRS, with RSO approval, for each lab area in which there are sources of ionizing radiation. The RSS is responsible for conducting day-to-day radiation protection functions. The RSS is a member of the research division which uses radioactive materials. It is the general duty of the RSS to work with supervisors, researchers, and technicians to assure that radioactive materials are used in a safe manner and managed in response to license conditions and regulatory requirements. Specific duties include, at a minimum, the following:

- Being familiar with all operating procedures, use of protective and warning devices, and protection principles (i.e., time, distance, shielding, and ventilation) applicable for the safe handling of radioactive materials under his/her jurisdiction.

- Preparing and identifying all necessary information and data needs with which to fulfill the requirements of research protocols.

- Insuring that all areas or locations where radioactive materials or radiation sources are stored or used are properly posted and maintained.

- Notifying the Radiation Safety Officer or his/her designee before making any changes or alterations in the use of radioactive materials including physical alterations or changes in location or use.

- Notifying the RSO when maintenance or other non-routine procedures are used which could increase radiation exposures, contamination levels, or effluent releases.

- Distributing and collecting film badges and otherwise serving as liaison between the RSO and Research and Development staff in regard to routine radiation protection functions.

- Follow-up on recommendations regarding the implementation of new or modified radiation safety procedures issued by the RSO and/or regulatory agency auditors.

- Checking, at specified intervals, that all surveys, checks, leak tests, etc., required for radiation protection purposes are completed in accordance with schedules and requirements.

- Where unsealed radioactive materials are used, inventory and disposal forms will be prepared and sent to the RSO.

- Becoming familiar with pertinent local regulations, administrative procedures, ALARA objectives, and NRC license conditions.

III.D. RADIATION SAFETY COMMITTEE

The Transcell Radiation Safety Committee (RSC) is established to ensure that the use of radioactive materials is performed in a safe and proper manner in compliance with company procedures, U.S. Nuclear Regulatory Commission (NRC) regulations and other requirements with the goal of protecting the health and safety of employees, visitors, members of the public, and the environment. Attachment 1 presents the resumes of the designated RSC members.

III.D.1 Responsibilities

The RSC is responsible for ensuring compliance and overseeing the use of all radioactive materials. Specifically, the RSC will:

- Review and approve of all protocol applications involving the use of radioactive materials. The review encompasses:

  - adequacy of facilities and equipment.
  - adequacy of training and experience of users.
  - adequacy of handling procedures.
  - adequacy of emergency procedures.

- Approve training and knowledge criteria of radioactive materials users. The training and knowledge must include:

  - storage, transfer, or use of radioactive materials in their areas.
  - health protection associated with radioactive materials exposures.
  - precautions and procedures to minimize exposures.
  - purpose and functions of protective devices.
  - prompt reporting of potential exposure conditions.

- incident investigation for unusual occurrences.
- radiation exposure reports workers may request.

o Approve ALARA limits for personnel exposure wherever Transcell may set levels below Federal and State limits.

o Ensure that all incidents of personnel exposures exceeding ALARA levels or Transcell established limits are thoroughly investigated.

o Approve procedures used to control and maintain inventory, procure radioactive materials, set individual possession limits, set total possession limits, internal transfer radioactive materials, and transfers to other licensees.

o Record the results of safety evaluations of the proposed uses prior to use of byproduct materials.

o Establish methods to maintain records of the RSC's proceedings and RSO evaluations of protocols for the use of radioactive materials.

o Review the radioactive practice performance annually, including a review of the records required to be maintained.

III.D.2 RSC Organization

The RSC will be composed of a Chairperson, Secretary, and two other Transcell staff members. The Chaiperson will be the facility Radiation Safety Officer (RSO). The other members will be composed of members from the Biology, Chemistry, and representatives from the facility maintenance department, when needed. Outside consultants or experts may be called upon by the RSC to address specific issues, as needed. The assigned R&D personnel will be representative of all the major user groups of radioactive materials. The term of the Chairperson is a permanent appointment with the function of the RSO. The research representatives will serve three-year terms. To ensure that at least two of the research representatives are experienced committee members, the terms of the current members will be staggered over a four-year period.

The RSC will meet at least once a quarter. Meetings may be scheduled on a more frequent basis, if warranted.

The Secretary will be responsible for sending out an agenda prior to each meeting and taking minutes. The minutes will be distributed to members for comments and revisions. At the

beginning of each meeting, the minutes from the previous meeting will reviewed and approved.

A quorum with full decision making authority will be composed of three members, two of which must be the Chairperson and Secretary.

Any decisions made by the RSC may be endorsed by all members present. If any RSC member has a question or reservation, it must be resolved before a decision is rendered.

IV. TRANSCELL FACILITIES AND EQUIPMENT (Item 9)

IV.A Laboratory Facility

Research and development activities will be conducted at the Transcell facility located at 8 Cedar Brook Drive, Cranbury, NJ, which is near the intersection of Dey Road and Route 130 (see Section I, Figures I-1 and I-2). A general facility layout is presented in Attachment 2-1. The office and laboratory floor spaces are leased from Cedar Brook Corporate Center, LP. Currently, the facility occupies about 32,000 ft^2. The balance of the building's floor space, about 43,000 ft^2, is being rented to other tenants and may be used by Transcell to accommodate future expansion needs. The floor space leased by Transcell will be under its full administrative control and physically separated from the other tenants.

The leased laboratory and office floor space is located in a one-story L-shaped building, with about 12,000 ft^2 of laboratory space situated in a central core (see Attachment 2-2). Of this total, 8 areas will be dedicated for the use or storage of radioactive materials. The Lab Room No. are 169, 170, 172, 173, 174, 175, 162, and 156. Of these labs, Room 170 (the RSO's Lab) will be used as the central receiving and inspection point for all incoming radioactive materials. Room 156 is dedicated for the storage of radioactive waste.

Depending upon R&D needs, the above identified labs will be used for other types of activities that do not necessarily require radioactive materials. In some instances, R&D activities may involve the use of limited amounts of radioactive materials on an infrequent basis. In such instances, the RSO will designate specific work areas (e.g., labs, hoods, and bench tops), specify the maximum amounts of radioactive materials to be used, and define radiation protection measures and monitoring requirements.

IV.A.1 General and Common Features

Several different types of laboratories will be used to conduct the anticipated range of research activities. Typical laboratories are equipped with the necessary equipment such as bench tops, hoods, cabinets, sinks, and necessary services (water, air, gases, vacuum, exhaust and supply ventilation, elephant trunk connections, electricity, communications, etc.). In addition, each lab contains a broad range of research equipment and instrumentation. Typical laboratory floor space is about 635 ft^2 for a typical full module and about half of that for the smaller labs (See Attachment 2-3). All floors are

finished with tiles and walls are painted with industrial enamel paints.
Each lab is provided with an emergency eye-wash. Safety shower stations are located in service corridors running between each row of lab modules. All full size laboratories have at least two exits leading into hallways or service corridors. All other labs have single entrance and exit doors.

IV.A.2 Dedicated Laboratory Space

Table IV-1 lists the laboratories and areas that are currently designated as radiologically controlled areas. The labs where most of the research work will be conducted are located in the central core of the leased floor space. Other labs and areas will be brought into the control of the radiation protection program as they are needed. These labs and areas will be evaluated by the RSO and the necessary radiological controls, such as ventilation, effluent monitoring, posting, radiation surveys, etc., will be established commensurate with the intended research activities. Routine research activities will involve about fifty experiments per month using such nuclides as H-3 and C-14, while infrequent research activities will involve P-32, P-33, Cr-51, S-35, I-125, and I-131. The RSO will use Lab No. 170 to support all related radiation protection program activities, sample analyses, dispensing, assays, etc.

Radioactive waste will be stored in the Radwaste Storage Room (No. 156), located along the East wall near (about 50 ft) the shipping and receiving dock. Transcell is authorized to store hazardous waste under EPA waste generator ID No. NJD 986650216.

IV.A.3 Ventilation Exhaust System

The facility's ventilation system is serviced by two dedicated exhaust fans. The hoods used for radioisotopes are typical air foil benchtop hoods (e.g., 6-foot fume hood), with top and bottom bypasses. Elephant trunk connections are also serviced by these exhaust fans, but only in specific labs. Currently, all designated hoods that discharge to the outside are not equipped with HEPA or charcoal filters. However, bio-safety cabinets equipped with HEPA filters will be used in specific labs. Exhaust flow rates are maintained to keep rooms or lab areas under net negative pressures. The difference between exhaust and supply flow rates is typically between 100 to 200 CFM. The designation, location, and nominal exhaust flow rates are given in Table IV-2 (see Attachment 2-4).

Table IV-1 Radiologically Designated Controlled Areas[a]

Room No.	Location	Designation	Major Nuclides
169	Cntrl Module	Bio./Chem.	H-3, C-14
170	Cntrl Module	RSO Lab/Biology	All
172	Cntrl Module	Biology	H-3, C-14
173	Cntrl Module	Mammalian Culture	H-3, C-14
174	Cntrl Module	Fungal Culture	H-3, C-14
175	Cntrl Module	Bacterial Culture	H-3, C-14
162	Cntrl Module	Robotics Bio-Chem	H-3, C-14
156	NW Side/Wall	Radwaste Storage	All

(a) See Attachment 2-2 for floor plan details.

Table IV-2 Operating Characteristics of Exhaust Ventilation System for Radiologically Designated Labs and Areas

Lab No.	Nominal Parameters Exhst Fan No.	Exhst Flow	Face Velocity	Filtration	No. of Elephant Trunk Connections and Flow Rate
162, 169, 170, 172, 173, 174, & 175.	EF-3/-4	14,000 CFM	100 FPM	none	n/a
162	EF-3/-4	800 CFM	n/a	none	4 200 CFM each
156	EF-13	400 CFM	n/a	none	n/a

Exhaust fans EF-3 and EF-4 service all areas, except the Radwaste Storage Room. Both fans operate in tandem and serve as backup for one another, with a flow rate of 14,000 CFM each. The stacks have a terminal height of about 10 feet above roof elevation. Both exhaust stacks are 30 inches in diameter, with an exhaust velocity of about 3,000 FPM. The nominal roof height is 26 feet above finished grade. The exhaust fan motors are located on the roof with controls located at each fan housing. The exhaust fan (EF-13) for the Radwaste Storage Room is located on the roof, with a downdraft discharge cap, located at about 2 feet above the roof line.

Outside air intakes servicing all areas of the laboratories are located on the roof, about 84 ft away for EF-3, 82 feet away for EF-4, and 76 feet away for EF-13, neglecting stack height, exhaust velocity, and plume rise. Accordingly, all releases will be controlled such that the roof of the building will be considered as an unrestricted area and non-occupational airborne concentration limits will be applied at all roof locations. Access to the roof will not be under the direct administrative control of Transcell.

Currently, the nearest structure is an office building located near Dey Road and Route 130, situated at about 1/8 of a mile from the building. In the near future, other buildings will be erected on an adjacent lot, with distances on the order of about 100 feet.

IV.B Liquid Effluent System

All liquid effluents discharged from the Transcell facility originate from three main sources, sanitary, laboratory chemical waste, and mechanical room. The facility has no floor drains in the Labs, only in the service corridors. Laboratory chemical waste originate from lab sinks and cup sinks in hoods and on benches. Floor drains are located in both equipment and glass washrooms.

All effluents are directed to sewer lines that merge to a common line located just beyond the rest and locker rooms, located on the Northwest corner, parallel to Cedar Brook Drive (see Attachment 2-5) and Plot Plan (Figure I-2). The facility's common line is connected to the sewer main located in the middle of Cedar Brook Drive. In addition to the street-manhole, the line to the sewer main is equipped with two clean-out traps, which can be used for sampling, if it were needed.

Sanitary effluents include discharges only from restrooms and personnel showers. Laboratory chemical waste and sanitary discharges are ultimately commingled before reaching the common sewer line to the Middlesex County Utilities Authority's treatment plant. The effluent flow rates has been estimated to be about 2,100 gal./day, from all sources, using engineering assumptions. Later, effluents will also be generated by other building tenants.

Discharges from the sewer may occur in two modes, dilution or effluent. Some of the effluents are only dilution streams, such

as mechanical room. Sewer effluents may include residual amounts of radioactivity from bench sinks and cup sinks, depending upon the types and numbers of ongoing research activities. When R&D work is not being conducted with radioactivity, this discharge stream is considered a dilution flow. All releases are regulated by the Middlesex County Utilities Authority.
A permit application has been filed with that agency, as part of the facility's building permit application.

In order to assess total radiological effluent releases and concentrations, the total effluent discharge flow rate will be monitored and determined by using water meter readings or water consumption rates given on invoices from the local water utility.

IV.C Radwaste Storage Room

Radioactive waste management activities will be conducted as described in Section VI. Briefly, such activities include the handling of solid waste, regulated and de-regulated spent-liquid scintillation vials, and decay-in-storage. Radioactive waste will be generated only from laboratories approved to use radioactive materials. Waste collection containers will be provided in each laboratory. Once full, the containers will be taken out and moved to the Radwaste Storage Room (No. 156, see Attachment 2-2). Low-level waste will be properly packaged before being shipped out for disposal and/or transferred to an offsite facility for treatment. The Radwaste Storage Room is located on the East side, situated about 50 feet away from the Shipping and Receiving dock. The Waste Storage Room provides a nominal floor space of about 142 ft^2. Transcell is authorized to store hazardous waste under EPA Waste Generator ID No.: NJD 986650216.

IV.D Personnel Facilities

Personnel decontamination will be performed in shower rooms (Room No. 114 and 115), both located in the Northwest corner of the facility. Beta/gamma survey meters will also be deployed at key locations for frisking purposes, when warranted. Equipment will also be available from the RSO's Lab, as well as those located in individual labs. Emergency eye-washes are located in each lab and emergency showers are located in service corridors.

IV.E Other Miscellaneous Facilities

Whenever protective clothing is required, it will be made available and worn in the immediate area where radioactive materials are used. Disposable lab coats, gloves, shoe covers, etc. will be collected as radioactive materials and an assessment

will be made as to whether they should be disposed of as radioactive waste or held for decay. Containers, such as drums or bins, will be provided and identified in designated areas.

Radioactive materials will be stored in lockable and shielded storage cabinets. Radioactive material stocks not currently used will be stored in lockable shielded storage containers or refrigerators or in ventilated enclosures, if readily dispersible or volatile. Surface exposure rates will be kept to $\leq$2 mr/h. Additional shielding may be provided by using, e.g., lead bricks to erect shielded vaults into hoods, ventilated enclosures, or bench tops. When required, self-standing see-through leaded-glass and plastic shields will also be used in hoods and on bench tops. The handling of isotope stored in vials will be performed using tongs or handling tools, as is specified by the RSO. When appropriate, the transfer of radioactive materials to and from laboratories or facilities will be performed using small shielded carrying case or lead pigs with a small cart. For P-32, lucite or other low-Z material will be used. In other instances, lead foils of varying thicknesses may be used to wrap around items or vials to reduce external exposure rates. The use and application of other shielding materials and/or storage requirements will be considered depending upon decay schemes, total activity, activity throughput, and compound forms.

IV.F Radiation Detection Equipment and Supplies (Item 9)

Table IV-3 presents a current listing of radiation monitoring equipment available at the Transcell facility (Note: Other brand names may be substituted with equivalent characteristics). The number of each type of equipment and descriptions are shown with typical responses or range of sensitivity. The type of equipment, instrumentation, and miscellaneous supplies used for radiation monitoring and surveillance purposes will be specified and procured in response to the implementation of R&D activities. Accordingly, an exhaustive breakdown is not provided for the sake of brevity.

The selection of any additional instrumentation will be made following an evaluation of each proposed measurement system, specific needs, required sensitivity, response characteristics, analytical method(s), background radiation levels, etc. Table IV-3 denotes such instrumentation as "Future Inventory." The needs for other types of miscellaneous equipment and supplies will be determined in a similar manner. Equipment usage is briefly described below:

1) External radiation exposure rates are measured using G-M, ion-chamber, and/or scintillation survey meters.

2) Surface contamination will be monitored using a combination of wipes and beta-gamma detectors or portable survey meters with beta and/or gamma sensitivity.

3) Personnel will have access to "friskers", or appropriate survey meter/detector in each laboratory to detect clothing and skin contamination.

4) Personnel external dosimetry will be accomplished by film badges and ring finger TLD dosimeters. Self-reading dosimeters may be issued whenever deemed necessary by the RSO. Thyroid uptakes will be assessed by dedicated sodium iodine crystals. Other bicassay techniques (i.e., urinalyses) will be performed by the RSO or via commercial services (e.g., Teledyne Brown Engineering, etc.) using liquid scintillation counting or other appropriate techniques.

5) Air sampling will be accomplished with continuous or periodic air samplers on stacks which vents the hoods or ventilated enclosures, as may be determined by the RSO. A pump and filter will acquire both particulate and radioiodine samples. Separate pumps will sample from areas where specific airborne radionuclides are likely to occur during experiments. In some instances, traps will be used to capture gases or vapors.

6) Analytic equipment (liquid scintillation counters, gamma counters, scalers with shielded gamma or beta detectors, etc.) will be used where specific measurements are required, either as part of an experimental procedure or to verify regulatory compliance.

IV.G Miscellaneous Equipment and Supplies (Item 9)

Additional support equipment and miscellaneous consumable supplies will also be used. Such equipment will be obtained in sufficient quantities to support on-going research activities. It should be noted that this type of equipment and supplies are commonly found in laboratory stocks and inventories. Accordingly, no attempts are made here to provide a detailed listing and required inventory for the purpose of supporting the activities of the radiation program.

Such supplies typically include:

1) Personnel protective equipment, including gloves, lab coats, booties, glasses, face shields.

2) Ventilated enclosures, for use during iodination procedures or other operations involving possible airborne contaminants. These will be equipped with appropriate filters, e.g., charcoal and/or particulate filters.

Table IV-3 Description of Radiation Detection Equipment(#)

Current Inventory

No.	Item	Detector	Characteristics	Use*	Calibration Frequency&
4	Model 3 survey meter, Ludlum	44-9 GM meter pancake probe	Gamma 2,100 cpm per mR/h, 10% eff. for C-14, frisker	Sr	A
1	Liquid scint. Beckman, LS6000TA, or equivalent	Liquid scint.	Smears, water samples, bioassay counting, & analyses	Q	A
1	Gamma counter Beckman, 5500B, or equivalent.	NaI(Tl) scint.	Smears, water samples, bioassay counting, & analyses	Q	A

Note: Above inventory may be augmented commensurate with scope of R&D activities.

* M, monitoring; Sr, survey; Sa, sampling; Q, measurements/assays.
& Q, quarterly; S, semi-annual; A, annual.

Table IV-3 Description of Radiation Detection Equipment, Cont'd

Future Inventory - As Warranted by R&D Activities and Radionuclides (1 of 2)

No.	Item	Detector	Characteristics	Use*	Calibration Frequency&
1	2200-1 ratemeter, Ludlum	44-23, NaI(Tl) 2 x 2 in.	For I-131 thyroid analysis	Q	A
1	2200-1 ratemeter, Ludlum	44-3, NaI(Tl) 1 mm x 2.5 cm	For I-125 thyroid analysis	Q	A
1	Ludlum 3-98 survey meter	44-38, energy compensated	Beta/Gamma, 200 mr/hr, 1,200 cpm per mR/h, 30 mg/cm^2	Sr	A
1	Ludlum 3-98 survey meter	44-3, 2.5 cm x 1 mm, gamma	NaI Scint. I-125, 38% eff., 14 mg/cm^2	Sr	A
1	Eberline, RAS-1, regulated air pump	N/A	Periodic/continuous air sampling, counted with scaler	Sa	A

* M, monitoring; Sr, survey; Sa, sampling; Q, measurements/assays.
& Q, quarterly; S, semi-annual; A, annual.

Table IV-3 Description of Radiation Detection Equipment, Cont'd

Future Inventory - As Warranted by R&D Activities and Radionuclides (2 of 2)

No.	Item	Detector	Characteristics	Use*	Calibration Frequency&
1	Opened face filter, charcoal cart. holders, Eberline	N/A	Ambient air sampling for use with above pumps	Sa	n/a
1	In line filter charcoal cart. holders, Eberline	N/A	Stack/duct sampling for use with above pumps	Sa	n/a
1	Pocket dosimeters, Model 541L, Victoreen	Ion chamber	200 mrem, detection limit, 4 mrem, direct reading	M	A
1	Dosimeter charger Model 2000A, Victoreen	N/A	Charger for above dosimeters	n/a	n/a

\# Other brand names may be substituted with equivalent characteristics.
* M, monitoring; Sr, survey; Sa, sampling; Q, measurements/assays.
& S, semi-annual; A, annual.

3) Other miscellaneous equipment will include tongs, paper supplies, lab trays, and warning signs, markers, ropes, and labels.

4) Check sources for calibration or verification of survey meter operation.

5) Decontamination equipment, including sprays and foams for washing areas, and paper towels and absorbent pads/pillows for collecting spilled liquids.

6) Lead bricks, for shielding gamma-emitting sources. Other shields will include self-standing see-through leaded-glass shields, lucite or plastic shields, lead foil, shielded storage containers, transfer shield case or pig, etc.

7) Laboratory analytical equipment, utensils, labware, such as beakers, hot-plates, planchets, laboratory micro-scale, oven graduates, calibrated pipetters, rubber-policeman, etc.

V. RADIATION SAFETY PROGRAM (Item 10)

The Radiation Safety Program is designed to implement the requirements of Nuclear Regulatory Commission (NRC) 10 CFR, Parts 19, 20, and 30 and Transcell license conditions. In addition, the Radiation Safety Program also presents administrative requirements and guidelines to control, monitor, and evaluate all personnel radiation exposures and environmental releases.

As was noted in Section II.B., all research activities will be initially reviewed and approved by the RSO or designated representative as part of the ALARA program. Under this process, before any experiment is allowed to proceed, each phase of the planned research activity will be evaluated for radiological considerations. The necessary radiological control measures will be identified and specified in the research protocol. All activities involving the use of radioactive materials will be conducted in concert with the ALARA philosophy.

V.A. ALARA PROGRAM

The goal of the Transcell Radiation Safety Program is to maintain all personnel radiation exposures and radioactive releases to the environment at levels which are as low as is reasonable achievable (ALARA) and to ensure compliance with all pertinent Federal and State and local regulations.

Because of the uncertainty of the effects of low doses of ionizing radiation, ALARA work practices mean that exposures should be reduced or prevented whenever possible by reasonable means and costs, even if the exposures are already considered acceptable from a regulatory standpoint.

The success of the ALARA program is dependent upon shared responsibilities and combined efforts of the Radiation Safety Officer, R&D and support staff, and the Radiation Safety Committee. The roles of each is described in Chapter III.

The following tabulation presents the relationships between regulatory exposure and ALARA limits.

Exposure	Dose Equivalent Limits Annual Regulatory Limits (Part 20)	Monitoring Required	ALARA Limits
Whole body	5 rem/yr	0.5 rem/yr	0.25 rem/yr
Extremities	50 rem/yr	5.0 rem/yr	2.5 rem/yr
Skin	50 rem/yr	5.0 rem/yr	2.5 rem/yr
Lens of eye	15 rem/yr	1.5 rem/yr	0.75 rem/yr
Pregnant worker	0.5 rem per gestation	0.05 rem per gestation	lowest possible dose
Uncontrolled areas	100 mrem/yr 2 mrem/hr	-- --	lowest possible dose or rate

V.A.1 Management

Transcell's management is committed to implement and manage the radiation safety program in accordance with all NRC regulations. Management will provide the necessary support and resources to make the ALARA program effective.

V.A.1.2 Radiation Safety Committee

The Radiation Safety Committee (RSC) is established to ensure that the use of radioactive materials is performed in a safe and proper manner in compliance with all company practices, NRC regulations with the goal of protecting the health and safety of employees, visitors, members of the public, and the environment.

The RSC's primary responsibilities include reviewing and approving all R&D protocols involving the use of radioactive materials and authorizing ALARA limits for personnel exposures, and ensuring that all exposures exceeding established ALARA limits are investigated and resolved.

V.A.1.3 Radiation Safety Officer

The Radiation Safety Officer (RSO) has the overall responsibility for developing, implementing, and maintaining the radiation protection program in accordance with all applicable regulations and license conditions. In fulfilling these responsibilities, the RSO has two primary roles:

a) conduct/oversee all routine activities required by the radiation protection program, and

b) interact with Transcell's management and staff as the focal point for all radiation-related issues.

V.A.1.4 R&D Staff

The research staff is responsible for ensuring that all research activities involving radioactive materials are conducted in accordance with established regulatory requirements and administrative procedures and programs. The research staff has assigned in each division a Senior Research Scientist (SRS) and a Radiation Safety Supervisor (RSS) who are responsible for day-to-day activities involving the use of radioactive materials. These activities require close coordination with the RSO and radiation protection staff.

V.A.1.5 Support Staff

The role of the support staff is equally essential in day-to-day activities involving the use of radioactive materials. The support staff includes materials management and building maintenance and services departments. The conduct of these activities also require close cooperation with the RSO and radiation protection staff and the R&D staff.

V.A.2 ALARA Functions

The implementation of the ALARA Program involves important functions that are key to its success. The Radiation Safety Program, as described here, embodies these functions. In summary they include:

V.A.2.1 Management

Management not only includes the responsibilities of implementing the Radiation Safety Program, but also includes establishing a working relationships to foster communication, motivation, and cooperation. In this context, the major objective is to ensure that the staff will seek the technical advice from the RSO and implement good radiological work practices on its own without being prompted.

V.A.2.2 Technical Assistance

The purpose of providing technical assistance to the staff is to review and approve R&D protocols, improve radiological work practices, identify methods to reduce radiation exposures, provide regulatory guidance, identify methods to minimize LLW generation, note conditions which may necessitate immediate corrective actions, and identify training needs.

V.A.2.3 Enforcement and Investigation

Enforcement include the authority to suspend any operations or R&D activities that present a radiological safety hazard to the staff or may result in the release of radioactive materials in the environment. This function also includes communications with regulatory agencies.

V.A.2.4 Monitoring

Surveys are conducted to assess the potential hazards in handling radioactive materials, effluent releases, processing and storage, disposal, and shipment. The surveys are conducted at specific intervals, during research activities, when using or handling radioactivity, and after completing work to verify that no radioactive materials have been spilled or released.

V.A.2.5 Surveillance

Routine and scheduled radiological surveillance are conducted by the RSO. The surveillance activities are incorporated and conducted during, for example, radiation and contamination surveys. Scheduled surveillance will involve conducting inspection tours, audits, or reviews of selected aspects of research activities or waste management program. Scheduled surveillance may target radioactive materials inventory, review of procedures, low-level waste storage, the training program, emergency contingency plans, etc., on a rotating cycle.

Routine and scheduled surveillance are conducted by the RSO and his/her designee in the course of discharging their functions. Scheduled surveillance is conducted either as separate activities or incorporated in routine functions. The RSO makes all necessary arrangements to coordinate these functions with the department or division being targeted for evaluation. Representatives of the department or division are required to participate to provide access to data or personnel and to convey to management an awareness of the nature and importance of these activities.

The purpose of conducting surveillance activities is to identify ways to prevent and minimize radiation exposures, provide technical and regulatory guidance to the research staff, observe and note trends as whether personnel are following good radiological work practices or established protocols, identify methods to minimize LLW generation rates, and note conditions which may necessitate immediate corrective actions.

V.A.2.6 Personnel Training

Personnel training includes conducting periodic training and refresher sessions, and introducing on-the-job training, such as conducting dry-runs before introducing radioactive materials.

V.A.2.7 Documents and Record Keeping

This functions requires that all relevant records are maintain in a central file. The records include licenses, permits, results of radiological surveys, personnel exposure and bioassay data, waste storage and dispositions, effluent releases, materials inventory, calibration documentation, documentation of radiological incidents, correspondence to and from regulatory agencies, yearly audits, and minutes of RSC meetings.

V.B. Occupational Exposure Evaluation

The types and potential for radiological exposures are a function of the physical and chemical forms of the radionuclides being used, amount of activity introduced in each experiment or process, and the methods used to handle, store and dispose radioactive materials and waste.

The range of experiments presents actual or potential sources of exposure, including:

1) direct external beta/gamma exposures to the whole body and any other parts (i.e., hands, fingers, eyes, and skin) and

2) internal exposures due to inhalation, skin adsorption or puncture, and inadvertent ingestion.

The former represents two types of exposures anticipated to occur during routine uses and handling of radioactive materials. The latter are not expected, but could occur during an accident.

The following subsections present a series of evaluations characterizing the types of potential occupational exposures and resulting doses associated with routine and accidental uses of some of the major nuclides applied in various R&D activities. The evaluation is based on information and data described in Appendix B to 10 CFR Part 20, ICRP-38 (Radionuclide Transformations), and NUREG/CR-4418 (Dose Calculation for Contamination of the Skin Using the Computer Code VARSKIN). Similarly, these documents will be used to evaluate other radionuclides not addressed here as such needs arise.

Section II.B presents a summary of the anticipated types of research

activities, radionuclides, and their anticipated inventories. For the purpose of this section, the following radionuclides were selected for evaluation: H-3, C-14, P-32, and radioiodines. These nuclides capture the full range of anticipated types of occupational exposure conditions.

V.B.1 Tritium

Tritiated water and organic compounds will be used in about eight experiments per month with an average of 35 µCi per experiment. The throughput of tritium is expected to be about 0.29 mCi per month.

The potential sources of internal occupational exposure from tritium are direct dermal contact, skin puncture, inhalation of tritiated water vapor, or inadvertent ingestion of tritiated water and tritiated organic compounds.

In a typical experiment using 35 µCi of activity, the radiological exposure is expected to be extremely small. External exposures from handling tritium are virtually nonexistent. Potential internal exposures are also extremely small. For example, if 1 mCi of tritiated water were inadvertently inhaled or ingested, the exposure would be over one percent of the annual occupational limits.

Organic tritium compounds have different biological properties than tritiated water and require special consideration. Regardless of the route of exposure, tritiated organic compounds have the potential to deliver a significantly higher dose than that associated with the same quantity of tritiated water. ICRP-30 states that the annual intake limit for tritiated thymidine, for example, may be as much as 50 times smaller than that for tritiated water. However, the exposure associated with an inadvertent intake of an organic tritium compound used in a typical experiment is not expected to exceed annual occupational exposure limits.

Notwithstanding the relatively small potential for exposure from routine uses of H-3, sound health physics procedures will be implemented. In addition, since exposures to tritium can only be evaluated through urine analyses, a bioassay program has been established for this purpose.

In light of these results, experiments utilizing less than 10 mCi of tritium will be performed on bench top using prudent health physics handling procedures to preclude contamination of the work area. Lab areas will be designated for radiological use and routinely surveyed for contamination.

Occasional experiments using greater than 10 mCi of tritium do not represent an external source of exposure, but may result in a potentially significant source of internal exposure if it were mishandled. For example, even if a small fraction of that activity as tritiated water, or yet smaller amounts in organic forms, were inadvertently inhaled, the resulting exposure could exceed the occupational limits. Accordingly, tritium experiments using in excess of 10 mCi may be performed in a vented hood or enclosure. Wipe samples will be taken and urine bioassay analyses will be conducted after such experiments. If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow-up investigations will be performed.

V.B.2 Carbon-14

C-14 will be used in various studies at a rate of 40 experiments per month. The quantity of C-14 will include up to 5 µCi per experiment. The total C-14 throughput will be less than 0.2 mCi per month.

C-14 is a pure beta emitter and, on direct contact, can cause an external dose rate of 1.1 rem/h per $\mu Ci/cm^2$ to the skin (at a density thickness of 7 mg/cm^2). However, the range of C-14 beta particles in air is about 1 foot. Except for direct contact, the potential for external exposure from unshielded C-14 sources is small. The range of C-14 beta particles in unit-density material is less than 1 mm. Most plastic or glass containers will minimize or totally eliminate the risk of beta exposures. As a result, C-14 is a potential source of external exposure if spilled, or internal exposure if inhaled or taken in via a puncture wound.

In its organic form, C-14 has the potential of causing higher internal exposures, as compared to tritium, due to its longer half-life and higher beta particle energy. Because of this, C-14 may present a potentially greater source of internal exposures than tritium, if mishandled. For example, internal exposures from the inadvertent inhalation of 1.0 mCi of C-14 could yield a dose that is about half of the annual occupational limits.

A distinction will be made among experiments that use microcurie quantities of C-14 vs those that employ millicurie amounts. If the quantities are less than 2 mCi and the material is non-volatile, the potential for internal exposure is extremely small and bench top use may be acceptable if proper procedures are followed. Experiments requiring several millicuries of C-14 or use volatile compounds will

be performed in vented enclosures.

The radiation protection program and procedures for storing, handling, and surveying C-14 will be based on sound health physics procedures. In addition, urinalysis and/or breath bioassay analyses will be routinely performed on targeted individuals to confirm the effectiveness of the radiation protection program. For each individual handling more than one mCi of C-14 (in non-volatile forms), bioassay analyses will be performed routinely. If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow-up investigations will be performed. Other requirements addressing proper radiation protection principles will be applied when using C-14. This includes the conduct for radiation and contamination surveys, air sampling, posting, eye protection, and issuing personnel dosimetry.

V.B.3 Phosphorous-32

P-32 will be used in occasional studies, each of which uses not more than 1 mCi. The monthly throughput of P-32 is expected to be less than 1 mCi. P-32 is a pure beta emitter. However, because of the energetic beta emissions (0.695 MeV average and 1.71 MeV max), it can lead to significant skin exposures. The lens of the eyes, however, may be the limiting organ unless adequate eye or face protection is provided. In addition, bremsstrahlung radiation can be produced by the interaction of beta particles with containers or shields made of high-Z materials. On direct contact, P-32 can yield elevated skin dose rates, i.e., 9.2 rem/h per $\mu Ci/cm^2$ (at a density thickness of 7 mg/cm^2). The range of P-32 beta particles in air is on the order of 20 feet.

Skin exposures from beta particles passing through a container wall could be substantial if the wall thickness is less than 1 cm. The range of P-32 beta particles in unit density material is 0.8 cm. Accordingly, a one-cm thick plastic or glass container will nearly eliminate all beta exposures. For containers less than 1 cm, or for portions of the container with minimal shielding (e.g., an injection septum), the beta dose rate could be considerably higher.

For a 0.1 mCi P-32, the skin dose rates for various container wall thicknesses and distances from the source are estimated as follows:

Container Thickness	Distance From Container	Dose Rate mrad/h
0.1 cm	contact	5,160
	10.0 cm	180
	100.0 cm	0.90
0.5 cm	contact	313
	10.0 cm	11.3
	100.0 cm	0.33
1.0 cm	10.0 cm	negligible

The above calculations are based on the assumption that P-32 is stored in a container. However, during experiments small amounts of P-32 will be placed into glassware, trays, syringes, etc. If properly handled, there will be no direct skin contact. However, if skin or surface contamination occurs, P-32 may deliver significant skin exposures, as noted above. Accordingly, direct contact and unshielded proximity to P-32 solutions will be controlled by proper handling and health physics procedures. Volatile forms P-32 will be handled in vented hoods or enclosures.

Bremsstrahlung radiation can be produced by the interaction of beta particles with container walls or shielding materials. For example, the contact skin dose due to bremsstrahlung from holding a 0.1 mCi vial of P-32 is estimated to be about 3.3 mrem/h. Assuming that P-32 is stored in 1.0 cm thick (unit density) containers, the beta dose will be negligible.

The bremsstrahlung radiation field is estimated as follows:

Distance from Container	Exposure Rate mrad/h
Contact	100
10 cm	5
100 cm	negligible

Based on these calculations, it is assumed that bremsstrahlung is of little concern since beta doses are dominant. However, P-32, in any form, should be contained in thick low-Z (e.g., plastic) materials. In addition, extremity dosimeters will be required when handling P-32 to monitor skin exposures along with whole body badges capable of measuring beta exposures.

Mishandling of P-32 could result in the inadvertent ingestion of P-32 with an associated internal dose. If it is assumed that 0.1 mCi of P-32 is inadvertently inhaled, the dose would be nearly 25% of the annual occupational limits. Accordingly, significant internal exposures from P-32 are highly unlikely. Nevertheless, the urine bioassay program will target selected individuals, based on the amounts of P-32 handled per experiment and cumulatively, to confirm the effectiveness of the internal radiation exposure protection program. If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow-up investigations will be performed.

Routine beta surveys and wipe samples will be taken prior to and following its use. If a spill has occurred or is suspected, direct and wipe surveys and air sampling will be performed. All P-32 storage areas will be routinely surveyed and wipe samples taken for gross beta analyses. Extremity dosimeters (e.g., finger TLDs) and whole body badges will be required. Eye protection, in the form of safety glasses or face shields, will also be required as part of general lab safety procedures.

V.B.4 Radioiodines

Both, I-125 and I-131 will be used in occasional experiments. Iodinated compounds will obtained from third party sources. Under the current R&D program, iodinations will not be conducted at Transcell. It is estimated that the I-125 and I-131 uses at the facility will be less than 0.25 mCi/month. The following discussion focuses on I-125, with the understanding that radiation protection issues and internal exposures are virtually identical to those of I-131 and the same types of controls will be applied.

I-125 is a weak gamma and X-ray emitter (less than 35 keV).

The radiation fields in the vicinity of various quantities of I-125 used in typical experiments are estimated as follows:

Distance (m)	-- Estimated Dose Rate (mR/h) -- Screening 0.5 µCi	Tracer 0.2 mCi	Storage 25 mCi
0.1	0.007	3.0	300
1.0	negligible	0.03	3.0
10.0	negligible	negligible	negligible

The resulting exposure rates are small and do not require shielding. The half-value layer for I-125 is 0.003 cm for Pb based on 35 keV photon emissions. However, in keeping with ALARA practices, all I-125 sources will be stored behind shields or kept in shielded storage cabinets, whenever practicable.

I-125 has an extremely restrictive intake limit because it accumulates in the thyroid gland. Iodine can, in addition to inhalation, be readily absorbed through intact skin. Protective clothing, primarily lab-coats and gloves, will be worn when handling radioiodines. If in a worse case scenario, it were assumed that 20 µCi were inadvertently inhaled, the resulting intake would be about 33% of the limit. Since radioiodines are volatile, experiments using I-125 more than 0.1 mCi will be performed in vented hoods or enclosures. Depending upon chemical forms, the RSO may establish alternate limits for non-volatile compounds.

Individuals handling I-125 will undergo routine thyroid scans and/or urine analyses. A bioassay program has been established based on the requirements of Regulatory Guide 8.20. If bioassay results exceed investigational levels, or an accident is suspected, additional bioassays and follow-up investigations will be performed. For thyroid scans, action level of $\leq$0.06 µCi will be used, based on 75% uptake, with 30% going to the thyroid and assuming a breathing rate of 20 LPM.

All other requirements previously addressing radiation protection principles will be applied when using I-125. This includes the conduct for radiation and contamination surveys, air sampling, posting, use of shielding materials, eye protection, and personnel dosimetry (extremities and whole body).

The following technical information on I-131 is presented for the sake of completeness. I-131 is gamma emitter with photon energies ranging from 80 to 722 keV. The specific gamma ray constant for I-131 is 0.22 R/h at 1 m per Ci. The gamma radiation field in the vicinity of I-131 is estimated as follows:

Distance (m)	Estimated Dose Rate (mrem/h) Storage 10 mCi	Imaging 0.5 mCi
0.1	220	11
1.0	2.2	0.11
10.0	0.02	negligible

While the gamma exposure rate is relatively low, external beta doses can be significant due particles ranging from 248 to 807 keV (averaging at 181 keV). The most energetic beta particle has a range of about 8 feet in air and 0.3 cm in unit density material. Direct skin contact delivers a dose rate of 6.3 rem/h per $\mu Ci/cm^2$ at a density thickness of 7 mg/cm^2. However, beta exposures may be eliminated when using plastic containers, while external gamma exposures can be controlled by using Pb shielding.

V.C. Radiation Dosimetry Program

The radiation dosimetry program is designed to monitor occupational exposures when handling or while in the vicinity of radioactive materials. Both, external radiation and internal exposures (via inhalation, accidental ingestion, and skin absorption or puncture) are covered by the program. All research activities will be initially reviewed and approved by the RSO his/her designee.
Under this process, before any type of experiment is allowed to proceed, each phase of the research activities will be evaluated for radiological considerations and the necessary control measures will be specified in the research protocol.

The prime objective of the dosimetry program is to verify that doses are within the radiation exposure limits and are consistent with the ALARA philosophy, as noted under 10 CFR 20, Part 20.1101. The limits or requirements of Parts 20.1201 to 20.1204, and annual limits on intake (ALI) given in Table 1, Columns 1 and 2 to Appendix B of Part 20 will be observed. The Transcell Radiation Safety Program does NOT include any provisions for planned special exposures, as defined in

Part 20.1206.
V.C.1 External Radiation Exposures

For ALARA purposes, an administrative limit of 5% of the occupational dose limits (Part 20.1201) is used to monitor and control all personnel exposures on a monthly basis. The corresponding administrative limits are:

a) Whole body exposures, 250 mrem/yr (DDE);

b) Extremity exposures, 2,500 mrem/yr (DDE);

c) Skin exposures (whole body or extremities), 2,500 mrem/yr (SDE); and

d) Exposure to the eye (lens), 750 mrem/yr (LDE).

e) For a "declared pregnant" worker, the dose will be limited to 500 (DDE) mrem during the entire pregnancy (Part 20.1208). An administrative limit of 50 mrem (DDE) per month will be imposed for the purpose of monitoring such exposures.

Any doses in excess of these limits will be investigated. The radiation safety program also identifies notification and survey requirements to ensure that such limits are observed. If exposures also involve internal intakes due to inhalation, ingestion, or skin adsorption, the administrative limits will based on all routes of exposures, i.e., summing of deep-dose equivalent (DDE) and committed effective dose equivalent (CEDE) for internal organs (see Section V.C.2).

External radiation doses will be monitored with film badges and thermoluminescent dosimeters (TLDs) worn as finger rings or wrist badges, exchanged on a quarterly basis. Self-reading dosimeters may be issued on a case-by-case basis by the RSO, whenever penetrating external radiation fields will be encountered. The RSO will review all exposure results monthly and determine whether such exposures are ALARA. Specific recommendations will be promulgated when necessary.

Film badges will be worn at mid and upper trunk levels. Workers will be instructed to wear their badges whenever entering a lab or other radiation area, and to store film badges and ring dosimeters only at designated locations.

Individuals using energetic beta emitters (e.g., ≥1 mCi of P-32) or gamma emitters will wear finger or wrist TLDs to monitor extremity doses. Safety glasses or face-shields are routinely required as part of general lab safety. Extremity TLDs will be exchanged and read monthly.

Dosimeters will be supplied and read out by NVLAP participants, for example, ICN. Dose results will be obtained on computer generated forms containing the information required on NRC Form 5 for current occupational radiation exposures. Any previous historical exposures will be established using NRC Form 4. All dosimetry records will be maintained indefinitely and in accordance with Parts 20.2104 and 20.2106. The requirements of Part 20.2105 do not apply since the Transcell Radiation Safety Program does not include any provisions for planned special exposures.

The RSO will make dosimetry results available to each employee when requested and terminating employment. The reporting requirements in 10 CFR, Parts 19.13, 20.2106, 20.2202, and 20.2203, and Regulatory Guides 8.7 and 8.34 will be observed. The reporting of individual monitoring results, under Part 20.2206(b) and (c), is exempted under the provisions of Part 20.2206(a)(7). The reporting requirements of Part 20.2204 for planned special exposures do not apply for the reason noted earlier.

Additional film badges will be placed at selected locations near the periphery of radiologically controlled areas to verify that exposure rates and doses in uncontrolled areas are within the annual limit of 100 mrem and 2 mrem/h above background. The badges will also be replaced on a quarterly schedule. In assessing exposures to members of the general public, the requirements of Parts 20.1301, 20.1302, and 20.2107 will be observed as well.

V.C.2 Internal Radiation Exposures

Internal radiation exposures will be monitored via the bioassay program, e.g., urine for H-3, C-14, P-32, etc. and thyroid for radioiodines. Breath analysis for $^{14}CO_2$ and fecal samples may be collected and analyzed for specific nuclides. Technical and analytical guidance will be applied to reflect the use of other radionuclides and activity throughput.

The bioassay program is based on the requirements of 10 CFR 20, Parts 20.1202, 20.1204, and 20.1502. Internal exposures are governed by the ALIs of Columns 1 and 2, and DACs of Column 3 contained in Table 1 of Appendix B to Part 20.

For the purpose of monitoring internal exposures and intakes, the following administrative limits are established:

1) Investigational level of 5% of the ALIs.

2) Action level of 10% of the ALI for investigational purposes to evaluate exposures and take necessary corrective actions.

The major elements of the bioassay program include:

1) Bioassay analysis and follow-up investigations will be performed when:

   (a) bioassay results indicate internal exposures in excess of (I) one investigational level (5% of the ALI), and (ii) the action level (10% of the ALI).

   (b) an accidental internal exposure is suspected or known due to inhalation, ingestion, skin puncture or absorption, or other injuries (e.g., open wounds).

2) Bioassay analyses and follow-up evaluations will be conducted for R&D activities using amounts of radioactivity which could result in internal exposures above one investigational level. Such determination will be made during the review and evaluation of the research protocol.

3) Researchers using more than the specified amounts of radioactivity (based on protocol criteria) will submit themselves to scheduled bioassay procedures, e.g., before and 24 hours after the work has been accomplished.

4) For continuous use, bioassay samples will be submitted or scans will be performed following a routine schedule, as noted in the protocol, or based on activity throughput.

5) Additional samples and/or scans will be used to follow excretion patterns. The RSO will evaluate samples and scans to reconstruct exposures and assess initial intakes.

6) The subject may return to work if the RSO determines that any action levels have not been exceeded and that further work is not likely to result in exceeding the action levels.

7) Individuals using I-125 or I-131 in excess of 0.1 mCi will be incorporated into the thyroid scan program. The scans will be performed within 72 hours following exposure. The initial scan will also be conducted no sooner than six hours post-exposure to allow for the redistribution of radioiodines. In assessing thyroid exposures and excretion patterns, urine samples may also be collected and analyzed, as necessary.

8) Individuals not routinely using radioactivity but working in areas where radioactive materials are being used will be required to follow bioassay procedures for the purpose of assessing the overall effectiveness of the radiological control measures and to ensure that investigational levels are not exceeded. The RSO will identify such individuals, type of bioassay, and schedule based on radioactivity uses.

The effectiveness of the radiological control measures will be based on the results of the bioassay program and monitoring results for radionuclides which cannot be readily detected in bioassay samples at the investigational or evaluation levels. In such instances, airborne concentration results and duration of exposures will be used to assess intakes.

In limiting internal exposures, radiological controls will NOT rely on the use of respiratory protection equipment. Rather, administrative and procedural controls will be applied to minimize the amounts of material handled and through the use of engineered systems, such as fume hoods, ventilated enclosures, etc. In the event that a respiratory protection program is necessary to routinely conduct R&D activities, the requirements of 10 CFR Part 20, Subpart H, and Appendix A to Part 20 will be used to develop the program. The program will be submitted to the NRC for review and approval prior to its implementation.

A limited respiratory protection program will be implemented only for emergency response personnel. All personnel designated to use respiratory equipment under emergency conditions will undergo medical examinations and be administered a qualitative respiratory fit test. Full face respirators and SCBAs will be used under conditions specified by the RSO. Personnel training, medical qualifications, and use of approved equipment will follow the requirements established by OSHA and NIOSH/MSHA. However, the respiratory protection factors contained in Appendix A to 10 CFR 20 will be applied when assessing internal exposures.

Other procedures (e.g., fecal sampling and analysis or whole body counting) will be developed as such needs arise. Supporting documents will be used to evaluate other types of exposures and nuclides (e.g., skin adsorption, puncture, open wounds, etc.), as needed. The following documents will be used for guidance:

- 10 CFR 20, Standards for Protection Against Radiation.
- 10 CFR 20, Appendix B, Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposures.
- Questions and Answers on New Part 20, four sets.

- ICRP-30, Limits for Intakes of Radionuclides by Workers.
- NUREG-0938, Information for Establishing Bioassay. Measurements and Evaluations for Tritium Exposure.
- NUREG-1400, Air Sampling in the Workplace.
- NUREG/CR-3332, Radiological Assessment.
- NUREG/CR-4418, Dose Calculation for Contamination of the Skin Using the Computer Code VARSKIN.
- NUREG/CR-4884, Interpretation of Bioassay Measurements.
- NUREG/CR-6050, Radiation Exposure Monitoring and Information Transmittal (REMIT) System.
- NUREG/CR-0006, DEPOSITION: Software to Calculate Particle Penetration Through Aerosol Transport Systems.
- Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion (U.S. EPA publication).

- Regulatory Guide 8.7, Instructions for Recording and Reporting Occupational Radiation Exposure Data.
- Regulatory Guide 8.9, Interpretation of Bioassay Measurements, rev. 1.
- Regulatory Guide 8.20, Applications of Bioassay for I-125 and I-131.
- Regulatory Guide 8.25, Air Sampling in the Workplace
- Regulatory Guide 8.26, Applications of Bioassay for Fission and Activation Products.
- Regulatory Guide 8.32, Criteria for Establishing a Tritium Bioassay Program.
- Regulatory Guide 8.34, Monitoring Criteria and Methods to Calculate Occupational Doses.
- Regulatory Guide 8.36, Radiation Dose to the Embryo/Fetus.
- Regulatory Guide 8.37, ALARA Levels for Effluents from Materials Facilities.

- Regulatory Guide 4.20, Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other Than Power Reactors.

V.C.3 Bioassay Program

The following subsections present the elements of the bioassay program.

V.C.3.1 Urine

Urine samples are collected to assess the systemic burden of radionuclides. The presence of radioactive materials in urine is dependent upon the radionuclides, route of entry, biochemistry, and target organs. Sequential analyses of urine samples taken over relatively long time periods provide the basis for estimating the fraction of the body burden and excretion rates. Typically, a large fraction of the intake is excreted in urine (and feces as well) during the first few days after exposure.

Two types of urine samples are collected, spot and 24-hour. Spot samples are collected (both at work and home, if necessary) within the first 24 hours and periodically after the exposure. On the other hand, a 24-hour sample captures all urine excreted over a full day, also collected during working hours and at home. For either type of sample, the RSO specifies the sampling frequency and conducts all sample analyses.

A concern with urine collection is that care must be exercised to ensure that the sample does not become cross-contaminated. All samples must be collected in new and clean container and after washing hands and removing contaminated clothing, if needed.

V.C.3.2 Thyroid

Thyroid measurements are made by scanning the thyroid gland with NaI(Tl) detectors for radioiodines. The scan is non-invasive and is performed rapidly, typically in few minutes. The scan involves placing the base of the neck in contact with the radiation detector and making the measurement for the specified time period. The operating instructions are posted with the thyroid scanner.

Log sheets are provided to record name, thyroid scan counts, background counts, and date and time of the scan. Under current procedures, thyroid scans are performed and recorded by each individual. The RSO reviews all results and determines the intake, if any.

V.C.3.3 Fecal

Fecal sampling and analysis provide another method for assessing the systemic burden of radioactivity. Sometimes, fecal and urine sample analyses are conducted simultaneously for estimating the time of exposure (via the feces-to-urine ratio). A large fraction of the intake is excreted in feces, along with urine, over the first few days following the exposure.

The presence of radioactivity in feces is more variable than that of urine because of several factors. It is dependent upon the types of radionuclides, fraction absorbed in the GI tract, and biochemistry. The route of entry and source of the radioactivity contributing to the excretion are also important. Generally, materials that are ingested appear first, followed by materials that were inhaled and cleared by the lung's mucociliary action. Some materials may also be cleared from systemic circulation to the GI tract, although at a much lower rate. Another complicating factor is that the daily rate of fecal (mass) excretion is more variable when compared to the urine volume.

As with urine samples, two types of fecal samples are collected, spot and 24-hour. Spot samples are collected both at work and home. The 24-hour sample captures all feces excreted over a full day and requires collection during working hours and at home.

Samples are collected in a container and analyzed whole without any processing. This is the preferred method for assessing the presence of gamma-emitting radionuclides. For other types of analyses (for beta and alpha emitters), some processing may be necessary. The RSO specifies when such samples are needed, sampling frequency, and types of analyses.

As with urine samples, care must be exercised to ensure that fecal samples do not become cross-contaminated. All samples must be collected in new and clean container and after washing hands and removing contaminated clothing, if needed.

V.C.3.4 Breath

The collection of breath samples can be used to assess the presence of radioactive materials that produce a gas or vapor when metabolized. This method can be used to measure the presence of tritiated water vapors and C-14 radio-labeled carbon dioxide with. Exhaled breath is collected in a bag or balloon of known volume and passed through a bubbler. The bubbler sample is then counted

using conventional methods. The RSO will specify when such samples are needed, sampling frequency, and types of analyses.

V.C.3.5 Skin Contamination

The presence of radioactivity on the skin is determined by making measurements over the affected areas. Measurements are made by scanning or in direct contact with the skin. Measurements are also made at specific intervals, first to determine initial activity levels and later to assess the effectiveness of the decontamination procedures or overall removal rate (due to decay and hand washing). In some instances, it may be required to shave hairs, clip finger nails, or trim off calluses to remove the contamination. For some types of injuries, decontamination may not be recommended, as doing so would promote the absorption of activity into the blood. All skin injuries or opened wounds will be washed and referred to the Medical Department for first aid treatment and decontamination, if needed. The RSO will make special arrangements with the Medical Department to provide technical assistance and collect the necessary information to estimate skin doses.

In some instances, it may be required to follow up skin contamination incidents with other types of bioassays. For example, skin contaminated with I-125 may require subsequent thyroid scans. Similarly, an incident involving tritium skin contamination may require the collection of urine samples. The same procedure is required for skin injuries involving punctures and opened wounds.

C.V.3.6 Whole-Body Measurements

Whole-body measurements may be performed under specific circumstances. Whole-body measurements may be conducted to support the assessment of other types of bioassay results or for monitoring the systemic presence of radioactivity that cannot be reliably monitored by the above noted methods. Typically, such measurements involve scanning the whole-body or organs (e.g., lungs or bone).

Whole body measurements will be conducted at other facilities, when needed. The nearest whole body counter is operated by:

RMC Medical, 3021 Darnell Rd, Philadelphia, PA
(215) 824-1300 and (215) 243-2990 for off hours

V.C.3.7 Bioassay Samples Disposition

The disposition of bioassay samples will be coordinated with the RSO. Most samples will be disposed of by flushing into the sanitary sewer system. Other samples may require special handling and disposition taking into account the presence of radioactivity.

V.C.4 Bioassay Measurements Interpretation

The following subsections present the methodology to estimate intakes and doses based on bioassay sample results. Working examples are presented in NRC Regulatory Guide 8.9 for how intakes and doses are estimated.

V.C.4.1 Intake Determination

V.C.4.1.1 Single Measurement

For a single measurement, the intake is derived as follows:

$I_i = A_i(t)\ (k) + IRF(t)$; where (1)

I_i = Best estimate of intake of radionuclide I, µCi.

(k) = Dimensional conversion factors, e.g., density adjustments, concentration to volume or mass, decay correction, etc., as required.

$A_i(t)$ = Measured activity in vivo or vitro at time t after exposure, µCi.

IRF(t) = Intake retention fraction associated with measurement at time t. See Appendix NUREG/CR-4884.

V.C.4.1.2 Spot Bioassay Samples

For spot samples, the following equations is used to estimate the accumulated activity in urine or feces:

$\Delta A_i = (C_i)\ E(t_i - t_{i-1})$; and (2a)

$A_i = \Delta A_1 + \Delta A_2 + \ldots + \Delta A_i$; where (2b)

ΔA_i = Activity or amount of radioactive material in sample I.

C_i = Radionuclide concentration in urine (µCi/L) or feces (µCi/g) of sample I, decay corrected to time of sampling.

E = Daily excretion rate (measured or assumed values, 1.4 L/d for urine or 135 g/d for feces).

t_i = Time, in days, after intake that sample I is collected.

A_i = Accumulated activity, µCi, up to time t_i.

V.C.4.1.3 Multiple Bioassay Measurements

For multiple measurements, the intake is derived as follows:

$$I_i = \Sigma_i IRF(I)\ A_i(I)\ (k) \div \Sigma_i (IRF(I))^2; \text{ where} \qquad (3)$$

I_i = Best estimate of intake of radionuclide I, µCi.

(k) = Dimensional conversion factors, e.g., density adjustment, concentration to volume or mass, decay correction, etc., as required.

$A_i(t)$ = Measurement (ith) of activity accumulated in bioassay sample, µCi. Accumulated sample means, e.g., 24-h our urine volume or fecal mass collected over a full day.

IRF(I) = Intake retention fraction associated with the ith measurement. See Appendix NUREG/CR-4884.

V.C.4.1.4 Multiple and Continuous Intakes

For multiple and continuous intakes occurring <u>during</u> an exposure time interval, the intake is adjusted as follows:

$$I = \frac{A(t)\ (T)\ (n)}{(t)\left[\left(\frac{IRF(t) + IRF(t=0.1\ d)}{2}\right) + IRF(u_1) + \ldots + IRF(u_{n-1})\right]}; \qquad (4a)$$

where:

I_i = Total intake of radionuclide I during time period T, µCi.

$A(t)$ = Amount of activity at time t following onset of intake, µCi.

$IRF(u)$ = Intake retention fraction at time u for a single intake of nuclide I. See NUREG/CR-4884.

T = Duration of intake or exposure time period, days.

t = Time from onset of intake to time of measurement, days.

u = Variable time unit between integration limits based on the selected number of increments n, hours or days.

n = Selected number of increments over the time interval, t - T.

For multiple and continuous intakes occurring <u>after</u> an exposure interval, the intake is adjusted as follows:

$$I = \frac{A(t)\ (n)}{\left[\frac{(IRF(t-T) + IRF(t))}{2} + IRF(u_1) + \ldots + IRF(u_{n-1})\right]}; \quad (4b)$$

where the terms are as previously defined.

In the context of equations (4a) and (4b), if the intakes are separated in time so that the retained or eliminated fraction from an earlier intake is less than 10% of the retention or excretion fraction for the next intake, each intake may be evaluated separately without regard to any previous intake.

The selected number of increments (n) used in either equation should be selected to minimize the uncertainty associated with the particular intake retention fraction values (IRF) over the time of integration.

V.C.4.1.5 Skin Contamination

The assessment of skin contamination is conducted by taking direct measurements and converting the results to surface activity levels ($\mu Ci/cm^2$). Skin contamination levels are estimated as follows:

$$S_{a,i} = (C_r)\ (CF_i); \text{ where} \quad (5)$$

$S_{a,i}$ = Skin surface activity level, µCi/cm^2.

C_r = Instrument count-rate, cpm.

CF_i = Dimensional conversion factors, e.g., efficiency, adjustments for detector probe area size, etc.

V.C.4.2 Dose Determination

V.C.4.2.1 Committed Effective Dose Equivalent Using ALIs

The committed effective dose equivalent (CEDE) for each radionuclide, based on the estimated inhalation or ingestion ALI (stochastic), is calculated as follows:

$H_{i,e} = (5)\ (I_i) \div (ALI_{i,e})$; where (6)

$H_{i,e}$ = Committed effective dose equivalent from nuclide I, rem.

5 = Committed effective dose equivalent due to the intake of 1 ALI, rem.

I_i = Intake of nuclide I by inhalation or ingestion during period of interest, µCi. For multiple intakes, I_i is the sum of all intakes.

$ALI_{i,e}$ = Value of stochastic inhalation ALI, µCi. See Table 1, Column 2, or Table 1, Column 1 in Appendix B to Part 20.

V.C.4.2.2 Committed Dose Equivalent Using ALIs

The committed dose equivalent (CDE) for each radionuclide, based on the estimated inhalation or ingestion ALI (nonstochastic), is calculated as follows:

$H_{i,t} = (50)\ (I_i) \div (ALI_{i,t})$; where (7)

$H_{i,t}$ = Committed dose equivalent to organ or tissue t from nuclide I, rem.

50 = Committed dose equivalent to maximum exposed organ or tissue due to the intake of 1 ALI, rem.

I_i = Intake of nuclide I by inhalation or ingestion

during period of interest, µCi. For multiple intakes, I_i is the sum of all intakes.

$ALI_{i,t}$ = Value of nonstochastic inhalation ALI, µCi. See Table 1, Column 2, or Table 1, Column 1 in Appendix B to Part 20.

V.C.4.2.3 Committed Effective Dose Equivalent Using DACs

The Committed effective dose equivalent (CEDE) is derived, based on DACs (stochastic) for each radionuclide, using estimated airborne concentrations. The CEDE is calculated as follows:

$H_{i,e} = (5)\ (C_i)\ (t) \div (2000)\ (DAC_{i,e})$; where (8)

$H_{i,e}$ = Committed effective dose equivalent from nuclide I, rem.

5 = Committed effective dose equivalent due to the intake of 1 ALI, rem.

C_i = Concentration of nuclide I to which worker is exposed by inhalation during period of interest t, µCi/mL.

t = Exposure duration, hours.

2000 = The number of hours in a working year.

$DAC_{i,e}$ = The stochastic DAC for nuclide I, µCi/mL. See Table 1, Column 3, Appendix B to Part 20.

V.C.4.2.4 Committed Dose Equivalent Using DACs

The Committed dose equivalent (CDE) is derived, based on DACs (nonstochastic) for each radionuclide, using estimated airborne concentrations. The CDE is calculated as follows:

$H_{i,e} = (50)\ (C_i)\ (t) \div (2000)\ (DAC_{i,e})$; where (9)

$H_{i,e}$ = Committed dose equivalent from nuclide I, rem.

50 = Committed dose equivalent due to the intake of 1 ALI, rem.

C_i = Concentration of nuclide I to which worker is exposed by inhalation during period of interest t, µCi/mL.

t = Exposure duration, hours.

2000 = The number of hours in a working year.

$DAC_{i,e}$ = The nonstochastic DAC for nuclide I, µCi/mL. See Table 1, Column 3, Appendix B to Part 20.

V.C.4.2.5 Skin Dose

The assessment of skin contamination is conducted by taking direct measurements and converting the results of surface activity levels (µCi/cm^2) to skin dose (rem) using radionuclide specific dose conversion factors. The dose is calculated as follows:

$S_{d,i} = (S_{a,i})\ (CF_i)\ (I_{f,i})$; where (10a)

$S_{d,i}$ = Integrated skin dose, rem.

$S_{a,i}$ = Skin surface activity level, µCi/cm^2.

CF_i = Conversion factor, rem/h per µCi/cm^2. See the VARSKIN computer manual (see NUREG/CR-4418).

$I_{f,i}$ = The integration factor over duration of exposure, derived as:

$[1 - \exp-(\lambda_e)(t)] \div [\lambda_e]$; where (10b)

λ_e = effective removal rate, radioactive decay and decontamination mechanism, h^{-1}.

t = actual exposure time interval, h.

For an infinite time, ∞, until the last atom has decayed,

$I_{f,i} = 1/\lambda_e$.

V.C.4.3 Compliance Evaluation

The following subsections present the methodology to determine compliance with administrative and regulatory limits. The RSO monitors and evaluates all internal (and external) exposures. As part of the routine surveillance activities, the RSO evaluates monthly exposures against past facility activities. If any trends are noted, corrective actions will be recommended to each R&D division. In addition, the RSO conducts a yearly review and evaluation of all bioassay exposures.

V.C.4.3.1 Internal Intakes and Doses

The estimated dose or ALI results are compared to administrative limits (evaluation level and action level) 10 CFR 20 Subpart C requirements, and limits of Appendix B to 10 CFR 20.

Doses and intakes are recorded on U.S. NRC Form 5, or its equivalent. The REMIT computer code may also be used for this purpose.

V.C.4.3.2 Total Effective Dose Equivalent

If exposures also involve external penetrating radiation, compliance with the investigational level is based on all exposures, i.e., summing of deep-dose equivalent (DDE) and committed effective dose equivalent (CEDE) for internal organs.

Doses and intakes are recorded on NRC Form 5, or its equivalent. The REMIT computer code may also be used for this purpose.

V.C.4.3.3 Routine and Special Provisions

Baseline measurements are conducted for the purpose of assessing the presence of radioactive materials in the body before any work is conducted using radioactive materials. Baseline measurements are required for new employees and those with work reassignments.

Routine measurements are conducted when radioactive materials are used in day-to-day activities. This is typically the case for iodinations, where thyroid scans are conducted before and after each iodination. The research protocols specifies the types and frequency of such measurements.

The RSO may specify the conduct of periodic measurements, e.g., at a lesser frequency, to assess the likelihood of exposures. In identifying the needs for periodic measurements, the following factors are considered:

a) Types and amounts of radioactive used,

b) work practices (current and historical),

c) prior radiological survey and bioassay results, and

d) types of R&D activities and potential exposure durations.

The results of such an evaluation may be used to update the types and frequency of measurements specified in research protocols.

Special measurements are taken for the purpose of assessing unusual situations or to provide additional or confirmatory information for earlier bioassay samples and analyses.

1) Unusual situations may include any of the following conditions:

   a) Inadvertent intakes associated with known or suspected failure of engineered safety respiratory protection equipment.

   b) Inadvertent ingestion, skin exposures, injuries, and presence of facial or nasal radioactive contamination.

   c) Entry into an airborne radioactivity area without appropriate exposure controls.

   d) Activities or events that are known or suspected of exposing workers to airborne radioactive materials.

2) Additional or confirmatory measurements may include any of the following:

   a) Verifying time of intakes and exposure durations.

   b) Conducting time-motion studies to reconstruct the event.

   c) Establishing the physical, chemical, and radiological characteristics of the nuclide(s) involved.

d) Conducting sequential sampling or analyses to establish excretion and retention patterns.

For employees who are no longer handling radioactive materials, because of termination or change in responsibilities, termination measurements are conducted to quantify the presence of activity, if any. The results of the termination bioassay measurements are used to update the employee's final exposure records.

In the event that potential intakes are found to exceed the ALIs, the bioassay results may be evaluated to account for specific considerations. For example, such considerations include taking into account the physical and chemical characteristics of the nuclides involved and the individual's physical and biokinetic processes. The RSO will determine, based on nuclide excretion and retention data, whether the exposed individual differs significantly from the standard metabolic model.

In some instances, it may be required to seek medical assistance to prevent an intake, enhance excretion rates, or take care of serious injuries. For example, thyroid blocking agents (e.g., KI) may be prescribed to minimize radioiodine uptake in the thyroid. For a large tritium uptake, a diuretic may be administered along with forced fluids to increase the urination rate. For bone seekers, a chelating agent may be administered shortly after the intake. Any recommendations addressing the use of prescribed agents will be conducted by a medical doctor with the full and informed consent of the employee. The NRC will also be notified of such actions.

Employees who are administered radioactive materials as a result of diagnostic or therapeutic procedures (e.g., radioiodine) under the control of a physician should report to the RSO. If necessary, the RSO will determine if work with radioactive materials is to be temporarily restricted. This determination will be based on the capability of monitoring methods to distinguish exposures from medical procedures and radioactive materials used in R&D activities.

V.C.5 Surveillance

The RSO will monitor and evaluate all external and internal exposures. As part of the routine surveillance activities, the RSO will evaluate monthly exposures against past facility activities. Trends, if any, will be noted and corrective actions will be recommended to each Research Division and/or site.

In addition, the RSO will conduct a yearly review and evaluation of

all personnel exposures. This evaluation will be contained in an annual report to management and the Radiation Safety Committee. Section V.D.11 presents the surveillance program.

V.D. Environmental Release Evaluation

Radionuclides utilized in R&D activities at the Transcell facility may be subjected to any of the following fates:

1) storage as a research product for subsequent uses. This includes transfers to other licensed research facilities.

2) disposal as low-level radioactive waste at a licensed waste disposal facility;

3) Storage for radioactive decay at the site; or

4) Shipment for waste processing at a licensed facility. Waste processing includes the treatment of spent liquid scintillation fluids, supercompaction, incineration of de-regulated waste, etc.

In addition, small amounts of radioactive materials handled at this facility may be discharged in liquid and gaseous effluents. Such discharges will be maintained within the limits set forth in Parts 20.1301, 20.1302, 20.2107, Appendix B Table 2. As was noted in Section II.B, all research activities will be initially reviewed and approved by the RSO. Under this process, before any experiment is allowed to proceed, each phase of the research activities will be evaluated and the necessary radiological control measures will be identified and specified in the research protocol.

V.D.1 Liquid Effluents

Trace levels of liquid radioactive materials will be disposed of into the sanitary sewage system in accordance with 10 CFR, Parts 20.2003, 20.2007, 20.2108, Appendix B Table 3 limits, and 20.2005. Effluents will typically consist of low-specific activity labware and glassware washings, rinses, etc. The total annual quantity of H-3 and C-14 will be limited to 5 and 1 Ci per year, respectively, and 1 Ci per year for all other radionuclides combined.

Whenever practicable, short-lived radionuclides will be collected and stored for radioactive decay. Similarly, long-lived radionuclides will be solidified and stored or disposed of as low-level waste. Discharges from other liquid effluents into surface

streams or water bodies are not authorized. Accordingly, the requirements given in Part 20.1302 and Table 2 Column 2 of Appendix B are not applicable in the context of routine effluent releases into the sanitary sewer systems.

Based on projected practices, it is estimated that the following amounts of liquid waste will generated. Only aqueous waste will be released to sewers. Solvents and other organic waste will be solidified and disposed of laboratory waste or incinerated at an offsite facility.

It is anticipated that future releases will be maintained to within similarly small fractions of NRC limits. The expected releases are:

Source	Amounts L/yr.	Disposition	Average Daily Dilution Factor
Synthesis			
- Aqueous:	4	sewer,	$\sim 10^6$
- Solvents:	11	evaporation, solidification, incineration at an approved facility	n/a
Bioanalytical			
- Aqueous:	100	sewer,	$\sim 10^5$
- Solvents:	50	evaporation, solidification, incineration at an approved facility	n/a

The dilution factors are based on an average daily effluent flow rate of 2,100 gallons (7,948 L), based on design assumptions.

V.D.2 Gaseous Effluents

Small quantities of the more volatile radionuclides, such as H-3, C-14 and radioiodines, will become airborne during the conduct of research activities. The amounts which become airborne depend on the physical and chemical forms of the radioisotopes and the process being used.

All volatile nuclides and processes which could result in gaseous

effluent releases in excess of the limits specified in Parts 20.1301, 20.1302, 20.2107, and Part 20, Appendix B, Table 2, Column 1, will be performed in vented fume hoods or enclosures. Such experiments will be conducted in designated exhaust ventilation systems equipped with sampling systems and charcoal and/or particulate filtration, as determined by the RSO.

Airborne releases to unrestricted areas will be limited to Part 20, Appendix B, Table 2, Column 1 concentrations. Grab and/or continuous sampling from effluent discharge stacks will be performed to confirm the effectiveness of emission control system(s) and demonstrate compliance with NRC regulations.

Gaseous effluents from Transcell facilities are difficult to predict due to the varied nature of R&D activities. However, it is expected that such releases will be minimal to non-measurable as most of the R&D work will involve non-volatile compounds. In view of these practices and atmospheric dilution to unrestricted areas, it is anticipated that releases will be maintained within a small fraction of the limits for unrestricted areas.

V.E. Radiological Sampling and Monitoring

The requirements to conduct radiological sampling and monitoring are contained in 10 CFR 20, Parts 20.1302, 20.1501, 20.1502, 20.2103, 20.2106, and 20.2107. The surveys will be conducted to assess the potential hazards in handling radioactive materials, effluent releases, processing and storage, disposal, and shipment. As was noted in Section II.B, all research activities will be initially reviewed and approved by the RSO. Under this process, before any experiment is allowed to proceed, each phase of the research activity will be evaluated and necessary controls will be specified in the research protocol.

In addition to assessing radiological conditions, such evaluations also include surveillance and monitoring of laboratory areas and other facilities or equipment as well as making measurements of external radiation exposure rates, surface contamination levels, and analyzing airborne or sewer effluents. The surveys will be conducted at specific intervals, during research activities, when using or handling radioactivity, and after completing work to verify that no radioactive materials have been spilled or released.

V.E.1 External Radiation Exposures

External radiation surveys will be conducted in areas where exposure rates, and resulting deep-dose equivalent (DDE), could exceed one or more of the following conditions, when:

a) Whole body exposures could exceed 250 mrem/yr;

b) Extremity exposures could exceed 2,500 mrem/yr;

c) Skin exposures could exceed 2,500 mrem/yr;

d) Exposures to the eye (lens) could exceed 750 mrem/yr;

e) Working with an unshielded source which could produce gamma or beta absorbed dose rates exceeding 0.5 mrem/h at 0.3 meter;

f) It is known or suspected that whole body exposure rates of 100 mrem/hr or greater exist;

g) Whole body exposure rates in any controlled areas could exceed 5 mrem/h or results in a dose in excess of 250 mrem per year;

h) Whole body exposure rates in any uncontrolled areas could exceed 2 mrem/h or result in a dose in excess of 50 mrem in any one year;

I) Deemed necessary by the RSO or designated representative to supplement existing survey results.

Routine survey frequencies will be conducted, based on Regulatory Guide 8.21 (Health Physics Surveys for Byproduct Materials at NRC-Licensed Processing and Manufacturing Plants, Rev. 1, October 1979) and Part 20.1003, under the following schedule:

<u>Weekly</u>

- Weekly in the RSO's Lab and immediately adjacent areas where radioactive materials are used and stored.

- If the source of activity could exceed 50 mrem/h at 30 cm,

Monthly

- If the source of activity could exceed 0.5 mrem/h at 30 cm, or

Monthly

- For any and all other conditions for which the above two conditions do not apply.

Semiannually

- Verification of location and inventory of all radioactive materials used in R&D activities.

- Accountability and leak tests of all sealed sources, when used.

Radiation surveys will also be conducted by the research staff in support of research activities whenever handling, dispensing, or processing radioactive materials. These requirements will be established by the RSO or his/her designee commensurate with the anticipated work activities.

The conduct of routine surveys will not be used to verify routine compliance with the exposure limits of Part 20.1201 and 20.1301. Thermoluminescent dosimeters and/or film badges will be issued for this purpose. In the event of an accidental loss of dosimetry data (e.g., as a result of losing the dosimeters or due to physical or chemical damage), radiation survey results will be used in conjunction with doses received by co-workers. Occupancy factors may be used to derive estimated exposure durations and doses. Survey results will also be used to supplement personnel monitoring data when it is required to identify exposure trends, changes in radiological conditions, to ensure that all personnel are adequately monitored, and to verify that all postings reflect current radiological conditions, based on Part 20, Subpart J. The RSO will review all completed radiation survey results and make the necessary recommendations.

Completed survey forms will be maintained for a period of three years in accordance with Part 20, Subpart L requirements. If survey results are used to backup or document personnel exposures when dosimetry data are not available, these results will be retained indefinitely or until the NRC authorizes their disposition.

V.E.2 Airborne Concentrations

Airborne radioactivity will be monitored with air samplers whenever materials are handled in non-encapsulated forms that could result in internal exposures or intakes above 10% of the limits specified in Parts 20.1201 to 20.1203, Column 3, Table 1 of Appendix B, Subpart F to Part 20. The air sampling program will be structured using the guidance of Regulatory Guide 8.25 (Air Sampling in the Workplace, Rev. 1, June 1992), Regulatory Guide 8.21 (Health Physics Surveys for Byproduct Materials at NRC-Licensed Processing and Manufacturing Plants, Rev. 1, October 1979) and NUREG-1400 (Air Sampling in the Workplace, 9/1993).

Air sampling will be conducted under any of the following conditions, when:

a) Handling radioactive material (unsealed form) in quantities greater than 10,000 times the inhalation ALI.

b) Internal exposures could exceed 10% of the inhalation ALI.

c) A "declared pregnant" worker could exceed 50 mrem (CEDE).

d) Verifying that air concentrations are low and sampling is not needed, i.e., for concentrations <0.01 DAC.

e) Concentrations are likely to exceed 0.1 DAC, averaged over 40 hours, or longer.

f) Demonstrating that air sampling is representative of the breathing zone if the ALIs are based on air sampling results and concentrations are likely to exceed 0.3 DAC, averaged over 40 hours.

g) Verifying conditions or before resuming work if the resulting intakes could exceed 40 DAC-hours in one week. Credit may be taken for protection factors, if respirators are used in accordance with 10 CFR, Part 20, Subpart H requirements.

h) Verifying conditions or before resuming work if the resulting intakes could exceed 40 DAC-hours in one day. Credit may be taken for protection factors, if respirators are used in accordance with 10 CFR, Part 20, Subpart H requirements.

i) Whenever volatile or resuspendable radionuclides are handled, dispersed, or processed in non-encapsulated forms out of ventilated hoods and enclosures;

j) A spill has occurred or when surface contamination has been detected in levels high enough or is associated with volatile or resuspendable nuclides which could result in airborne radioactivity.

k) Whenever deemed necessary by the RSO or designated representative.

Air samples will be collected by continuous or intermittent grab sampling using particulate filters, traps, and/or carbon absorber cartridges. Tritium and C-14 air sampling will be conducted using traps (bubblers and desiccants). Samplers will be located at representative locations to characterize typical working environments, and average and maximum airborne concentrations. Breathing zone samples will be taken by using lapel samplers, or their equivalent. Such locations include work stations in front of hoods, dispensing areas, analytical equipment, radioactive material stocks, waste storage areas, exhaust ducts, etc. The RSO will establish the location, numbers, sampling and analytical frequencies, and type of air samplers to be deployed throughout each laboratory or site.

Posting requirements will also be updated after reviewing survey results to reflect current radiological conditions, as specified in Part 20.1902. The results of the air sampling program will be documented and retained in permanent files and in accordance with Part 20, Subpart L. Survey results are retained for a minimum of three years, while those surveys which are used to assess or backup personnel exposures are kept indefinitely or until the NRC authorizes their disposition.

V.E.3 Surface Contamination

Routine surface contamination surveys will be conducted throughout each radiologically controlled area and also in the adjacent areas which are not radiologically controlled. Survey requirements are defined in Parts 20.1501 and 1502, Subpart F of Part 20, Regulatory Guide 8.21 (Health Physics Surveys for Byproduct Materials at NRC-Licensed Processing and Manufacturing Plants (Rev. 1, October 1979). Surface contamination surveys include both removable and fixed contamination.

Survey frequencies will be conducted as follows:

a) Weekly in the RSO's Lab and immediately adjacent uncontrolled areas where radioactive materials in non-encapsulated forms are used and stored, and in any other labs using ≥200 µCi at any one time.

b) Monthly in all designated and controlled areas and uncontrolled areas adjacent to controlled areas where radioactive materials in non-encapsulated forms are used in amounts less than 10 times the quantities of App. C to Part 20 or ≤200 µCi at any one time, whichever is less.

c) At the end or completion of each research test or experiment which involves direct handling, dispensing, processing, or movement of radioactive materials in non-encapsulated forms.

d) At the end of each day or shift whenever a process or test is anticipated to last more than one shift or day;

e) Whenever a spill has occurred or it is known or suspected than any area and/or item are contaminated;

f) Whenever it is known or suspected that personal clothing or skin is contaminated;

g) Whenever airborne concentrations have been detected which could result in internal exposures or intakes in excess of the requirements identified in subsection V.E.2, above.

h) Whenever deemed necessary by the RSO or designated representative to supplement current survey frequencies.

I) Removable Contamination

Loose surface contamination surveys are conducted by taking smears on surfaces which are known or suspected to be contaminated. Such surfaces include bench tops, floors, work station areas, walls, equipment, exposed surfaces within hoods, personnel traffic zones, etc. In addition, such surveys also consider areas or locations which are known to be likely mechanisms for the transfer of contamination. Such areas include door knobs, door push plates or handles, entrance ways, instrumentation and equipment control knobs, valve handles, light switches, etc.

Surface contamination surveys are conducted using two techniques: smear and direct scan surveys using portable radiation survey meters. Smears are taken over a 100 cm^2 (4 in. by 4 in.) area and counted using the appropriate analytical equipment. Smears may be taken by using wet or dry filter papers. H-3, C-14, and P-32 are counted using liquid scintillation. Gamma emitting radionuclides, such as I-125, are counted using gamma scintillation counters. Direct surveys are conducted using G-M tubes (pancake), proportional detectors, and gamma and beta scintillation probes. A list of equipment, detection, and response characteristics are described in Section IV, Table IV-3.

The results are documented on forms depicting the area surveyed. Diagrams for each area or laboratory are provided with each form providing the following information: location, authorized user, make, model, type and serial number of counting instrument, radionuclides checked for, efficiency of counter, "action level" by radionuclides, system detection efficiency, background count-rate, smear test results (gross count-rate), surveyor's signature, and date of survey.

Areas where swipes were found to exceed the action level will be cleaned up and surveyed again thereafter. All survey results will also be compared to the limits given in Table V-1. Appropriate recommendations will be provided commensurate with survey findings. Posting requirements will also be updated accordingly in accordance with 10 CFR, Part 20, Subpart J.

ii) Fixed Contamination

Fixed surface contamination is defined as radioactivity remaining on surfaces or items after repeated decontamination attempts have failed to remove or significantly reduce contamination levels. In order to assess the presence and levels of fixed surface contamination, smear and direct survey techniques are used together. Smears are used to determine the levels of loose or removable contamination, while direct readings are used to assess the presence of loose and fixed contamination. Accordingly, fixed contamination surveys will always be conducted using both techniques. Measurement and analytical considerations are identical to those described above for removable contamination. Documentation requirements are also identical to the methods noted above for removable contamination.

Table V-1 Removable and Fixed Surface Contamination Limits[a]

Surface and Condition	Beta/Gamma/X-ray Emitters[b] $\mu Ci/cm^2$	dpm/100 cm^2
Restricted areas	10^{-4}	2,200
Protective clothing worn in restricted areas	10^{-4}	2,220
Unrestricted areas	10^{-6}	222
Personal clothing worn out of restricted areas	10^{-6}	222
I-125 Removable©	10^{-7}	20
Skin[d]	$<10^{-6}$	<222
Fixed surface contamination	Average of 0.2 mrad/h at 1 cm and not exceeding 1 mrad/h at 1 cm, for all emitters.	

(a) Adapted from Regulatory Guide 8.21, Table 2, Oct. 1979, Rev. 1, and Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for By-Product, Source, or Special Nuclear materials, August 1987, U.S. NRC.

(b) Measurements should not be averaged over areas greater than 1 square meter.

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(d) Skin and personal clothing contamination should always be maintained within non-detectable levels. Skin and personal clothing will be monitored and any contamination will be washed off when detected regardless of the levels. It should noted that in attempting to remove any contamination, the skin should not be abraded so as to introduce or increase radioactivity uptake.

Depending upon the area or item being surveyed, consideration will be given to the detector and surface counting geometries given radionuclide emissions, and whether or not the surface or items being surveyed have inaccessible areas. Such inaccessible areas include, for example, knurled or finished surfaces, scratches, recessed surfaces, internally inaccessible openings, ports, etc. In such instances it may be necessary to dismantle such items or to discard them if it cannot be assured that all areas have been adequately monitored.

Appropriate recommendations will be provided commensurate with survey findings. Table V-1 presents acceptable limits. Posting requirements will also be updated accordingly in accordance with 10 CFR, Part 20, Subpart J regulations. Survey results will be maintained for at least three years. Survey results which are used to assess or backup personnel exposures will be retained indefinitely or until NRC authorizes their disposition.

V.E.4 Personnel Survey and Frisking

Research and other personnel routinely or periodically entering radiologically controlled areas will be required to monitor themselves while working and upon exiting. Monitoring requirements include self or assisted whole-body or extremities frisks using the provided monitoring equipment.

Such surveys will be conducted as follows:

a) Whenever it is known or suspected that personal clothing or skin has become contaminated;

b) Periodically during research activities or when handling, processing, dispensing radioactive materials;

c) Whenever handling or using volatile or resuspendable radionuclides;

d) Whenever leaving a controlled area (i.e., where unsealed materials are being used);

e) After removing protective clothing such as gloves, lab coat, coveralls, shoe-covers, respirator, or any other forms of protective clothing;

f) After being exposed to known or suspected elevated airborne activity concentrations;

g) Prior to going on a break, lunch, and at the end of each shift or workday;

h) During and following skin or personal clothing decontamination;

I) After a spill has occurred;

j) Whenever it is known or suspected that radionuclides have been inhaled or ingested; and

k) Whenever directed by the RSO or designated representative.

When conducting such surveys, particular attention will be paid to the nose, mouth, facial hair, hands and fingers, elbows, seat of the pants, knees, shoes and pockets. Depending upon the area surveyed and nuclides, the detector will be passed over the skin or clothing at a slow rate (ca <10 cm per second), knowing the response characteristics of the detector and ratemeter. Any clothing, skin, or hair found to be contaminated will be cleaned up (see Table V-1). Clothing (personal or protective) will be handled accordingly with contamination levels, nature of radionuclides, and whether or not the clothing is disposable.

Any skin decontamination will be conducted under the direct supervision of the RSO or medical surveillance. Decontamination measures will not be continued if further attempts fail to yield significant reductions in levels or threaten to irritate the skin. Decontamination without supervision is restricted to washing using a mild soap and water. Invasive decontamination or surveying of nose, mouth, eyes, etc., will be conducted under medical surveillance using approved procedures and trained personnel. Emergency response support services for injured and contaminated workers have been secured with local hospitals. Attachment 3 presents letters of intent from nearby hospitals.

If residual skin contamination levels remain, the individual will be released. However, periodic surveys will be conducted to monitor the effective biological removal and uptake. Bioassay sampling and analyses will be performed depending upon the route of entry and nuclides. The bioassay program will include urine and fecal sample analyses and thyroid scans, if needed. Since the research staff will be handling millicurie quantities of non-encapsulated radioactive materials, periodic bioassay analyses will be performed annually.

The results of such analyses will be documented in accordance with

10 CFR, Part 20, Subparts F and L, and retained in personnel exposure records for an indefinite time period or until the NRC authorizes their disposition.

V.E.5 Survey of Equipment Prior to Release for Unrestricted Use

Any item, equipment, materials, tools, components, furnishing, etc., when taken out of controlled areas for unrestricted use will be surveyed to ensure that surface alpha/beta/gamma contamination levels (loose and fixed) are within the contamination limits given in Table 1 of Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for By-Product, Source, or Special Nuclear Materials, U.S. NRC, August 1987.

If any contamination is measured, decontamination procedures will be initiated until repeated additional efforts do not significantly reduce the contamination levels. Rather than just reaching or meeting the decontamination criteria, efforts will be made to reduce the contamination to within non-detectable levels, whenever possible. Surveys will be conducted using both smears and direct survey measurements. The survey form will also indicate whether the item will be returned to controlled areas, the recipient or custodian, and its ultimate disposition. For components which must be disassembled for survey, a parts breakdown will be provided with survey results documented for every part. The survey results will be retained for three years and in accordance with Part 20, Subparts F and L requirements.

V.E.6 Survey of Packages Received and Prepared for Shipment

External radiation and surface contamination surveys will be conducted on packages received or intended for shipment at the receiving/shipping dock or staging area to minimize unwarranted radiation exposures and inadvertent contamination. All such packages will be surveyed to verify compliance with NRC requirements under 10 CFR, Parts 20.1906 and 20.2006, Appendix F to Part 20, and DOT regulations under 49 CFR, Parts 170 through 189. All radioactive materials bearing "Yellow-II" or "Yellow-III" labels will be transported by cart to minimize personnel exposures. Incoming packages containing significant amounts of volatile or resuspendable radioactive materials will be inspected in vented fume hoods or enclosures.

In addition to conducting the necessary radiological surveys, each

package received or destined for shipment will be inspected for leakage, damage, proper labeling and proper closure. Packages awaiting shipment will be stored in a designated area of the loading dock and the area will be surveyed, monitored, posted, and kept under lock, if necessary, accordingly with the ambient radiation levels.

All allowable surface contamination limits and radiation exposure rates are as follows:

a) Beta/gamma nuclides: 10^{-5} µCi/cm^2 or 2,220 dpm/100 cm^2. The RSO will be notified whenever exceeding 220 dpm/100 cm^2.

b) Alpha emitting nuclides: 10^{-6} µCi/cm^2 or 220 dpm/100 cm^2. The RSO will be notified whenever exceeding 22 dpm/100 cm^2.

c) Whenever removable surface contamination levels in excess of 10^{-4} µCi/cm^2 or 22,200 dpm/100 cm^2 are observed on incoming packages, the RSO will immediately notify by telephone the carrier, shipper, and the NRC.

The allowable surface and index radiation exposure rates are as follows:

a) Label White-I: less than 0.5 mR/h at any point on the external surface of the package.

b) Label Yellow-II: less than 50 mR/h at any point on the external surface of the package and 1.0 mR/h or less at 1 meter.

c) Label Yellow-III: less than 200 mR/h at any point in the external surface of the package and less than or equal to 10 mR/h at 1 meter from the package.

V.E.7 Radiation Posting, Labeling, and Control

Whenever radiation and contamination surveys are conducted, the RSO will ensure that all postings and labeling are properly updated and legible. This function will also ensure that notices to workers are posted and copies of all licenses are made available to the staff under 10 CFR, Parts 19.11, 19.12, and 20.1901 to 20.1905. Routine requirements include posting radiation areas, controlled contamination areas, radioactive materials and waste storage areas, and airborne contamination areas.
The established posting and the radiological conditions requiring it

will be documented in radiation survey forms. All survey results will also be made available to all personnel requiring access to such areas.

V.E.8 Sealed Source Leak Tests

When used, sealed sources containing more than 100 µCi of beta-gamma emitting by-product materials with a half-life of more than 30 days will be tested for contamination or leakage at a six-month interval. Sealed sources containing more than 10 µCi of alpha emitting material, and designed for the purpose of emitting alpha particles, will be tested for contamination of leakage at a three-month interval. The contamination must not exceed 0.005 µCi per test or smear. If the leak test reveals contamination levels greater than 0.005 µCi, the source will be withdrawn from use, repaired, decontaminated, disposed of in accordance with NRC requirements, or returned to the manufacturer. Surveys may be conducted using test kits supplied by manufacturers. All such survey results will be documented and retained for three years and in accordance with 10 CFR, Part 20, Subparts F and L.

V.E.9 Exhaust Ventilation Survey and Testing

Fume hoods and ventilated enclosures will be surveyed yearly to verify that adequate ventilation face velocity is maintained at 100 fpm or more, based on multiple measurement points across the hood face. For ventilated enclosures, single measurements will made at each access port. The survey will also include noting filter differential pressures, verifying air flow rates, that hood sash travel is free and unrestricted, that ventilated enclosures are maintained under negative pressure, and that access ports and makeup air are unrestricted.

Filter collection efficiency testing will be conducted whenever it is safe to do so. Stored radioactive materials will be temporarily relocated to conduct such tests. Filter collection and absorption efficiency tests, however, may be conducted in parallel with research activities, wherever the appropriate radionuclides are being used, e.g., radioiodines.

Surveys will be conducted using properly calibrated velometers and/or thermo-anemometers by Transcell or qualified contractor. All such survey results will be retained for at least three years and in accordance with 10 CFR, Part 20, Subparts F and L.

V.E.10 Effluent Monitoring

Radioactive effluents released to unrestricted areas from both designated hoods (No. 502 and 512) will be monitored on as needed basis to ensure that the limits given in 10 CFR, Part 20, Appendix B, Table 2, Column 1, are not exceeded. Sources of radioactivity may originate from various R&D activities, involving both volatile and non-volatile compounds. The RSO will determine when such monitoring is required.

Liquid effluents may originate from bench sinks and hood cup-sinks. All sewer discharges will be controlled to ensure that the limits given of Part 20, Appendix B, Table 3, and 20.2003 and 20.2005 are not exceeded. Additional requirements (see Part 20.2007) may be imposed in response to State and local regulations.

As was noted in Section II.B., all research activities will be initially reviewed and approved by the RSO. Under this process, before any type of experiment is allowed to proceed, each phase of the research activity will be evaluated for radiological considerations and the necessary control measures will be established for both liquid and gaseous effluent releases.

The description of the airborne and liquid effluent monitoring program are discussed separately below.

1. Airborne Effluents

Ventilation exhaust effluents from designated release points will be monitored for particulates and radioiodine emissions. In each case, the selection of releases points and sampling methods and durations will reflect whether radioactive materials are being used and facility specific ventilation system features. The following description is typical of the approach used in monitoring and assessing airborne radioactive releases.

A typical sampling system consists of the following components:

a) A sampling probe is installed into the air duct past, i.e., downstream of the filter housing, when installed. The sampling probe is installed in a section of the ductwork where the air flow stream is the least disrupted. The diameter of the sampling probe is selected to provide near-isokinetic sampling for a range of anticipated system exhaust and sampling flow rates.

b) The sampling filter train is connected as closely as possible to the sampling probe. The filter train consists of a particulate filter paper followed by an activated carbon cartridge. The filter train typically consists of a single unit equipped with quick disconnects to facilitate changes.

c) The sampling flow rate is measured by a calibrated flow rotameter. The range of the flow rotameter is adjustable to cover the range of anticipated system exhaust and sampling flow rates.

d) The vacuum pump is the last component of the sampling system. The actual flow rate is set to the required setting to maintain near-isokinetic sampling conditions.

Particulate filters and activated carbon cartridges will be replaced and analyzed after each sampling period. The sampling and analytical frequency will be adjusted to reflect the use of short or long-lived nuclides, as is necessary. Air sample analyses will consist of a gross-beta or gamma counts of particulate filter papers. Predetermined gross-beta and gamma count-rates will be established as action levels above which more sophisticated analytical techniques will be used to identify specific nuclides. Carbon cartridges will be directly analyzed for I-125, e.g., during or after iodinations. A gamma counter will be used for such analyses.

The predetermined action level (for gross-beta or gamma activity) will be derived taking into account stack exhaust flow rates, sampling flow rates, anticipated sampling device collection efficiency, system counting efficiency, and applicable limits. Based on a weekly replacement schedule, the anticipated activity on the particulate filter paper and carbon cartridge will be estimated assuming a 90% collection efficiency and selecting 10% the limit to account for sampling and counting uncertainties.

Any filter or carbon cartridge which exceeds the specified action levels will be subjected to more rigorous analyses in order to identify the source of activity. The analyses will be performed in-house and, at times, by licensed commercial laboratories, and for QA/QC purposes. For areas where iodines are routinely used, the particulate filter and carbon cartridge will be analyzed weekly. Corresponding action levels will be developed for other release points and nuclides, as needed. Sampling flow rates, volumes, and counting times will be adjusted to reflect actual conditions and to ensure that all action levels have been met.
The results of the particulate filter or carbon cartridge analyses

will be compared against allowable concentrations for known radionuclide(s), or against the most restrictive limits, if the identity of each nuclide cannot be identified in the mixture, the following procedure will be used:

a) If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture will be the most restrictive DAC of any radionuclide in the mixture.

b) If the identity of each radionuclide in a mixture is not known but it is known that certain radionuclides specified in Appendix B are not present in the mixture, the DAC for the mixture are the lowest values specified in Appendix B for any radionuclide that is not known to be absent from the mixture; or for situations in which it is not possible to identify any nuclides, a default limit of 1.0×10^{-12} µCi/mL will be used, based on the provisions of App. B, Note 2, Table 2, Column 1.

c) If tne identity and concentration of each radionuclide in a mixture are known, the limiting value should be derived as follows: for each radionuclide in the mixture, determine the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B for the specific radionuclide when not in the mixture. The sum of such ratios for all radionuclides in the mixture may not exceed "1", i.e., unity.

Any concentrations noted at the point of release which exceed 10% of the limits, based on any consecutive 12 months, will be evaluated to determine whether or not such releases are ALARA. In any case, the recording and reporting requirements under 10 CFR, Parts 20.2107, 20.1301, 20.2202, and 20.2203 regulations will be observed whenever radioactive materials concentrations in unrestricted areas exceed the stated limits. As was noted in Section IV.B, the roofs of the buildings where effluent stacks are located will be considered as unrestricted areas for the purpose of demonstrating compliance. However, access to the roof will be administratively controlled.

2. Liquid Effluents

Liquid effluents will be monitored at the time of release at designated sink(s). Samples will be collected and composited and analyzed monthly, depending upon radionuclide half-lives. A more frequent schedule may be establish by the RSO, as conditions warrant. No liquid radioactive waste will be discharged in sinks unless:

a) it is readily soluble and dispersable biological material in water.

b) it has been or is being diluted with additional water at the time of discharge in the sink.

c) the radionuclide concentration and/or quantity limits posted for that sink have been met.

This procedure will be used for bulk quantities of liquid waste with concentrations expected to be $\geq$1/4 of the limits of Table 3 to Appendix B, with the exception of I-125 or I-131. When in use, the RSO will establish specific limits for radioiodines. The amounts of radioactivity associated with liquid waste generated as dilute washes and rinses containing only very low concentrations ($<10^{-3}$ µCi/mL) will be recorded as estimates, based on R&D protocol or process knowledge.

Additional sampling may be performed at other selected points (e.g., clean out traps) to identify and characterize specific releases or effluent streams, as warranted by conditions. These requirements will be established on case-by-case basis by the RSO. Effluent flow rates will be established monthly using facility water flow meter readings or water consumption reported on invoices from the local water utility. Radioactive materials inventory released into sewers will be established by recording each radionuclide and its respective activity. Sampling and analytical frequencies will be adjusted to reflect the presence of short-lived radionuclides.

Sample analysis will consist of LSC, gross-beta, or gamma counting using appropriate sample volumes and counting times to meet the required MDC, $\leq$10% of the limits of Table 3 to App. B. Pre-determined action level count-rates will be established to determine when more sophisticated analytical techniques will be used to identify and quantify specific radionuclides. Action levels will be derived based on a review of 10 CFR, Part 20, App. B, Note 2 to Table 3, and the requirements of Part 20.2003 for releases into

sanitary systems. The derivation of any action levels are based on using 10% of the limit to account for sampling and analytical uncertainties. For radionuclides that are known to be present or readily identifiable, their respective limits will be used accordingly.

Water sample volumes, analytical techniques, and counting times will be adjusted to ensure that the derived action levels can be met. For the most routinely used radionuclides (e.g., H-3 and C-14), the analyses will be performed using liquid scintillation counting (LSC) systems. Other analytical techniques (e.g., gross-beta, gamma counting, or gamma spectroscopy) will be used as is required for specific radionuclides. Such analyses will be conducted in-house or performed by licensed commercial laboratories, and for QA/QC purposes.

The results of composite (e.g., monthly) sample analyses will be evaluated and compared against Part 20 Appendix B, Table 3 limits, and the requirements addressing disposal by releases into sanitary sewerage systems under Part 20.2003. If the radionuclide is known, the evaluation will be based against each nuclide's concentration limit. If any radionuclide cannot be resolved or identified in the mixture, the following procedure will be used:

a) If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the limit for the mixture will be the most restrictive concentration of any radionuclide in the mixture.

b) If the identity of each radionuclide in a mixture is not known but it is known that certain radionuclides specified in Appendix B are not present in the mixture, the effluent concentration for the mixture is the lowest value specified in Appendix B for any radionuclide that is not known to be absent from the mixture; or for situations in which it is not possible to identify any radionuclides, a default limit of 1.0×10^{-5} µCi/mL will be used, based on the provisions of Appendix B, Note 2, Table 3.

c) If the identity and concentration of each radionuclide in a mixture are known, the limiting value will be derived as follows: for each radionuclide in the mixture, determine the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B for the specific radionuclide when not in the mixture. The sum of such ratios for all radionuclides in the mixture may not exceed "1", i.e., unity.

Furthermore, the requirements established for releases in sewers will be observed with respect to the solubility of radioactive materials; dilution volumes; radioactive material concentrations and total quantity; and yearly activity limits of 5 Ci for H-3, 1 Ci for C-14, and 1 Ci for all other radionuclides combined. Any concentrations noted at the point of release exceeding the allowable limits, based on average monthly water releases, or other requirements of Part 20.2003, will be evaluated to determine whether such releases are ALARA. The recording and reporting requirements of Parts 20.1302, 20.2107, 20.2202, and 20.2203 will be observed whenever concentrations and material quantities released in unrestricted areas exceed the limits. All files and records will be maintained in accordance with Part 20, Subpart L.

V.E.11 Radiological Surveillance

The major objective of the radiation protection program is to maintain radiation exposures ALARA by emphasizing that doses should be kept well below NRC limits. As was noted in Section II.B, all research activities will be initially reviewed and approved by the RSO. Under this process, before any type of experiment is allowed to proceed, each phase of the research activity will be evaluated and the necessary radiological control measures will be specified as part of the research protocol.

Routine and scheduled radiological surveillance will be conducted by the RSO or designated representative to ensure that this operational concept is observed, based on 10 CFR 20, Parts 20.1501 and 20.1502 requirements. The requirements of Part 20.1601 will be implemented whenever high radiation areas are present. Given the possession limits authorized under this license, the access control requirements of 20.1602 and 20.1603 do not apply. Radiological surveillance consists of observing and monitoring radiological working conditions.

These surveillance activities are incorporated and conducted during, for example, radiation and contamination surveys. Scheduled surveillance will involve conducting inspection tours, audits, or reviews of selected aspects of research activities or LLW management program. Scheduled surveillance, for example, may target radioactive materials inventory, review of procedures, low-level waste storage, the training program, emergency contingency plans, etc., on a rotating cycle.

1. Routine Surveillance

Routine surveillance will be conducted by the RSO or his/her designee during the conduct of routine surveys and in the course of discharging their functions. The objectives will be to:

a) identify ways to prevent and minimize radiation exposures whenever practical and cost-effective,

b) provide technical and regulatory guidance to the research staff,

c) select appropriate times for conducting radiological surveys or taking measurements,

d) observe and note general trends as to whether facility personnel are following good radiological work practices, established protocols, etc.,

e) identify methods to minimize LLW generation rates whenever practical and cost-effective, and

f) note conditions which may necessitate immediate corrective action.

In performing these surveillance activities, the RSO will be familiar with the varied research activities and potential radiological hazards associated with each.

2. Scheduled Surveillance

Scheduled surveillance will be conducted either as separate activities or incorporated in routine functions. The RSO will make all necessary arrangements to coordinate these functions with the department or division being targeted for evaluation.

Representatives of the department or division will be required to participate to provide the RSO with access to data or personnel and to convey to management an awareness of the nature and importance of these activities. The schedule will target the following topics:

- Review of radiation safety program - yearly
- Review of radiation safety training - yearly
- Review and evaluation of personnel exposure - yearly
- Review and evaluation of environmental releases yearly
- Review and evaluation of low-level radioactive waste generation, storage, and disposal practices - yearly
- Report to management, i.e., summary of above - yearly

Any findings and recommendations will be transmitted to the audited department and Radiation Safety Committee. The findings will be clearly detailed, whether or not procedural or regulatory violations exist will also be noted, and the appropriate corrective actions will be described. The findings and recommendations will be retained in the RSO files for three years. Findings involving personnel exposures will be permanently retained in files or until their disposition is authorized by the NRC. All files and records will be maintained in accordance with Part 20, Subpart L.

V.F. Instrument Calibration

All radiation detection equipment will be maintained and calibrated in accordance with the instrumentation calibration program. All calibration procedures will follow recognized and accepted industry practices. Table IV-3 presents the instrumentation list and calibration schedule.

V.F.1 Analytical, Bench Top, and Survey Instrumentation

All bench top and analytical instruments used to collect samples and perform analyses, such as smears, air filters, water samples, carbon cartridges, personnel friskers, scintillation counting, thyroid scanner, etc. will be calibrated by the RSO and/or research division to whom the equipment is assigned. All portable survey instruments will be calibrated annually. All bench top equipment and analytical instruments will be calibrated yearly.

Calibrations will be performed using sealed, plated, or solution sources. The calibration sources will be NITS/NBS traceable. Any standard prepared in-house will be fully documented. The calibration of instrumentation used to analyze smears, and air, water, and bioassay samples will be verified annually. All instruments will be checked prior to each use with check sources or other approved methods. Background count-rates will also be verified prior to each use. Any instruments, whenever defective, will be taken out of service and scheduled for repairs. All instruments will bear a calibration sticker indicating the next calibration due date. Each instrument will have a separate record log which will contain the following information:

- o Instrument make, model, and serial number.
- o Detector make, model, and serial number.
- o Manufacturer supplied certificates of calibration or repairs.
- o Date of calibration and next due date.
- o Description of troubleshooting findings and repairs for instrumentation which have failed.
- o Date returned to or taken out of service.

V.F.2 Exposure Rate Survey Instrumentation

All stationary and portable radiation survey instrumentation used to measure exposure rates will be maintained by the RSO. All calibration, however, will be performed commercially by:

Teledyne Brown Engineering
50 Van Buren Avenue
Westwood, NJ 07675
NRC License No. 29-00055-14

Such services may be secured from other qualified firms. Such equipment will typically include GM survey meters, self-reading dosimeters, etc. The vendor will provide with each instrument a certificate of calibration for two or more calibration points within the useful range of the instrument. A sticker will be affixed to each instrument showing the next calibration due date. The record keeping requirements for such instrumentation will be identical to those already noted above.

All files and records will be kept and maintained in accordance with Part 20, Subpart L requirements.

V.F.3 Other Instrumentation and Equipment

Other instrumentation such as air sampling pumps, air measuring devices (rotameter, velometer, etc.), lapel air samplers, liquid flow meters, etc. will be calibrated annually either in-house or will be performed commercially. The calibration will be performed using recognized procedures and methods. The record keeping and documentation requirements will be maintained as is described above and in accordance with Part 20, Subpart L requirements.

V.F.4 Radioanalytical Program

All radiological analyses and radiation monitoring will be performed using recognized industry practices and NITS (or NBS) traceable radioactive standards and sources.

V.F.5 Record Keeping Requirements

All calibration methods and procedures will be documented and retained in permanent files by the RSO, as required under Part 20.2103. The calibration results and instrumentation log for each instrument or groups of instruments will be retained for three years.

Instrumentation records used to determine occupational exposures and/or estimate personnel radiation doses, either for routine or accident conditions, and environmental releases will be permanently retained until their disposition is approved by the NRC.

V.G. Radioactive Materials Procurement and Storage

The requisitions for radioactive materials will be initiated by the Radiation Safety Supervisor authorized to possess and/or supervise their use. The requisition will be forwarded to the RSO for processing. Requisitions will be filled from materials already in stock, as is practicable. If a sufficient inventory is not on hand, the RSO will process the requisition in accordance with the licensed possession quantities noted in Section II, Table II-1. The procurement process will be centralized at the RSO's office.

V.G.1 Requisition and Approval Process

The RSO will verify that the requested radionuclide(s) and quantity are within the licensed possession limits. The facility inventory (decay corrected) will be reviewed to ensure that the requisition, when filled, will not exceed the site's total inventory limit. More specifically, the radioactive material inventory system will address the following:

- Materials in storage for decay
- Materials or stock held in storage
- Materials or stock in current use
- Materials contained in low-level waste
- External transfers (e.g., to other labs)
- Materials released via ventilation systems
- Incoming order(s) still outstanding
- Internal transfers (among R&D divisions)
- Materials released in lab sinks
- Materials awaiting disposal pickup by waste broker or processor

Once it has been established that the requested quantities are within the facility possession limits and that the requester is an authorized end-user, the RSO will approve the purchase requisition form and transmit it to the purchasing department for processing.

The purchase requisition will specify the following information:

- Name of vendor or supplier
- Radionuclide and atomic mass
- Activity in curie or millicurie at time of receipt
- Chemical and/or physical forms
- Requester's name and R&D division
- Transcell's NRC license number, and
- Name and phone number of the RSO

V.G.2 Radioactive Materials Receipt and Distribution

External radiation and surface contamination surveys will be conducted on packages received at the receiving/shipping dock to minimize unwarranted radiation exposures and inadvertent contamination of the facility and personnel. All such packages will be surveyed to comply with NRC requirements under 10 CFR, Part 20.1906, Part 20.2006, Appendix F to Part 20, and DOT regulations under 49 CFR, Parts 170 through 189.

Radioactive materials will be received at the Shipping and Receiving Dock. From there, materials will be sent directly to the RSO's Lab for inspection. In addition to conducting necessary radiological surveys, each package received will be inspected for leakage, damage, proper labeling, and proper closure (See Section V.E.6). Once the integrity of the package, contents, and quantities have been ascertained, the material will be accounted into the facility material inventory system. Once inspected, the material will be forwarded to the end-user depending upon the amount of activity and type of research activity or temporarily stored there. All radioactive materials bearing "Yellow-II" or "Yellow-III" labels will be transported by cart to minimize personnel exposures. Incoming packages containing volatile or resuspendable radioactive materials will be opened in vented hoods or enclosures.

All inventory files will be kept and maintained in accordance with Part 20, Subpart L requirements.

V.G.3 Radioactive Materials Storage and Shielding

All radioactive materials will be stored in closed containers within locked and placarded shielded storage cabinets or refrigerators/freezers. Additional shielded storage will be provided, as needed, by locating lead bricks/sheets and leaded and lockable storage containers in each laboratory. These requirements will be established by the RSO on a case-by-case basis. All posting and labelling requirements and storage control measures identified in Part 20, Subparts J and I criteria will be followed, as required.

All containers will be labeled to indicate their contents and the date of the initial or most current assay. Access to the storage rooms, cabinets, containers, etc. will be monitored and controlled by designated personnel (i.e., SRS and RSS), who will maintain a list of personnel authorized to use radioactive materials. An inventory will be maintained of all radioactive stock solutions, etc. in storage. All withdrawals and replenishments will be recorded in the inventory.

Empty containers, stock solution vials, or sealed sources which have decayed past their useful life will be removed periodically and disposed of as radioactive, medical, or chemical waste. All gaseous radioactive materials or compounds or those with high vapor pressures (e.g., H-3 as hydrogen gas, tritiated water; C-14 as CO or CO_2, and radioiodines) will be stored in sealed containers to prevent inadvertent releases. Ambient radiation levels in each room

or lab where radioactive materials are being stored will be monitored. The needs for air sampling and ambient radiation monitoring will be determined by the RSO.

All gamma-emitting radioactive stock solutions will be stored in closed containers and placed within shield enclosures to limit external radiation exposure levels within the storage facility or areas to less than 1 mR/h. The need for shielding will be determined by the RSO. In assessing the need for shielding, the RSO will consider:

- Radionuclide, half-life, quantity
- Specific gamma-ray constant
- Beta/gamma energies and yields
- Shielding materials thickness and layering
- Bremsstrahlung
- Shielding geometry
- Build-up factor
- Exit exposure rates
- Radiation survey requirements
- Posting and labeling

Whether any and all of the above factors need to be considered will depend upon specific applications, research needs, physical constraints, time-motion studies, extremity vs. whole-body exposure or dose accumulation ratio, etc.

V.G.4 Radioactive Materials and Waste Shipments to Other Facilities

Radioactive materials (e.g., waste or research products) may be shipped to other facilities. The shipments will be made as needed and, consequently, no schedule is established. The RSO will provide the oversight and identify technical requirements for such transfers. All shipments will be made in accordance with the requirements of U.S. Department of Transportation contained in 49 CFR, Parts 170 to 189. Shipments will be made using only unrestricted access highways. A shipping manifest, using the carrier's, will be used to initiate and verify the arrival of each shipment.

The shipping manifest system will identify:

a) The origin and destination of each shipment by site, building, research department, and contacts and phone numbers.

b) The physical, chemical, and radiological properties of the materials or waste being transferred. This characterization will also include volumes, weights, and types and number of containers.

c) All labeling and marking requirements specified in U.S. DOT 49 CFR, Parts 170 to 189, including vehicle placarding criteria.

d) Emergency instructions to use in the event road accidents and vehicle breakdown or theft.

The above information will be entered or attached to the form prior to shipment. All shipments will be performed using only commercial carriers and trained drivers. Privately owned employee vehicles will not be authorized for such uses.

V.H. Emergency Preparedness

The following subsections address and present the onsite and offsite emergency response requirements. The requirements identify the coordination of emergency response activities with local fire, police, and medical facilities. Letters of commitments are also included from nearby medical facilities for the treatment of contaminated and injured individuals. These emergency procedures are also supplemented by the Transcell Contingency Plan and Transcell Employee Safety Plan.

V.H.1 Offsite Contingency Planning

An emergency preparedness plan is not required since Transcell's possession limits are not in excess of the requirements given in 10 CFR, Parts 30.32 (i)(1) and 30.72, Schedule C. Section II, Tables I and II demonstrates that total radionuclide inventories will be below Schedule C limits.

V.H.2 Onsite Response

All individuals working at the Transcell facility will receive instructions in the proper response to unusual and emergency conditions. The instructions will address each of the major classes of events which could occur at the facility. Emergency response support for injured and/or contaminated workers needing medical care have been arranged with a local hospital. Attachment 3 presents a letter of intent from the local hospital.

The following outlines each class of event and general rules for responding to each event. It should be noted that in addition to these outlines, the Transcell Contingency Plan provides more detailed information and procedures.

a) Radiological Contamination Accompanied by Personnel Injury

- Evacuate personnel from the contaminated area.
- Depending on the extent of the injury, immediately administer first aid, or assist the injured individual out of the contaminated area and administer first aid. The first priority is proper medical care of injured individuals. If the individual is severely injured, wrap in blanket for immediate transport to hospital.
- Isolate the contaminated area and notify the RSO and/or local authorities designated on the emergency call list.
- Appraise the RSO of conditions and follow all given instructions.
- If airborne radioactivity is suspected, turn off all unnecessary ventilation systems, but leave fume hood and ventilated enclosure exhaust fans turned on.
- For injuries that are not life threatening, survey the injured individual for contamination and remove contaminated clothing and skin contamination by washing.
- All individuals in the area of the accident should be surveyed for external contamination and decontaminated, as required.
- Follow the directions of the RSO and other emergency personnel upon their arrival.
- Keep all persons away from the incident area except those immediately active in the emergency response team; detour vehicular and pedestrian traffic; and permit access only to those persons identified with emergency organizations and to those with official responsibility for site, buildings, equipment, or materials affected by the emergency. If it is necessary to clear a way for traffic through the incident area before a radiation monitoring team arrives, vehicles and debris should be identified for later monitoring.

- If it is known or believed that radioactive materials or waste containers have been damaged, it should be assumed that radioactive materials have been released and that personnel and property (e.g., equipment, vehicles, buildings, the ground) are contaminated until proven otherwise.

- The RSO or designated representative will initiate the necessary radiological surveys including, ambient exposure rates, air sampling, surface contamination, and personnel frisking and monitoring.

- The police or firemen will be provided with contact names and phone numbers for radiological assistance at the emergency scene. This information will be immediately available through the Radiation Safety Officer and security office.

b) Fires and Explosions

- Keep unnecessary people at least 150 feet upwind; greater distances may be necessary if advised by the RSO or designated representative, or on-site emergency coordinator.

- Isolate the affected hazard area and deny entry.

- Wear positive pressure breathing apparatus and full protective clothing.

- Detain persons and equipment exposed to radioactivity until instructions are issued by the RSO or designee.

- Delay clean-up until specific instructions are provided and support is available.

- In the event that radioactive materials are released in storm drains, on city streets, or county roads, inform local authorities, and the NRC.

- Do not move damaged containers. Move undamaged containers out of fire zone.

- For small fires, use dry chemicals, CO_2, water spray, or foam. For larger fires, use water spray or fog. For fires involving radioactive waste, coordinate all fire-fighting activities with the RSO or designee.

- Enter the spill area only to save life; limit entry to shortest possible time.

- Do not touch damaged containers or spilled material.

- Contain all spills with non-combustible absorbent material. Dam far ahead of the spill, including storm and sewer drains.

V.H.3 Reporting and Notification Requirements

The following summarizes the reporting requirements identified in Subpart M to 10 CFR 20. Before making any notification to the NRC, the most current regulatory requirements will be followed.

1. Theft or Loss of Radioactive Materials (Part 20.2201)

In case of theft or other unaccountable losses of radioactive materials, contact the RSO/SRS/RSS, who will make a survey of the area. Sealed sources can often be located by surveying the work area with a survey meter. The RSO is responsible for estimating and evaluating the amount of lost material, based on known inventory. The RSO is also responsible for organizing a survey or search to locate the lost materials. Appropriate notifications to the NRC will be made:

a) immediately when radioactive materials in quantities $\geq$ 1,000 times of the limits of Appendix C are unaccounted for.

b) within 30 days when radioactive materials in quantities $\geq$ 10 times of the limits of Appendix C are unaccounted for.

All notifications will be followed with a written report 30 days after the date of the initial notification.

2. Notification of Incidents (Part 20.2202)

Whenever conditions threaten to result in radiation exposures above criteria, appropriate notifications to the NRC will be made:

a) immediately when an individual has received or exceeded a total effective dose equivalent of 25 rem, an eye dose equivalent of 75 rem, or a shallow-dose equivalent of 250 rad.

b) immediately when the release of radioactive materials, inside or outside of restricted areas, could result in an intake of 5 times the ALI over 24 hours.

c) within 24 hours when an individual has received or exceeded a total effective dose equivalent of 5 rem, an eye dose equivalent of 15 rem, or a shallow-dose equivalent of 50 rad.

d) within 24 hours when the release of radioactive materials, inside or outside of restricted areas, could result in an intake of 1 times the ALI over 24 hours.

All notifications will be followed with a written report as directed by the NRC.

3. Reports of Exposures Radiation Levels and Concentrations of Radioactive Materials Exceeding the Limits (Part 20.2203)

In addition to the requirements of Part 20.2202, the following notifications will be made to the NRC:

a) when doses exceed limits for occupationally exposed workers (total effective dose equivalent of 5 rem, eye dose equivalent of 15 rem, or shallow-dose equivalent of 50 rad).

b) when doses exceed limits for exposed minors (total effective dose equivalent of 0.5 rem, eye dose equivalent of 1.5 rem, or shallow-dose equivalent of 5 rad).

c) when doses exceed limits for exposed embryo/fetus for declared pregnancy (0.5 rem for the entire gestation).

d) when doses exceed limits for individual members of the public (total effective dose equivalent of 0.1 rem and 2 mrem/h in unrestricted areas).

e) when doses exceed limits specified in license conditions, if any.

f) when levels of radiation or radioactive material concentrations in excess of 10 times any applicable limits of Part 20 or limits specified in license conditions, if any.

A written report will be submitted to the NRC 30 days after learning of such occurrences.

4. Reports of Planned Special Exposures (Part 20.2204)

The Transcell Radiation Safety Program does NOT include any provisions for planned special exposures, as defined in Part 20.1206.

5. Reports of Individual Monitoring (Part 20.2206)

Under the provisions of Part 20.2206(a)(6), Transcell is exempted from these reporting requirements for this license.

V.H.4 Coordination With Local Emergency Response Units

All county and local police and fire-fighting units are subject to being called in emergencies, even though the emergency may not result in a fire. Many accidents and other emergencies involve the use of more than one type of emergency response organization; therefore a cooperative response is essential. Fire-fighters or police, who may be the first emergency personnel to arrive on the scene, will have RSO available for radiological assistance. Emergency response protocols will dictate one responder and two backup staff members available or on call 24 hours per day.

- If notified of an emergency (or a fire) involving the presence of radioactive materials, ascertain that emergency response units have been notified; then follow normal procedures for fire emergencies.

- Normal procedures require that a member of the RSO staff will be available or on call to perform necessary radiological assessment at the scene.

- If called to the scene of an accident or other emergency situation where the presence of radioactive material is known or suspected, obtain the names and addresses of any individuals present in the immediate area affected if this has not been done by RSO at the scene.

- When ambulance or rescue squad personnel arrive, they should be informed of the known or suspected presence of radioactive materials by the RSO or designee.

- If the police or firemen take an injured person to a doctor, hospital, or other medical facility, the person being transported should be wrapped in a blanket, or other available cloth or plastic covering to permit handling the person with

the least direct contact with contaminated clothing. This will minimize the spread of radioactive contamination in emergency vehicles and response staff.

It should be noted that in addition to the above outlines, the Transcell Contingency Plan provides more detailed information and procedures. Table V-2 presents emergency notification call list. Medical emergency services have been secured with the following local hospital:

Robert Wood J[illegible] Hospital
Emergency Roo[illegible] Trauma Center
180 Somerset St.
New Brunswick, NJ

For other emergency conditions, non-traumatic, the patient will be taken to Princeton Medical Center, St. Peters Hospital, or other facilities at the discretion of the EMS Team.

Table V-2 Transcell Emergency Call List

LOCAL EMERGENCY RESPONSE

Robert Wood Johnson Hospital..... (908) 937-8689
Emergency Room and Trauma Center

Cranbury First Aid.. 911

Cranbury Fire Dept.. 911

Cranbury Police Dept..... 911

COMMON GOVERNMENTAL AGENCIES

NRC-Office of Enforc. & Insp., Region 1..... (215) 337-5000

NJDEPE-Bureau of Environmental Radiation..... (609) 292-5560
(609) 292-7172

V.I. PERSONNEL TRAINING (Item 7/6)

Personnel training is an essential component of the Radiation Safety Program. The primary objective of this training is to establish employee responsibilities in achieving the corporate goal of safe and prudent use of radioactive materials in all research programs. The training will stress Transcell's commitment to the ALARA policy.

In meeting the requirements of 10 CFR, Part 19, the training program will provide specific information for all individuals who work with or frequent areas where by-product materials are used. The training will address potential radiation hazards specific to each facility and present the requirements of the Radiation Safety Program.

The training program will fulfill the following functions:

a) Inform all personnel of management's commitment to ALARA;

b) Describe the Radiation Safety Program and its procedures for the safe use of by-product material and machine sources and license conditions and regulations governing their use;

c) Provide instructions on the biological effects of radiation and its relative risk in the work place;

d) Provide specific instructions and safety measures which individuals will use to minimize radiation exposure; and

e) Provide instruction to pregnant or potentially pregnant employees regarding prenatal radiation exposure.

V.I.1 Program Objectives

It is recognized that there will be differences in the level of education, experience, and training among workers. Nevertheless, common learning objectives will be included in the training commensurate with R&D activities and responsibilities. This will include:

a) Familiarization with the basic principles of atomic structure and radiation physics in order to provide a foundation for understanding the hazards involved.

b) Familiarization with the risk from radiation exposures, how and to what degree radiation affects the human body, radiation protection limits, and external and internal radiation exposure and its measurements.

c) Instill a knowledge about external radiation, the units and methods for its measurement, and how to protect against it.

d) Address the nature of hazards for internal exposures, the sources of such radiation hazards, considerations in monitoring internal radiation, and the means of preventing and minimizing it.

e) Discuss the sources and potential types of radiation accidents, the radioactive materials involved, and types of occupational exposures at both facilities.

f) Demonstrate how to perform radiation surveys of areas and conduct personal frisking.

g) Familiarization with principles of contamination control, source of contamination, and means of decontamination.

h) Present the requirements and methods for rescue, first aid, and fire fighting in radiation emergencies.

I) Discuss the need for and specific radiation control measures that are appropriate for particular research activities. Use "dry or cold runs" for all new procedures, to maintain doses ALARA.

k) Present the requirements of the low-level radioactive waste management program, implementation plans, and procedures.

The training program will be conducted under the supervision of the Radiation Safety Officer (RSO). It will be reviewed yearly and updated as necessary. The program will be changed to reflect changes in R&D operations and/or revisions to the radiation safety program or license conditions.

V.I.2 Training Audience and Schedule

In accordance with 10 CFR, Part 19.12, all personnel, including management, who work in or frequent controlled areas will receive radiation protection training and periodic refresher courses on a yearly schedule.

This will also include ancillary personnel who work in restricted areas on an occasional basis, e.g., materials management, maintenance, janitorial, security, secretarial, etc. The topical training outline is listed by subject in Table V-3.

a) Routinely and incidentally exposed staff, such as clerical or maintenance personnel, will receive a general orientation lecture upon hiring, and periodic refresher training thereafter. Such lectures will include familiarization with "radioactive" warning notices and signs and will serve to introduce general safety protocols aimed at keeping all doses ALARA. Training will be two hours long. The need to conduct periodic retraining sessions will be determined by the RSO for specific conditions, e.g., following major changes and/or revisions to the radiation safety program.

b) Workers whose assignments routinely involve working in proximity to radioactive materials or to animals undergoing experiments with radioactive materials will receive more extensive training including that noted in item a) above. Management's commitment to maintaining doses ALARA will be reinforced by specific examples of work practices helping to reduce time spent in proximity of radiation sources.

c) For full-time radiation workers, training will include both lectures, demonstrations, and hands-on practice of safe work procedures. Although credit may be taken for applicable training received during formal education or during previous employment, facility-specific training will be mandatory. The initial training session will include both classroom lectures, facility walk-through, and hand-on exercises. All full-time radiation workers will take the radiation safety exam to document proficiency of the subject matter.

Table V-3 Radiation Protection Training Program Topical Outline

1. Radiation Fundamentals

   a. Radioactive materials and radioactive decay
   b. Radioactive decay process
   c. Sources of radioactivity
      1) natural background sources
      2) man-made sources
   d. Sources of radioactivity
      1) unsealed materials
      2) others

2. Measurement and Control of Exposure to Radiation and Contamination

   a. Types of radiation and their characteristics
   b. External and internal dosimetry
   c. Controlling exposure
      1) time
      2) distance
      3) shielding
      4) source strength reduction
      5) use of protective apparel and respirators
   d. Types and form of radioactive material
   e. Detection and control of contamination and decontamination
   f. Radiation measurement/survey instruments
   g. Radioactive waste/storage, handling, and disposal

3. Radiation Protection Program

   a. Purpose/relationship to individual
   b. ALARA policy
   c. Radiation areas
   d. Airborne radioactivity areas
   e. Controlled surface contamination areas
   f. Signs, labels, and posting
   g. Personnel monitoring and exposure control
   h. Bioassay
      1) thyroid scan
      2) urine analysis
      3) other analysis (e.g., fecal and breath)
   I. Air and area monitoring

Table V-3 Radiation Protection Training Program Topical Outline, Cont'd.

j. Radiation surveys - purpose and methods
k. Pertinent NRC regulations
    1) dose, limits, and concepts (DDE, CDE, SDE, LDE, CEDE, TEDE, and TODE)
    2) DAC, DAC-hours, and ALI concepts and limits
    3) reporting requirements - 10 CFR 20
    4) reporting responsibility - 10 CFR 19.12

4. Biological Effects of Radiation

a. Carcinogenesis
b. Genetic effects
c. Acute effects
d. Latent effects
e. Collective Dose Concept
    1) total person-rem risk
    2) individual dose risk
f. Dose-effect relationships
    1) external radiation
    2) internal radiation
g. Prenatal radiation exposure

5. Site Protocols and Operating Policies

a. Acquisition of radioactive materials
b. Handling of radioactive materials and sources
    1) on-the-job review of techniques
    2) use of hoods and ventilated enclosures
c. Radioactive materials disposal and storage
d. Emergency plan and procedures
e. First aid care
f. Reporting of accidents/spills/losses to RSO
g. Use of protective clothing
h. Research protocol authorization process
I. Radioactive waste minimization
j. Implementation of ALARA concept
k. Self-frisking procedure
l. Use of radiation survey meters
m. Respiratory protection

V.I.3 Training Program Evaluation

For full time radiation workers, an exam will be administered to verify that a basic understanding of safety requirements has been achieved. Other employees who will occasionally work in proximity to radiation control areas (e.g., labs, loading docks, etc.) will receive specific training, as determined by the RSO, involving practice sessions, where they can demonstrate the ability to complete routine tasks and minimize exposures.

All full time radiation workers undergoing training will be administered a test. A passing grade of 75% will be mandatory for qualifying as a radiation worker. The effectiveness of the training program will be evaluated through periodic reviews of radiation exposure records. Such reviews will include individual and aggregate exposures and observations noted by the RSO and radiation protection staff.

For administrative purposes, all training records will be maintained by the RSO. Records will contain such information as attendance list, test results, social security number, department of each individual in attendance, date of the training session, lecture outline title(s), and the name of the individual who conducted the training session. Training files for each employee will be maintained indefinitely or until disposition is approved by NRC.

VI. RADIOACTIVE WASTE MANAGEMENT (Item 11)

The Low-Level Radioactive Waste Amendments Act of 1985 (Public Law 99-240) established, as a Federal policy, that each State is responsible for "disposal of low-level radioactive waste generated within its borders. The Amendments Act further requires that such "... low-level radioactive waste can be most safely and efficiently managed on a regional basis." Consequently, states were authorized and encouraged to enter into interstate compacts to establish and operate regional low-level waste disposal facilities. The Amendments Act of 1985 provided a series of milestones, incentives, and penalties to encourage states and compact regions to fulfill their responsibilities by January 1, 1993 to safely dispose of the low-level radioactive waste generated in their States or regions.

The Northeast Compact, consisting of New Jersey and Connecticut, has established an agreement that each State will provide the necessary facility. New Jersey is establishing the mechanism for site selection process and construction of the disposal facility. However, the State has not been able to meet the January 1993 Federal milestone. It is currently anticipated that a disposal facility will not become operational until the next century.

Accordingly, Transcell will be forced to store some of its radioactive waste on-site until the New Jersey disposal facility is operational or ship waste to Barnwell and Richland as they become available. Transcell has instituted a waste management program that includes waste minimization, decay-in-storage, and long-term storage. The use of commercial services for the treatment and disposition of specific waste streams will be arranged through a waste broker.

The Nuclear Regulatory Commission has provided specific technical and regulatory guidelines for the purpose of storing radioactive waste. This technical guidance was issued in Information Notice No. 90-09, titled: Extended Interim Storage of Low-Level Radioactive Waste by Fuel-Cycle and Materials Licensees, dated February 5, 1990. The NRC Information Notice includes several technical elements which need to be addressed in evaluating the feasibility of long-term storage. The storage method considered includes a Radwaste Storage Room located within the East side(Room No. 156). Waste will also be compacted to further reduce the needs for storage space and to ensure long-term stability. The objective is to store waste such that they can be shipped directly to the disposal site without any further processing.

The following discussions incorporate the relevant technical issues identified in NRC Information Notice No. 90-09.

VI.A. Waste Management Program

In keeping with the commitment to minimize waste generation, total nuclide activity will be minimized by maintaining minimal inventories. Radioactive materials will be ordered on an "as needed" basis. Every effort will be made to order only what is necessary, while still ensuring an adequate inventory. When feasible, radionuclides will be ordered in their final compound forms to reduce additional processing. This approach will help limit both the volume and waste activity levels.

The type of waste forms that are being generated are typical of pharmaceutical research and development activities. Research involves the use of radioactive materials in bio-chemical, bio-physical, and physiological investigations. Such investigations involve the use of radioactive tracers introduced into tissue samples and cell cultures study drug metabolism, bio-kinetics, and reactions to varying doses. A wide spectrum of waste will be generated during R&D activities, including dry solids, biological, compactible and non-compactible materials, and aqueous and organic liquids. Typically, such waste will be classified as Class A waste, as defined under 10 CFR, Parts 61.55 and 61.56. The following presents an overview of the primary types and forms of waste routinely generated.

VI.A.1 Waste Streams

VI.A.1.1 Solid Waste

Solid waste include absorbent pads, paper towels, cloth, plastic and glass bottles, syringes, pipets, plastic trays, empty product or stock solution containers, spent resin columns and filters, pH probes, centrifuge and test tubes, beakers and graduated cylinders, cell culture dishes and flasks, plastic and glass tubing, analytical samples, and miscellaneous disposable labware supplies. Protective clothing items are also disposed as LLW, including gloves, lab coats, coveralls, shoe covers, and spent-filter respirator or sampling cartridges. Occasionally, laboratory equipment is also disposed as waste. Such items may consist of tube storage racks, dispensing apparatus, hot plates, vacuum pumps, mixers, hardware, components, and parts from centrifuges, cell dispensers, ventilated enclosures, spent HEPA and charcoal filters, etc.

VI.A.1.2 Liquid Scintillation Waste

Liquid scintillation waste consists of regulated and de-regulated spent organic fluids contained in plastic or glass vials. Liquid scintillation fluids primarily consist of toluene, xylene,

benzene, dioxane, trimethylbenzene, and cylohexane. These organic compounds are found, at varying concentrations, in both aqueous and non-aqueous forms. Spent cocktails also contain trace levels of research compounds, in addition to the radioactivity.

VI.A.1.3 Aqueous Liquids

Aqueous liquid waste consist of soluble compounds present in water solutions. Such solutions are generated during the washing or rinsing of laboratory equipment, while flushing dispensing units, by analytical equipment which segregate radioactive from non-radioactive fluid streams, when collecting initial solution baths or first rinses from electrophoresis units, analytical samples, etc. Typically, very dilute aqueous waste are collected into containers, which are then flushed into the sewer systems. Some liquid waste will be held for decay-in-storage whenever short-lived nuclides are present. Finally, other types of aqueous waste, at times, will be stabilized using approved solidification agents.

VI.A.1.4 Organic Liquids

Organic liquids have similar origins as that of aqueous waste, with the exceptions that solutes consist of solvents, such as alcohols, aldehydes, ketones, organic acids, acetone, benzene, acetonitrile, chloroform, diethyl ether, ethyl acetate, hexane, toluene, etc. Organic liquids will be held in storage until a permitted hazardous/radioactive waste incineration facility becomes commercially operational. Organic liquids may also be solidified using practices as described for aqueous waste.

VI.A.1.5 Biological Waste

Biological waste consist of tissues, cell cultures, and analytical bioassay samples. Typically, biological waste will be autoclaved or chemically treated and disposed of in sinks or by incineration at an approved facility.

VI.A.1.6 Stabilized Waste

Some waste forms are stabilized using solidification or absorbent materials. Such waste are generally classified as "stabilized" waste. For example, liquid waste will be mixed with solidification and allowed to cure into its container. Several types of solidification agents and limits on the presence of free standing liquids in stabilized waste have been established by the

disposal sites.
Absorbent materials are typically used when disposing of items containing minimal amounts of residual liquids, damp paper towels and absorbent pads.

VI.A.1.7 Gaseous Waste

Gaseous waste, which are rarely generated, will be vented to the atmosphere in accordance with NRC regulations. Possible forms of gaseous waste include H-3, as water vapors, C-14, as radio-labeled CO_2, and radioiodines.

VI.A.1.8 Other Waste

On occasions, Transcell may generate waste associated with routine decontamination or laboratory modifications. Such waste may include floor tiles, bench tops, hoods, ventilated enclosures, exhaust ventilation ductwork and filter housings, and sink drain piping and traps. Such materials will be handled as dry solid waste.

Unique waste forms may be generated in response to specific research needs. The processing requirements for such waste will be addressed as such needs occur.

VI.B Projected Waste Generation Rates

Future waste generation rates are inferred from similar types of research activities conducted elsewhere by the research staff. It is recognized that this approach introduces some uncertainties. For example, some of the R&D work will be phased in over several months and research objectives may change abruptly. It is expected that most of the waste will originate from two areas, the RSO's Lab and other labs. It is recognized that there may be, at any one time, other labs using radioactive materials. However, it is anticipated that such research activities will be intermittent in nature and involve relatively limited quantities of radioactive materials in bench-top experiments. It is also assumed, based on current plans, that the activity used in such bench-top experiments will be prepared in designated labs, where the bulk of the waste will be generated.

For each of the waste forms described earlier, the following yearly and activity generation rates (ft^3/y c i/y, rounded off) are estimated:

Waste Forms	No. of Drums	Volume (ft^3/y)		Activity (mCi/y)	
LSV:	1	7.5		0.3	
Storage for decay:	1		7.5		5
Long-term Storage:	1		7.5		5
Total:	3	7.5	15.0	0.3	10

Spent liquid scintillation vials will be shipped out regularly, typically quarterly to Teledyne Brown Engineering.

The distribution of radionuclides is assumed to be identical to that listed for the possession limits. Given the scope of research activities, the most predominant radionuclides typically include H-3, C-14, P-32, Cr-51, and I-125, representing about 80% of the activity. Based on past practices, such waste will be only "Class A Waste", as defined under 10 CFR, Parts 61.55 and 61.56. Over 90% of the activity will be contained in dry active waste. The remaining activity is contained in LSV waste. The following tabulation presents the distribution of nuclides by selected half-life groupings.

<30 d	<100 d	>1 yr	>100 yr
P-32	S-35	H-3	C-14
P-33	I-125		
Cr-51			
I-131			

VI.C. Waste Management Plan Implementation

All solid and liquid waste will be segregated at the point of generation to reduce volumes and activity levels. The major elements of the plan are:

- Use of radioactive materials will be minimized and short-lived radionuclides will be used whenever possible.

- All efforts will be made to segregate clean and uncontaminated items, i.e., supplies, equipment, labware, etc. from those that are contaminated, or from areas known to be contaminated. Non-radioactive solid waste will be segregated at the point of generation and disposed as hazardous materials, laboratory, or medical waste.

- Hazardous materials will be segregated from radioactive waste.

- Dry solid waste and nuclides with half-lives greater than 65 days will be segregated for long-term storage.

- Waste compaction will be implemented when needed to maximize the use of existing storage spaces. A waste compaction ratio of 2-to-1 is anticipated given the types of waste.

- Dry solid and liquid waste with half-lives less than 65 days will be stored for decay-in-storage. The containers will be appropriately identified and shielded, as needed.

- Stored waste will be held for 10 half-lives, monitored to confirm that the activity is no longer detectable, and released for disposition.

- Solid waste, that has been cleared, will be disposed of as laboratory and/or medical waste. All radioactive markings and labels will be defaced.

- When both short-and long-lived nuclides are handled in the same laboratory, separately marked waste containers will be provided for segregating these waste.

- Liquid scintillation fluids, including both regulated and de-regulated will be shipped out to a commercial facility, e.g., via Teledyne Brown Engineering.

- Dilute aqueous liquid waste will be released to the facility sewer system with the permission of the RSO, given that NRC limits (10 CFR Parts 20.2003 and 20.2005)regulations, and administrative requirements are met. Such releases, however, will be maintained ALARA. Some liquid waste will be solidified and placed into long-term storage.

Bulk dumping of liquid radioactive waste in laboratory sinks will not be authorized.

- The generation of spent solvents and organic liquids will be minimized by evaluating each research protocol. Liquid scintillation waste will be disposed by incineration at a commercially permitted hazardous waste facility. Other organic waste will be held pending the availability of disposal capacity or treatment methods.

- Deregulated waste may be disposed of without regard to its radioactivity in accordance with NRC limits under 10 CFR Parts 20.2005 and 20.2007 regulations, and local requirements established by the Middlesex County Utilities Authority.

- Volatile and gaseous waste may be discharged into the environment in accordance with established NRC (10 CFR Part 20, Appendix B, Table 2, Column 1) and facility administrative limits. Such releases, however, will be maintained ALARA.

VI.C.1 Decay-in-Storage

Liquid and/or solid waste containing radionuclides with half-lives of less than 65 days will be collected, labeled, and stored in sealed containers for at least 10 half-lives in accordance with NRC guidance, Decay-in-Storage Guidance for Non-Medical Waste (2/1/92 Rev.).

After this decay period, the waste will be surveyed and/or analyzed with appropriately sensitive radiation detection instruments, such as gamma scintillation, gamma spectroscopy, liquid scintillation, or via other appropriate methods. The implementation of such practices will be documented by showing survey methodology, criteria, instrument responses, and applicable waste streams.

In summary, the procedure for dry active and liquid waste requires that:

- Waste destined for decay-in-storage will be placed into coded (using labels, stickers, tags, etc.) containers identifying a specific nuclide or group of nuclides with similar half-lives. A tag will identify radionuclide(s), total activity of each, date of generation, laboratory location, and name of generator.

- Each container will be surveyed with the appropriate survey meter or method before shipment. Measurements will be made on all sides of the container. Once readings are non-detectable above background, a final measurement will be made by scanning the waste after removal from the container with an appropriate survey meter.

- For beta emitters, a thin window (ca 2 mg/cm^2) GM or beta scintillation survey meter will be used.

- For gamma and X-ray emitters, a scintillation survey meter will be used. The scintillation crystal thickness will be selected for the anticipated range of gamma energy emissions, e.g., thin crystal for I-125.

- If the waste meets the disposal criteria, it will be discarded as non-radioactive laboratory and/or medical waste. All radioactive labels and markings will be either removed or defaced.

- Liquid waste will be analyzed by using various analyses, including, liquid scintillation, and gamma counting.

- Records will be kept for all waste which have been stored for decay-in-storage, including survey results or analyses, survey methodology, radio-analytical techniques, and final disposal methods. The records will also provide the activity, date of placement into storage, name of generator, date of disposal, and the name of the person checking the waste prior to disposal as laboratory and/or medical waste.

VI.C.2 Sink Disposal

Aqueous liquids destined for sink disposal will be stored in appropriate containers, which will be segregated from other liquid waste. Bulk dumping of liquid radioactive waste in laboratory sinks will be supervised by the RSO. Only dilute rinses and washes are allowed without the permission of the RSO.

All sink disposals will be conducted in response to the requirements of 10 CFR, Parts 20.2003, 20.2005, 20.2007, and 20.2108, Appendix B, Table 3 limits. In addition, releases will also be conducted in accordance with the requirements of the Middlesex County Utilities Authority.

All sink releases will be limited by volume and activity prorated on daily and yearly basis for each site in order to not exceed the limits of 5 Ci/y for H-3, 1 Ci/y for C-14, and 1 Ci/y for all other combined radionuclides. All sink releases will take into account the facility's water discharge rate. Specific limits will be identified for each designated sink. Each disposal will take place according to procedures established by the RSO. All discharges will be recorded in a form identifying:

1) the point of generation by building and Lab number,
2) radionuclides and total activity,
3) associated volume and number of containers, and
5) date of discharge.

Aqueous liquid waste failing to meet specified radionuclide concentrations or total activity criteria (as noted above) will be disposed by solidification using approved solidification agents (e.g., Delaware Custom Media). Solidified liquids will be disposed in their respective containers as dry solid waste.

VI.C.3 Projected Waste Volume Storage Needs

The estimated storage needs are based on the yearly waste volumes and activity generation rates presented earlier. The following tabulation summarizes such estimates over the next two years:

- Anticipated LLW Volume Storage Needs (ft^3) -

Waste Form	Storage for Decay	Long-term Storage	Interim Storage	No. of Drums
DSW	7.5	15.0	--	3
LSV:	--	--	15	2

The currently planned facility provides a storage floor space of 11.3 x 12.6 feet, or about 142 ft^2. This area is capable of holding up to 24 drums, with a four-foot access aisle and single stacked. Technically, the area can hold up over four years' worth of waste, given these projections and assumptions.

VI.C.4 Projected Waste Activity

Waste activity possession limits are based on the data presented earlier. The possession limits reflects both the need to support on going research and development activities and waste held for decay-in-storage and long-term storage. Typically, short-lived radionuclides will require greater site inventories, when compared to those that are longer-lived. Table VI-1 presents the anticipated radionuclide distribution across all waste forms. It is estimated that less than 30 mCi will be contained in stored waste over the next two years.

This estimate is based, in part, on past inventories and assumptions about the scope of future R&D programs. This approach provides a conservative estimate since it does not take credit for decay of some of the shorter-lived radionuclides. This approach was used to compensate for uncertainties in characterizing future R&D and waste generation practices.

Table VI-1 Waste Radionuclide Distributions Across all Waste Forms[a]

Nuclide	Assumed Max. Activity (mCi) At any time	2-year inventory
H-3	4	8
C-14	3	6
P-32	1	2
P-33	0.5	1
S-35	1	2
Cr-51	1	2
I-125	2	4
I-131	1	2
Total:	13.5	27

(a) See text for details.

VI.D Waste Handling and Processing

All waste will be segregated at the point of generation. Containers marked for specific waste forms will be located in each laboratory or group of laboratories. Such waste forms include, both short- and long-lived radionuclides, dry solid waste, aqueous liquids, organic liquids, tissues and cell cultures, and LSV, both regulated and exempt.

Dry solid waste bearing long-lived radionuclides will be compacted, when needed. Dry solid waste destined for decay-in-storage will be stored in 55-gallon containers. Once decayed to background levels, waste will be monitored and disposed as laboratory and/or medical waste. All radioactive labels and markings will be removed or defaced.

Dilute aqueous liquid waste will be discharged under controlled conditions into designated laboratory sinks with prior RSO approval.

Liquid aqueous waste which cannot be released in sinks will be solidified using approved solidification media, e.g., Delaware Custom Media. Solidified waste will be disposed as dry solid waste in their sealed containers.

Regulated and de-regulated spent scintillation vials and most other organic liquids will be shipped out, via Teledyne Brown Engineering, to a commercial treatment facility. Other similarly approved facilities may be used, however. Some small quantities of organic liquids waste may be solidified using methods approved by licensed disposal facilities.

Biological waste will be neutralized by autoclaving or by using chemical disinfectant and disposed at an approved waste facility or incinerator.

VI.E Federal, State, and Local Approvals and Permits

The Radwaste Storage Room is already a part of the facility, built under the original construction permits. The permission to store radioactive waste will also be obtained from the Town of Cranbury, under existing zoning codes.

Transcell is authorized to store hazardous waste under EPA waste generator ID No. NJD 986650216.

VI.F Plans for Storage and Final Disposal

All applicable radioactive waste packaging criteria for specific waste forms, labeling, marking, posting, etc. will be observed to ensure that all transportation criteria and disposal site requirements are met. Once operational, all waste will be disposed in accordance with the disposal site's license conditions and requirements of 10 CFR, Parts 61.55, 61.56, 61.57, 20.2006, and Appendix F to Part 20 regulations. All waste will be shipped in accordance with U.S. DOT 49 CFR, Parts 170 to 189 requirements.

Once the New Jersey facility opens its low-level waste disposal site, Transcell waste held for long-term storage will be shipped there for burial. It is currently anticipated that a regional disposal facility will not become operational until the next century. In the interim, should Barnwell or Richland become accessible, arrangements will be made via a broker (e.g., Teledyne Brown Engineering) to dispose of all LLW at either facility.

Without any specific details, it is currently anticipated that the State will establish a priority system which will dictate how waste will be shipped to the newly opened disposal site. It is assumed that the State will authorize shipments on a rotational basis by category of waste generators and/or by regions. It is also assumed that the State will specify maximum waste volumes allowed in each shipment. Accordingly, Transcell will follow all applicable guidelines specified by the State.

Given the relatively minimal waste volume, it is anticipated that all waste will be shipped by truck. For the given waste volume estimates, it is assumed that one truck shipment will be required. It is anticipated that a full truck load can accommodate about 80 drums per shipment, as long as weight limits are observed. Since the waste will be stored in its final form for disposal, the only requirements will be to update all radionuclide inventories for the purpose of completing the shipping manifests.

VI.F.1 Description of the Radwaste Storage Room

Once full, waste drums will be taken out and moved to the Radwaste Storage Room (No. 156, see Attachment 2-2). The Waste Storage Room is located on the East side, situated about 50 feet from the Shipping and Receiving dock. The Waste Storage Room

provides a nominal floor space of about 142 ft^2. The walls and floor will be painted with industrial enamel and epoxy finishes, respectively. The floor is sunken by about 1-inch as a spill containment measure.
The building incorporates typical building services, such as electricity, fire detection, fire extinguishers, and ventilation. Access into the room will be through a personnel door under lock and key.

The Radwaste Storage Room is serviced by a dedicated exhaust system rated at 400 CFM; no filtration has been provided, however. Exhaust rates are maintained to keep a negative pressure. The discharge point is located, at about 2 feet above the roof line.

The Radwaste Storage Room is included within the building complex's facility operational coverage and security system. The entrance will be posted with radioactive materials and radiation warning signs, if needed. Additional signs will provide a call list and instructions for access during routine and emergency conditions.

In the event that radioactivity is found leaking, the source of radioactivity will be isolated and the affected container(s) will be put into an overpack and repackaged. Any residual contamination will be cleaned-up and surveyed. When needed, the assistance of a waste broker will be sought to complement Transcell's in-house capabilities.

In the event of an industrial accident or natural event, emergency measures will be implemented under the Transcell Contingency Plan. These procedures are also supplemented by those described in Section V. The procedures identify the coordination of emergency response activities with local fire, police, and medical facilities.

VI.F.2 Waste Container Integrity

Waste destined for long-term storage will be segregated to ensure the long-term stability and integrity of the containers. Other considerations will include storage stacking schemes to facilitate routine inspections, measures and facilities for handling drum retrieval and repackaging, should such needs arise.

The primary concern being to avoid premature internal corrosion and gas generation. Waste will be processed prior to being put

into storage. Waste processing will include identifying incompatible waste forms or streams, waste separation when found in the same container, compaction, solidification, and chemical neutralization and/or stabilization. Biological tissues will not be placed into long-term storage.

All long-term storage waste will be compacted and stored in U.S. DOT 17H drums while awaiting ultimate disposal. Waste packaging will include the use of inner coatings or liners (as bags or corrugated inserts) and the introduction of approved absorbents (e.g., Speedi-Dry) to capture any residual moisture which might be generated during degradation of some waste materials.

All drums will be sealed and readied for shipment. All drums put in long-term storage will be marked with tags identifying nuclides, activity, container ID No., waste form, weight, generator name and location, surface exposure rates, and other DOT required labels and markings.

Waste held for decay-in-storage will be stored in 55-gallon containers. The containers will identify a specific radionuclide or group of radionuclides with similar half-lives. All containers held for decay-in-storage will be marked with tags/labels identifying the nuclide(s), activity, date of container closure, expected inspection date (10 half-lives post-closure), waste type, generator name and lab, and surface exposure rate(s) at closure. Both types of containers will be wipe tested for surface contamination upon closure.

Following each visual inspection, notes will be entered in a logbook if any drum or container is found damaged or leaking. Drums or containers found to be externally contaminated or leaking will be moved in overpacks or other spill containment. Except for the use of a manual forklift, no other remote handling method will be used since the total waste specific activity will be low.

VI.G Radiation Protection Program

It should be noted that many of the technical elements identified in the NRC Information Notice No. 90-09 are already covered by the existing radiation safety program and procedures (see Section V for details). The degree to which these elements will be upgraded is determined following:

1) a review of waste generation practices, and

2) once final waste storage procedures have been formulated.

Most of the technical elements will be addressed by simply extending current requirements to waste storage facilities.

Some unique aspects, however, are addressed here as they are not currently covered by the existing radiation safety program. These aspects are routine inspections, measures and facilities for handling drum retrieval and repackaging, shielding requirements for walls and adjacent areas, and routine radiological monitoring requirements. Additional procedures required to address such requirements are covered separately below.

VI.G.1 Waste Placement and Inspection

Low-level waste destined for long-term storage will be contained in DOT approved 55-gallon drums. The drums will be configured such that there will be no need for repackaging prior to shipping and disposal. Waste will consist of dry solid waste that are inherently stable and compatible. Waste will be stored in rows, up two drums high, when needed. An aisle space will be left between each row to ensure sufficient space to conduct visual inspections. The inspections will include:

- Conducting external radiation surveys along the row of drums and in adjacent areas.

- Conducting smear surveys on randomly selected drums or on those which upon visual inspection appear to be degrading, over-pressurized, or possibly leaking. Smears will also be taken along personnel and forklift traffic paths.

- Air samples will be taken periodically before allowing personnel to enter. Air samples will be taken by opening the access doors, and include particulates, vapors, H-3, C-14, and radioiodines using filter papers, traps, bubblers, and charcoal cartridges.

- A visual inspection will be made for the purpose of identifying leaks, signs of premature corrosion, bulging, venting, fading drum markings or tags, etc. A check list will be used for this purpose.

- Following the evaluation of the visual inspections and survey results, all posting and labelling requirements will be updated to reflect the current radiological status.

- The results and findings noted during inspections will be documented and kept in files. Any recommendations will be reviewed by the RSO and implemented as is necessary.

Inspections will be conducted initially on a quarterly schedule until operating experience shows that the schedule can be shifted to a semi-annual program, and finally on an annual basis, as a minimum. Inspections, however, may be returned to the quarterly schedule if new waste forms are being generated or if observations made in past inspections make it mandatory.

VI.G.2 Projected Exposure Rates and Shielding

External radiation exposure rates are expected to be typically low, given the radionuclides and amounts of activity used per experiment. Surface external radiation exposure rates are expected to be on the order of a few millirem per hour. The contribution from bremsstrahlung radiation is also expected to be negligible for waste contained in 55 gallon drum. The interaction of beta particles and X-rays will be for the most part shielded or absorbed by the container wall or waste itself. It is also assumed that the exposure rate due to bremsstrahlung alone will be a small fraction of that produced by the presence of other radionuclides in the waste.

If external radiation exposure rates were found to be elevated, the offending drums will be nested among other drums for shielding or placed in the far corners of the Radwaste Storage Room.

VI.G.3 Emergency Procedures

Section V.H presents the onsite and offsite emergency response requirements. The requirements identify the coordination of emergency response activities with local fire, police, and medical facilities. Letters of commitments are also included from a nearby medical facility for the treatment of contaminated and injured individuals. These emergency procedures are also supplemented by the Transcell Contingency Plan.

In the event that radioactivity is found to be leaking out of the Radwaste Storage Room, the source of radioactivity will be

isolated until appropriate corrective actions can be taken. Surveys will be performed in all immediate areas. Samples will be taken in all affected floor drains, traps, and storm drains or culverts.

VI.G.4 Waste Inventory and Accountability System

An inventory system will be used to keep track of the waste volume and activity placed in storage. The system will keep track of the information by waste drum or container, waste forms, radionuclides, volume, weight, date placed in storage, date of disposal, generator, and by Lab location. Waste inventories will be periodically decayed corrected for the purpose of updating the total inventory against licensed possession limits. The waste inventory will be updated as additional waste are placed in storage.

VI.G.5 Personnel Training

Section V.I presents the basic personnel radiation safety training program. All personnel designated to work in any of the two waste storage areas or in support of the waste management program will receive additional training. A specific training module will focus on the following aspects:

- Objectives, description, and implementation of the waste management program.
- Entry requirements and procedures into the Radwaste Storage Room.
- Safe movement of waste containers using forklifts.
- Waste materials and/or drum repackaging.
- Conduct of inspections and walk through, survey measurement spot-checks, and identification of drum leakage, signs of premature corrosion, bulging, and venting.
- Waste and radioactive materials accountability, inventory system, and associated records keeping requirements.
- Emergency procedures addressing response and notifications, fire fighting, loss of radioactive materials, drum spillage or rupture, drum drop from elevated heights, personnel injuries, and personnel contamination.

VI.G.6 Emergency Preparedness

An emergency preparedness plan is not required since the Transcell possession limits are not in excess of the requirements given in 10 CFR, Parts 30.32(I)(1) and 30.72, Schedule C.

VI.G.7 Financial Assurance and Funding Plan

A financial assurance and funding plan is not required given the possession limits presented in Section II.

Attachment 1

Resumes of Radiation Safety Officer
and
Key Radiation Protection Personnel

Clifford Boles Longley

Education:

1971	Western Michigan University, Kalamazoo, Michigan. B.S., Biology
1976	Wayne State University, Detroit, Michigan. M.S., Biology
1978-1980	Wayne State University,School of Medicine, Immunology and Microbiology, Detroit, Michigan . Post Graduate.

Professional Experience:

1994- present	Biologist, Biology Department, Transcell Technologies, Monmouth Junction, New Jersey
1993 - 1994	Senior Research Scientist, Antibody Evaluation, CYTOGEN Corporation, Princeton, New Jersey
1990 - 1993	Senior Research Scientist, Conjugative Biochemistry, CYTOGEN Corporation, Princeton, New Jersey
1983 - 1990	Manager of Research Services, AMC Cancer Research Center, Denver, Colorado
1981 - 1990	Research Associate, AMC Cancer Research Center, Denver, Colorado
1973 - 1981	Senior Research Assistant, Michigan Cancer Foundation, Detroit, Michigan
1972 - 1973	Instructor, Wayne State University, School of Medicine, Department of Immunology and Microbiology, Detroit, Michigan

Radioisotope Experience:

Mr . Longley has used radionuclides since 1973. From 1973 - 1982 at the Michigan Cancer Foundation, Detroit, Michigan, Mr. Longley used ^{3}H, ^{14}C, ^{35}S, ^{125}I, ^{131}I, ^{51}Cr, and ^{59}Fe in millicurie amounts. At AMC Cancer Research Center, Denver, Colorado from 1982 - 1990, Mr Longley additionally used ^{54}Mn, ^{153}Gd and ^{111}In at millicurie amounts. Also while at the AMC Cancer Research Center, Mr. Longley recieved training and performed *in vitro* and *in vivo* irradiations using a seal source cesium irradiator and a therepeutic X-ray machine. As manager of Research Services for AMC Cancer Research Center he was responsible for management of all Laboratory Safety programs and was a member of the Radiation Safety Committee. During 1990 - 1993, Mr. Longley, while at

CYTOGEN, Princeton, New Jersey, used millicurie amounts of ^{111}In, ^{90}Y at 100 millicuries levels, and ^{99m}Tc at near curie amounts. Mr. Longley was also alternate Radiation Safety Officer for CYTOGEN.

Professional Affiliations:

Society of Nuclear Medicine

Honors:

Beta Beta Beta Biological Honor Society, Western Michigan University, Kalamazoo, Michigan

1971-1972 Graduate Professional Scholarship, Wayne State University, Detroit, Michigan

1978-1980 Graduate Fellowship, Michigan Cancer Foundation, Detroit, Michigan

Publications:

P. Furmanski, **C. Longley**, D. Fouchey, R. Rich, and M.A. Rich. Normal Human Mammary Cells in Culture: Evidence for Oncornavirus-like Particles. J. Natl. Cancer Inst., 52:975-977 (1974).

P. Furmanski, **C. Longley**, D. Fouchey, R. Rich, and M.A. Rich. Oncornavirus-like Particles in Normal Human Mammary Cells in Culture. Fed. Proc., 33:753 (1974).

C.M. McGrath, P. Furmanski, H. Soule, P. Grant, and **C. Longley**. Immunological Relationships Between MuMTV, 734B, and a Virus -like Particle Isolated from Human Milk. Proc. Am. Assoc. Cancer Res., 16:164 (1975).

M. Dietz, P. Furmanski, **C. Longley**, and M.A. Rich. The Role of LLV in Spontaneous Regression of Virus Induced Murine Leukemia. Abstracts of the Annual Meeting of American Society for Microbiology, 75:275 (1975).

P. Furmanski, C.P. Loeckner, **C. Longley**, L. Larson, and M. A. Rich. Identification and Isolation of the Major Core Proteins from the Oncornavirus-like Particles from Human Milk. Cancer Res., 36:4001-4007 (1976).

M. Dietz, P. Furmanski, S.P. Fouchey, L. Hall, **C. Longley**, and M.A. Rich. Spontaneous Regression of Lymphocytic Leukemia in Mice. Proc. Am. Assoc. Cancer Res., 17:125 (1976).

M. Dietz, S.P. Fouchey, **C. Longley**, M.A. Rich, and P. Furmanski. Spontaneous Regression of Friend Virus Induced Erythroleukemia. I. The Role of the Helper Murine Leukemia Virus Component. J. Expt. Med., 145:594-606 (1977).

M. Dietz, **C. Longley**, S.P. Fouchey, L. Hall, M.A. Rich, and P. Furmanski. Spontaneous Regression of Friend Virus Induced Erythroleukemia. II. Regression of Friend Murine Leukemia Virus Induced Lymphocytic Leukemia. J. Natl. Cancer Inst., 59:957-961 (1977).

W.L. Kirkland, N.S. Yang, T. Jorgensen, **C. Longley**, and P. Furmanski. Growth of Normal and Malignant Human Mammary Epithelial Cells in Culture. J. Natl. Cancer Inst., 63:29-41 (1979).

P. Furmanski, **C. Longley**, C. Bolles, D.L. Hines, and M. Dietz. Spontaneous Regression of Friend Virus Induced Erythroleukemia. VI. Structural and Antigenic Differences Between Regressing and Conventional Strains of Virus. J. Virology 33:1083-1096 (1980).

R.A. Weigand, C.I. Paquette, **C. Longley**, and P. Furmanski. Immunologic Localization of Murine Leukemia Virus Antigens in Thin Sections. 39th Ann. Proc. Electron Microscopy Soc. Amer. p402 (1981).

N.S. Yang, C. Park, **C. Longley**, and P. Furmanski. Prognostic Significance of Expression of Plasminogen Activator Isozymes by Primary Human Breast Cancers. 13th International Cancer Congress, p 168 (1982).

C. Longley and P. Furmanski. Spontaneous Regression of Friend Virus Induced Erythroleukemia. IX. Role of Complement in Leukemia Regression. Leuk. Res., 6:703-710 (1982).

C.S. Johnson, J. Marcelletti, **C. Longley**, and P. Furmanski. Inhibition of Normal Erythropoiesis in Mice with Friend Virus Induced Erythroleukemia. Exp. Hematol., 10:743-753 (1982).

N.S. Yang, C. Park, **C. Longley**, and P. Furmanski. Effect of Extracellular Matrix on Plasminogen Activator Isozyme Activities of Human Mammary Epithelial Cells in Culture. Molecular and Cell Bio., 3:982-990 (1983).

Y. Manabe, **C. Longley**,and P. Furmanski. High Level Conjugation of Chelating Agents onto Immunoglobulins: Use of an Intermediary Poly(L-lysine)-diethylenetriaminepentaacetic acid Carrier. Biochemica et Biophysica Acta, 883:460-467 (1986).

D. Hofheinz, D. Dienhart, G. Miller, S. Healy, P. Furmanski, S. Sedlacek, **C. Longley**, P. Bunn, and K. Kortright. Monoclonal Antibody KC4G3 Recognizes a Novel Widely Expressed Antigen on Human Epithelial Cancers. Proc. Am. Assoc. Cancer Res., 28:391 (1987).

P.Furmanski and **C. Longley**. Metaloporphyrin Enhancement of Magnetic Resonance Imaging of Human Tumor Zenografts in Nude Mice. Cancer Res., 48:4604-4610 (1988).

D. Bloedow, D. Dienhart, R. Schmelter, P. Furmanski, **C. Longley**, D. Hofheinz, K. Kortright, and P. Bunn. Kinetics of 111-Indium Labeled Monoclonal Antibody KC4G3 in Mice. Pharmaceutical Research, 5:5188 (1988).

D. Dienhart, R. Schmelter, J. Lear, G. Miller, **C. Longley**, P. Furmanski, T. Braun, D. Hofheinz, S. Glenn, K. Kortright, and P. Bunn. Imaging and Therapy of Metastatic Non-small Cell Lung Cancer with Monoclonal Antibody KC4G3. Proc. 3rd Int. Conference Monoclonal Antibody Immunoconjugates for Cancer, (1988).

D. Dienhart, D. Hofheinz, G. Miller, S. Healy, K. Kortright, P. Furmanski, **C. Longley**, and P.Bunn. Human Milk Fat Globule Antigens Should Be Involved in the Lung Cancer Cluster Designation of Tumor Antigens. Abstracts of Fifth World Conference on Lung Cancer. (1988).

D. Dienhart, R. Schmelter, S. Sedlacek, J. Lear, G. Miller, **C. Longley**, P. Furmanski, M. Tagawa, D. Hofheinz, S. Glenn, K. Kortright, and P. Bunn. Imaging Breast Cancer with Indium-111 Labeled Monoclonal Antibody KC4G3. Proc. Am. Assoc. Cancer Res., 29,419 (1988).

C. Longley, P. Furmanski, D. Dienhart, J.Lear, R. Ritenour, D. Bloedow, K. Kortright, R. Ceriani, and P. Bunn. Biodistribution of 111-In-KC4G3 and 131-I-MC5 Human Milk Fat Globule Monoclonal Antibodies in Mice. Proc Am. Assoc. Cancer Res., 30:398 (1989).

C. Longley, P. Furmanski, D.G. Dienhart, J. Lear, D. Bloedow, R. Kasliwal, and P.A. Bunn. Pharmacokinetics, Biodistribution, and Gamma Camera Imaging of 111-In-KC-4G3 Murine Monoclonal Antibody in Athymic Nude Mice With or Without Human Tumor Xenografts. Cancer Res., 50:5954-5961 (1990).

P.A. Bunn, D.G. Dienhart, R. Gonzalez, R. Kasliwal, D. Bloedow, C. Hartman, J. Lear, T. Johnson, P. Furmanski, G.J. Miller, S. Glenn, **C. Longley**, R. Ceriani, and G. Butchko. Imaging, Pharmacokinetics, Dosimetry, and Anti-tumor Effects of Radiolabeled Anti-breast Cancer Antibodies in Mouse and Man. In Breast Epithelial Antigens, R.L. Ceriani ed. Plenum Press: New York; pp. 215-225 (1991).

M.R. Rosenstraus, M. Ultee, **C. Longley**, M.J. Abrams, G. Bridger, D.A. Schwartz, P. Padmanabhan, and S.K. Larson. Antibody Immunoconj. Radiopharm., 6:81 (1993).

M. Ultee, **C. Longley**, M.J. Abrams, G. Bridger, P. Padmanabhan, D.A. Schwartz, and S.K. Larsen. Antibody Immunoconj. Radiopharm., 6:84 (1993).

M. Ultee, M.R. Rosenstraus, **C. Longley**, G. Bridger, P. Padmanabhan, D.A. Schwartz, S.K. Larsen, and M.J. Abrams. Comparison of Direct and Indirect Labeled Immunoconjugates in MCF-7 Tumor Bearing Nude Mice. (in preparation).

M. Ultee, **C. Longley**, G. Bridger, P. Padmanabhan, D.A. Schwartz, S.K. Larsen, and M. Abrams. Comparison of Metabolizable and Non-Metabolizable Technetium Pyridylhydrazine Linkers in LS174T Tumor Bearing Mice. (in preparation)

C.A. Burton, **C. Longley**, S. Vaghasia, and M. Ultee. Technology transfer of an anti-breast cancer immunodiagnostic agent from research to production for clinical trials. 7th Annual Cancer Workshop. New Jersey Commission Cancer Research (1993).

HELENA R. AXELROD, PhD

EDUCATION:

1978-1980	Sloan-Kettering Institute for Cancer Research, New York, NY, Postdoctoral fellow in the Laboratory of Developmental Genetics
1972-1978	Princeton University, Princeton, NJ, Ph.D. in Biology
1968-1972	Brooklyn College, City University of New York, Brooklyn, NY, B.S., Chemistry and Biology, Summa Cum Laude, Sigma Xi, Phi Beta Kappa

Advanced Courses:

1990-1993	Management Courses, CYTOGEN Corp.
1989	Tumor Microcirculation, Carnegie Mellon University
1979	Mammalian and Medical Genetics, The Jackson Laboratory
1975	Immunogenetics, Cold Spring Harbor Laboratories

PROFESSIONAL EXPERIENCE:

1993-Present	Director, Biological Research, TRANSCELL TECHNOLOGIES, Monmouth Jct., NJ,
1991-1993	Assistant Director, Biological Research, CYTOGEN CORPORATION, Princeton, NJ
1990-1991	Group Leader, Molecular and Tumor Biology, CYTOGEN CORPORATION, Princeton, NJ
1989-1990	Group Leader, Tumor Biology, CYTOGEN CORPORATION, Princeton, NJ
1988-1989	Principal Research Scientist, Tumor Biology, CYTOGEN CORPORATION, Princeton, NJ
1986-1988	Head of HybridomaGroup, INTERFERON SCIENCES, INC., New Brunswick, NJ
1982-1986	Research Investigator, Laboratory of Developmental Biology, WISTAR INSTITUTE, Philadelphia, PA
1972-1973	Teaching Assistant, Department of Biology, PRINCETON UNIVERSITY, Princeton, NJ

HELENA R. AXELROD, PhD

RADIONUCLIDE EXPERIENCE:

Dr. Axelrod began using isotopes in 1973 as a graduate student at Princeton University. While at Princeton she used ^{35}S and ^{3}H for the labelling of proteins and DNA in cells, handling quantities up to 100 mCi . In addition, she performed radioiodinations of cell surface proteins, which involved using up to 100 mCi of radioactivity. During her post doctoral work at Memorial Sloan-Kettering Institute and while working at the Wistar Institute and Interferon Sciences, Dr. Axelrod, continued to used ^{35}S, ^{3}H and ^{125}I at 10 - 100mCi levels. Also while at the Wistar institute, she recieved formal training in and performed studies using a sealed source cesium irradiator. Dr. Axelrod joined CYTOGEN Corporation in 1988 and supervised personnel using ^{51}Cr, ^{99m}Tc, ^{111}In and ^{90}Y.

Professional Organizations:

American Association for the Advancement of Science
American Association of Pharmaceutical Scientists
Association for Women in Science
American Society for Cell Biology
Controlled Release Society
International Society of Tumor Targeting
New York Academy of Sciences

CURRICULUM VITAE

Nicole Theriault Hatzenbuhler

Education:

1973	College Bois-de-Boulogne, Montreal, Quebec, Canada. DEC (Diploma of Collegial Studies in Pure and Applied Sciences)
1976	McGill University, Montreal, Quebec, Canada. B.S.
1981	McGill University, Montreal, Quebec, Canada. Ph.D.

Post Graduate Training:

1983	Basic Radioisotope Techniques, The Upjohn Company, Kalamazoo, Michigan
1991	Radiation Safety Training, The Upjohn Company, Kalamazoo, Michigan

Professional Experience:

1993 - present	Scientist, Transcell Technologies, Monmouth Junction, New Jersey
1991 - 1992	Senior Research Scientist III, The Upjohn Company, Kalamazoo, Michigan
1987 - 1991	Research Scientist II, The Upjohn Company, Kalamazoo, Michigan
1983 - 1987	Scientist I, The Upjohn Company, Kalamazoo, Michigan
1981 - 1983	Post Doctoral, The Upjohn Company, Kalamazoo, Michigan

Radioisotope Experience:

Dr. Hatzenbuhler recieved formal training in the use of radioisotopes in 1983 from The Upjohn Company, Kalamazoo, Michigan. She recieved additional training in Radiation Safety from The Upjohn Company in 1991. Dr. Hatzenbuhler used ^{32}P at microcurie

levels and was approved by Upjohn to use ^{3}H, ^{14}C and ^{35}S. After joining Transcell Technologies in 1993, Dr. Hatzenbuhler established and has chaired the Laboratory Safety Committee.

Publications:

45 Refereed journal publications

Patents:

Two patent applications

Honors:

1977 - 1981	Quebec Goverment Postgraduate Scholoarship
1977 - 1980	NSERCC Postgraduate Scholarship
1980 - 1981	NSERCC Postdoctoral Fellowship
1981	D.W. Ambridge Award, McGill University
1982	Winkler Award, McGill University

Eugene R. Baizman
curriculunm vitae

Education:

1968	Massachusetts College of Pharmacy B.S. Pharmacy
1970	Massachusetts College of Pharmacy M.S., Pharmacology
1976	Ohio State University Graduate School Ph.D. Pharmacology

Professional Experience:

1976-1978	Addiction Research Foundation Palo Alto, CA. N.I.D.A. Postdoctoral Fellow
1978 - 1992	Sterling Winthrop Research Institute Rensselaer, N.Y. 12144 Senior Research Biologist
1992-1994	Sterling Drug Inc., Div of Eastman Kodak Corp. Collegeville, PA Senior Research Investigator
1995-present	Transcell Technologies, Inc 2000 Cornwall Rd. Monmouth Jct., N.J. 08852 Senior Research Scientist

Radioisotope Expertise:

1) Ohio State University Graduate School: Radioisotope Methodology -1 semester course, covering: types of radiation; radiation hazards; protection/mitigation techniques; medical/research use of radioisotopes; safety in radioisotope handling and storage; measurement techniques and instrumentation for various types of radioisotopes. Some practical experience working with ^{3}H, ^{14}C, and ^{32}P.

2) Addiction Research Foundation: Practical, on-the-job experience working daily with ^{3}H-opioid ligands (microcurie range - from commercial vendors, supplied as

ethanol/water stock solutions) used for metabolic (receptor) labelling studies. Waste handling techniques.

3) Sterling-Winthrop Research Institute: Formal training in low-level activity radioisotope handling/use/safety/storage/disposal by the resident Radiation Safety Officer. Periodic yearly refresher courses. Practical, on-the-job experience with ^{3}H-ligands, supplied as ethanol stock solutions (microcurie range) from commercial vendors, and used for metabolic (receptor site) labelling. Also experience with ^{125}I-labelled ligands, also for receptor labelling (millicurie range)

4) Sterling Drug Inc, Div of Eastman Kodak: Formal 2-day training session by resident RSO in handling/safe use/storage/disposal of radioisotopes w/yyearly referesher courses. On-the-job experience with low-activity level (microcurie range) ^{3}H-radioligands (ethanol/water stock solutions from commercial vendors) used for metabolic (enzyme/receptor site) labelling.

5) Transcell Technologies, Inc: Formal training course at Rutgers University (by RSO) plus perioidic refresher updates by in-house RSO. Practical experience with low-level ^{14}C-radioligands (microcurie range) used for metabolic labelling

Professional Affiliations/Fellowships/Awards:

Society for Neuroscience
Society for Biomolecular Screening
American Association for the Advancement of Science
Sigma Xi
National Institute of Drug Abuse Postdoctoral Fellow
Fellow, American Foundation for Pharmaceutical Education
Fellow, Biological Sciences Department, Mass. Coll.of Pharm.
Frederick Kleinschmidt Scholarship
Rho Chi Honor Society
Mongomery County Pharmaceutical Association
American Society of Health-System Pharmacists:Bux-Mont chapter

Publications:

Manuscripts

Witiak, O.T., Seth, S.K., **Baizman, E.R.**, Weibel, S.L. and Wolf, H.H.: Para-substituted N-acetyl-L(S)- and D(R)-alpha amino N-phenylsuccinimides and -glutarimides. Substituent effects on stereoselective anticonvulsant activity. J. Med. Chem. 15:1117-1123, 1972.

Baizman, E.R., and Jenkins, H.J.: Mechanisms of methacholine-induced rise in intraocular pressure in the dog. J. Pharm. Sci. 66: 1013-1015, 1977.

Baizman, E.R. and Cox, B.M.: Endorphin in rat pituitary glands: Its distribution within the gland and age-related changes in gland content in male and female rats. Life Sci. 22:519-526 1978.

Grevert, P., **Baizman, E.R.** and Goldstein, A.: Naloxone effects on a nociceptive response of hypophysectomized and adrenalectomized mice. Life Sci. 23:723-728, 1978.

Baizman, E.R., Cox, B.M., and Goldstein, A.: Experimental alterations of endorphin levels in rat pituitary. Neuroendocrinology 28:402-424, 1979.

Bailey, D.M., Hansen, P.E., Hlavac, A.G., **Baizman, E.R.**, Pearl, J., DeFelice, A and Feigenson, M.D.: 3,4-Diphenyl-1H- pyrazole-1-propanamine antidepressants. J. Med. Chem. 28:256-268, 1985.

Baizman, E.R., Ezrin, A.M., Ferrari, R.A. and Luttinger, D.: Pharmacologic profile of fezolamine fumarate: A nontricyclic antidepressant in animal models. J. Pharmacol. Exp. Ther. 243:40-53, 1987.

Haubrich, D.R., Ward, S.J., **Baizman, E.**,Bell, M.R., Bradford, J., Ferrari, R., Miller, M., Perrone, M. Pierson, A.K., Saelens, J.K. and Luttinger, D.: Pharmacology of Pravadoline, a novel antinociceptive agent. J. Pharmacol. Exp. Ther. 255:511-522, 1990.

Ward, S.J., **Baizman, E.R.**, Bell, M., Childers, S., D'Ambra, T., Eissenstat, M., Estep, K., Haycock, D., Howlett, A., Luttinger, D., Miller, M., and Pacheco, M.: Aminoalkylindoles (AAIs): A new route to the cannabinoid receptor? NIDA Research Monographs, 105:425-426, 1991.

Bell, M.R., D'Ambra, T.E., Kumar, V., Eissenstat, M.A., Herrmann,Jr, J.L., Wetzel, J.R., Rosi, D., Philion, R.E., Daum, S.J., Hlasta D.J., Kullnig, R.K., Ackerman, J.A., Haubrich, D.R. Luttinger, D., **Baizman, E.R.**, Miller M.S., and Ward, S.J.: Antinociceptive Aminoalkylindoles. J. Med. Chem. 34:1099-1110, 1991

D'Ambra, T.E., Estep, K.G., Bell, M.R.,Eissenstat, M.A., Josef, K.A., Ward, S.J., Haycock, D.A., **Baizman, E.R.**, Casiano, F.M., Beglin, N.C., Chippari, S.M., Grego, J.D., Kullnig, R.K. and Daley, G.T., (1992): Conformationally restricted analogs of pravadoline: Nanomolar potent, enantioselective, (Aminoalkyl)-indole agonists of the cannabinoid receptor. J. Med. Chem.35:124-135.

Johnson, R.F., **Baizman, E.R.**, Becker, C., Bohnet, E.A., Bell, M.H., Birsner, N.C., Busacca, C.A., Carabateas, P.M., Chadwick, C.C., Gruett, M.D., Hane, I.T., Pareene, P.A., Perni, R.B., O'Connor, B.O., Salvador, U.J., Sanner, M.A., Schlegel, D.C., Silver, P.J , Swestock, J., Stankus, G.P., Tatlock, J.H., Volberg, W.A., Weigelt, C.C., and Ezrin, A.M. (1993): 4,5-Dihydro-1-phenyl-1H-2,4-benzodiazepines: Novel Antiarrhythmic Agents. J. Med. Chem. 36:3361-3370

Sawutz, D.G., Salvino, J.M., Dolle, R.E., Casiano, F., Ward, S.J., Houck, W.T., Faunce, D.M., Douty, B.D., **Baizman, E.R.**, Awad, M.M.A, Marceua, F., and Seone, P.R. (1994) The nonapeptide WIN 64338 is a bradykinin B_2 receptor antagonist. Proc. Natl. Acad. Sci. 91:4693-4697.

Wetzel, J.R., Mallamo, J.P., DeHaven-Hudkins, D.L. and **Baizman, E.R.** (1994): (+)-2'-Hydroxy-2-[(3,3-dimethylcyclobutyl) methyl]-cis-5,9-dimethyl-6,7-benzomorphan: A potent ligand for the sigma binding site. Med. Chem. Res. (1995).

Hill, R.J., Grant, A.M., Volberg, W., Rapp, L. Faltynek, C., Miller, D., Pagani, K., Baizman, E., Wang, S., and Krafte, D.S. (1995): WIN 17317-3: Novel non-peptide antagonist of voltage activated K^+ channels in human T-lymphocytes. Mol. Pharmacol. 48:98-104.

Book Chapters

Cox, B.M., **Baizman, E.R.** Su, T.P., Osman, O.H., and Goldstein, A. (1978): Further studies on the nature and functions of pituitary endorphines. In: Advances in Biochemical Psychopharmacology, Vol. 18, E. Costa and M. Trabucci, eds. Raven Press, N.Y. pp 183-189.

Cox, B.M. and **Baizman, E.R.** (1982): Physiological functions of endorphins. In: Endorphins, Chemistry, Physiology, Pharmacology and Clinical Relevance. J.B. Malik and R.M.S. Bell, eds. Marcel Dekker, N.Y. pp.113-196.

Haubrich, D.R., **Baizman, E.**, Morgan, B.A. and Saelens, J., (1984): The role of endogenous non-endorphin analgesics. In: Analgesics: Neurochemical, Behavioral and Clinical Perspectives. M.J. Kuhar and G.W., Pasternak, eds. Raven Press, N.Y. pp. 195-234.

Abstracts

Witiak, D.T., Seth, S.K., **Baizman, E.R.**, Weibel, S.L and Wolf, H.H.: The pharmacology of some novel succinimide and glutarimide anticonvulsants of known absolute configuration. Fed. Proc. 31:249, 1972.

Baizman, E.R. and Wolf, H.H.: Central mechanisms involved in morphine-induced hypothermia: Differentiation by selective receptor blockade. Fed. Proc. 34:787, 1975.

Baizman, E.R., Osman, O.H. and Cox, B.M.: Endorphin levels in rat pituitary. Soc. Neurosci. 3:286, 1977.

Baizman, E.R., Pearl, J., Ferrari, R.A. and Piwonka, R.W.: A novel anti-depressant in animal models. Fed. Proc. 40:248, 1981.

Pierson, A., Cumiskey, W., Wescoe, D., Lawyer, H., **Baizman, E.R.**, Michne, W.F. and Feigenson, M.: In vitro receptor selectivity profile and the in vivo constipative effects of opiates. Soc. Neurosci. 8:221, 1982.

Baizman, E.R., LoPresti, D.M., Meo, N.J., Pierson, A.K. and Morgan, B.A.: In vitro and in vivo studies of substance P (SP) and two putative SP antagonists. Soc. Neurosci. 8:986, 1982.

Baizman, E.R., Kiefer, D.A., LoPresti, D.M., Meo, N.J., Perrone, M.H., Diehl, R.E., Pierson, A.K., Hansen, P.E., Gordon, T.D. and Morgan, B.A.: Novel hexapeptide analogs of substance P (SP) as putative SP antagonists. Soc Neurosci. 9:142, 1983.

Baizman, E.R., Gordon, T.D., Hansen, P.E., Kiefer, D., LoPresti, D.M., McKay, F.C., Morgan, B.A. and Perrone, M.H.: Structure and antagonist activity in a series of hexapeptide substance P analogs. In: Peptides: Structure and Function. Proc. 8th Am. Peptide Symp. W. Hruby and D.H. Rich, eds., Pierce, 1983, pp 437-440.

Baizman, E.R., Gordon, T.D., Hansen, P.E., Kiefer, D., McKay, F.C., Morgan, B.A., Posi, D., Singh, J., Stevenson, J. and Ward, S.J.: Structure-function studies in a series of substance P antagonists. In: Peptides, 1984. Proc. 18th European Peptide Symp. U.R. Almquist, ed., Wiskell International, Stockholm, pp. 359-364.

Ward, S.J., Kiefer, D., and **Baizman, E.R.**: Naloxone-induced contractures in the capsaicin-pretreated guinea pig ileum preparation: possible involvement of kappa receptors. International Narcotics Research Conference Abstracts, 1985. pp. 65.

Baizman, E.R., Bentley, H., Ferrari, R.A. and Ward, S.J.: Ulcerogenic potential of non-steroidal antiinflammatory drugs (NSAIDs) in the mouse. The Pharmacologist 27:243, 1985.

Ferrari, R.A., Zobre, C., Connell, M.J., **Baizman, E.R.** and Bentley, H.: Comparative inhibition of PGE2 formation in mouse stomach ex vivo by acetaminophen and non-steroidal antiinflammatory agents. Fed. Proc. 45:924, 1986.

Baizman, E.R., Bradford, J.C., Bentley, H., Pierson, A.K. and Ward, S.J.: Win 48098: A non-opioid analgesic lacking ulcerogenic effects in animal models. The Pharmacologist 28(3):140, 1986.

Haubrich, D.R., **Baizman, E.R.**, Bell, M.R., Miller, M., Pierson, A.K., Saelens, J.K., Stecher, V.J., Ward, S.J., Perrone, M.H. and Luttinger, D.: Antinociceptive activity of Win 48098. The Pharmacologist 28(3):140, 1986.

Baizman, E.R., Bell, M.R., Bradford, J.C., Ferrari, R.A., Haubrich, D.R., Luttinger, D., Miller, M.S., Perrone, M.H., Pierson, A.K., Saelens, J.K. and Ward, S.J.: Antinociceptive activity of Win 48098. Br. J. Pharmacol. 90(Suppl):66P, 1987.

Ward, S.J., Luttinger, D.L., **Baizman, E.R.**, Berger, B.M., Bradford, J.C., Grieco, G., Haubrich, D.R., Miller, M.S., Perrone, M.H., Pierson, A. , Saelens, J.K., Skinner, J.B., and Stroshane, R.: Pharmacologic profile of WIN 48098, a new analgesic. Pain Suppl. 4:847, 1987

Morgan, B.A., Singh, J., **Baizman, E.R.**, Bentley, H., Kiefer, D. and Ward, S.: Structure-function studies in a series of tachykinin antagonists containing the conformationally constrained tryptophan analog, 2,3,4,9-tetrahydro-1H- pyrido[3,4-6]indol-3-carboxylic acid. Proc. 10th Amer. Peptide Symp. St. Louis, Escom publishers,pp. 508-509, 1988

Ward, S.J., **Baizman, E.R.** and Morgan, B.A.: Antinociception and Substance P Antagonist Activity in a Series of Analogs of Subtance P6-11. The Pharmacologist, 30:A154, 1988.

Baizman, E.R., Beglin, N., Koonz, D. and Luttinger, D.: Inhibition of NSAID-induced Antinociception in Mice by Alpha-2 Adrenergic Receptor Blockade Soc. Neurosci. 14:851, 1988.

Gordon, T., Hansen, P., McKay, F., Morgan, B., Singh, J., **Baizman, E.**, Kiefer, D, and Ward, S.: Peptide Azoles: A novel approach in the design of peptide mimetics and its application to tachykinin antagonists. Abstr 20th European Peptide Symposium, Tubingen, FRG, 1988.

Gordon, T., Hansen, P., Morgan, B., Singh, J., **Baizman, E.** and Ward, S.J.: Peptide Azoles: A new class of biologically active dipeptide mimetics. Proc. 11th Amer. Peptide Symp., 1989

Baizman, E., Grant, A., Horan, P., Ezrin, A., and Harris, A.L. (SPON: A.L. Maycock): Inhibition of batrachotoxinin-B (BTX-B) binding in rat brain. Relationship to antiarrhythmic effects of ipazilide and reference agents in the guinea pig. FASEB J. 4: A1004, 1990

Luttinger, D., **Baizman, E.**, Miller, M. and Ward, S.: The in vivo effects of aminoalkylindoles, a new class of compounds interacting with a cannabinoid binding site. Comm. for Prevention of Dependence Disorders. June, 1990

Longley, C., **Baizman, E.**, Hui, Y.-W., Chen, A., Weber, S. and Axelrod, H. Pharmacokinetics and metabolism of a novel glycosteroid oral absorption enhancer in rats. Abstr. of Amer. Assoc. of Pharmaceutical Scientists, Eastern regional meeting, New Brunswick, N.J., 1996.

CURRICULUM VITAE

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(908) 940-6928

Summary of Research Expertise:
Diversified experience in molecular biology, bacterial and viral pathogenesis, gene expression and regulation, vaccine development, bacterial genetics, and cell biology.

Education:

1990 Ph.D. (Biomedical Sciences)
Wright State University, Dayton, Ohio.

1983 B.S. (Biochemistry)
Northern Michigan University, Marquette, Michigan.

Professional Research Experience:

Oct. 1996 - Present
Research Scientist
Transcell Technologies, Inc.

May 1992 - Oct. 1996
Research Microbiologist,
Walter Reed Army Institute of Research. Washington, DC.

June 1990 - May 1992
Postdoctoral National Research Council Associate,
Walter Reed Army Institute of Research, Washington, DC.

Feb. 1989 - May 1990
Director/Consultant of DNA Analysis,
National Paternity Laboratories, Inc., Dayton, OH.

Aug. 1983 - March 1990
Predoctoral Fellow, Biomedical Sciences Ph.D. Program,
Wright State University, Dayton, OH.

Radioisotope Experience:

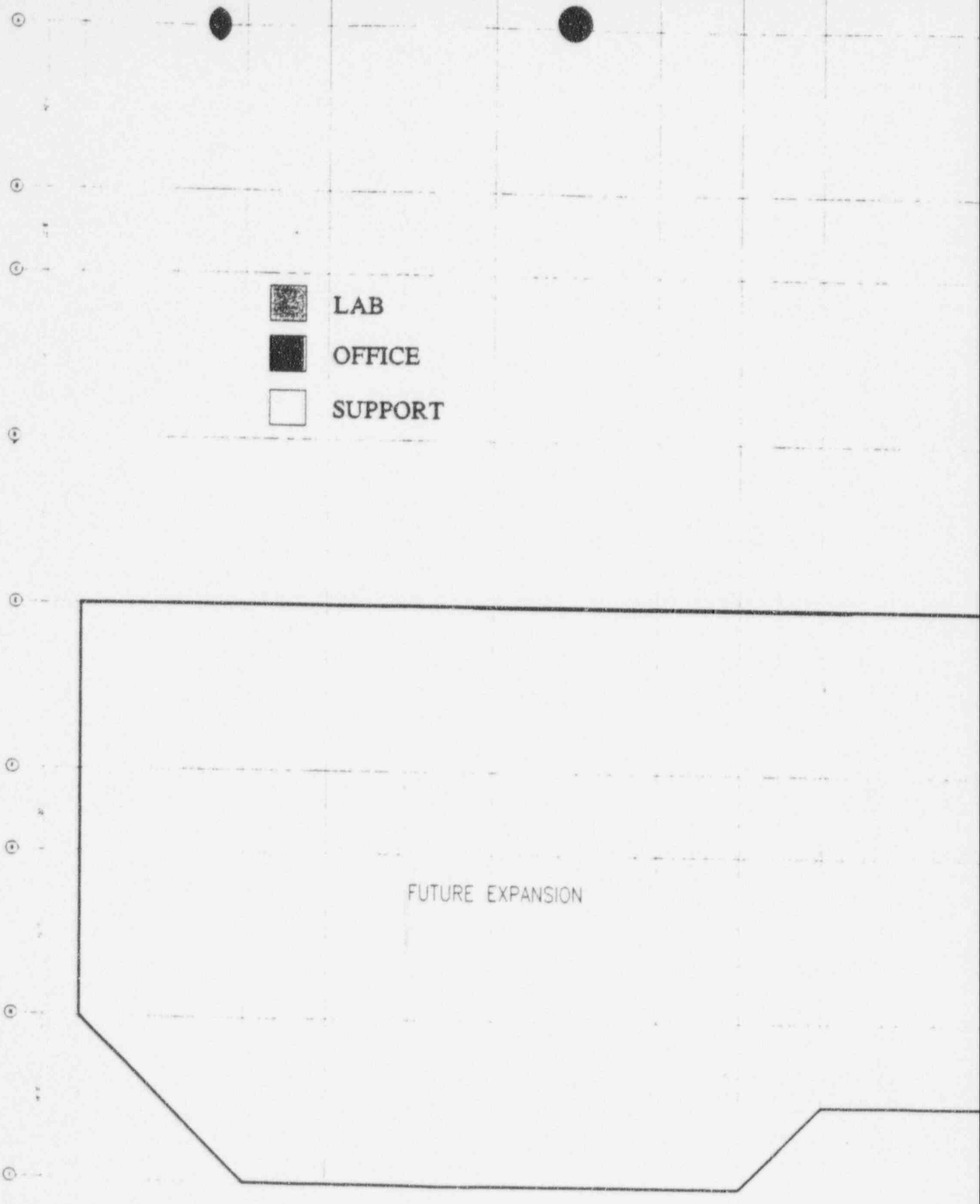
Arthur Branstrom has hands-on experience using radionucleotides since 1984 when a career in science was initiated by performing experiments as a graduate student at Wright State University. Work involving the characterization of bacterial genes involved in the regulation of virulence properties necessitated the use of ^{32}P for DNA labeling and DNA hybridizations. DNA Sequencing also required the use of ^{35}S in amounts not exceeding 250 μCi. Metabolic studies and enzymatic assays using bacteria employed the isotopes ^{3}H and ^{14}C. Safe and proper procedures for the use of radioisotopes was adhered to while performing experiments and was supported by the complete absence of radioactive contamination after clean-up of the work areas and subsequent monitoring. While at the Walter Reed Army Institute of Research, experiments involving ^{32}P, ^{35}S and ^{3}H were also performed routinely. Quantities used never exceeded 250 μCi at any one time.

Attachment 2

Facility Floor Plans and Systems

Attachment 2-1

General Facility Layout



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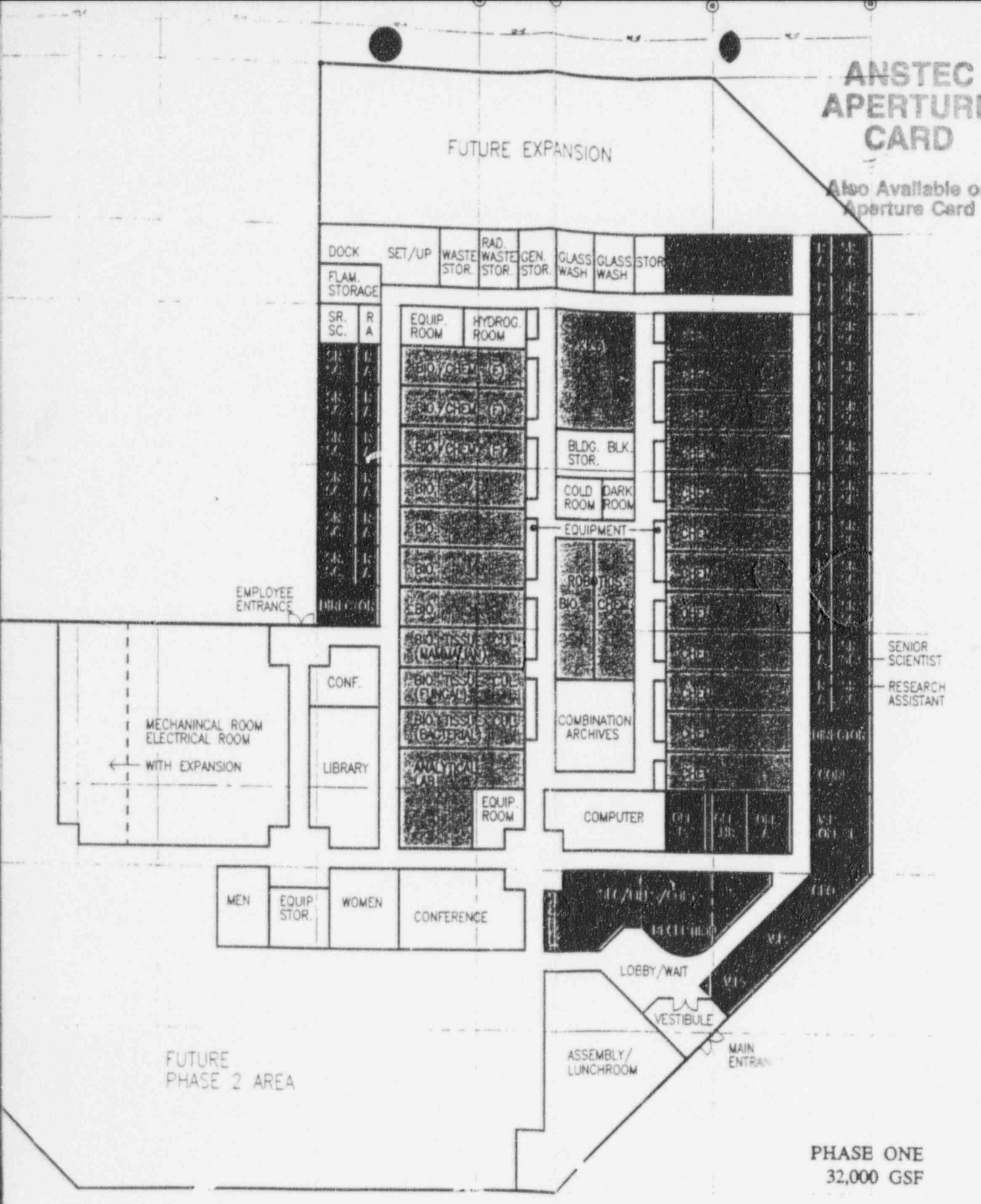


PHASE ONE
32,000 GSF

TRANSCELL TECHNOLOGIES INC.

PHASE ONE PLAN 1" = 32' 07/18/96

9706240062 - 03

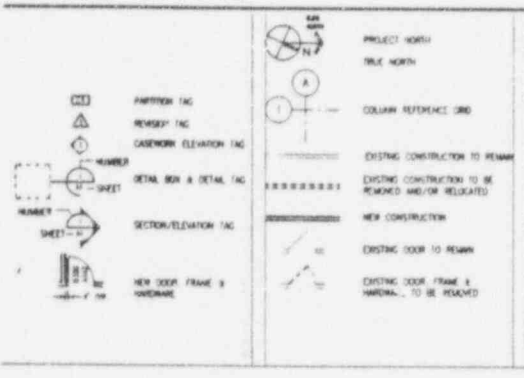
Attachment 2-2

Laboratory Floor Plan

TRANSCELL TE
CRANBURY,

CEDAR BROOK C
1000 EAST
CRANBURY

SYMBOL LEGEND



APPLICABLE CODES & GUIDELINES

STATE OF NEW JERSEY
1) BOCA BASIC BUILDING CODE - 1993
2) AMERICAN WITH DISABILITIES ACT (ADA) 1991
3) NATIONAL ELECTRIC CODE 1993
4) NATIONAL PLUMBING CODE 1993
5) NATIONAL MECHANICAL CODE 1993

CODE REQUIREMENTS SUMMAR

	BOCA NATIONAL BLDG CODE/1993
OCCUPANCY/USE GROUP CLASSIFICATION	BUSINESS
CONSTRUCTION TYPE	2C UNPROTECTED
INTERIOR FIRE SEPARATIONS	
VERTICAL OPENINGS/SHAFTS	TWO HOUR
EXIT ENCLOSURES	TWO HOUR
SUITE SUBDIVISION PARTITIONS	0 HOUR
EXIT ACCESS CORRIDORS	0 HOUR
TENANT SPACE SEPARATIONS	0 HOUR
DEAD END CORRIDORS	20 FEET MAX
LENGTH OF EXIT ACCESS TRAVEL	150 FEET WITH FIRE SUPPRESSION
FLAMMABLE STORAGE	TWO HOUR

DRAWING LIST

ARCHITECTURAL

A0	TITLE SHEET
A1	1/8" PLAN
A2	1/8" REFLECTED CEILING PLAN
A3	1/4" PLANS
A4	CASEWORK ELEVATIONS
A5	MISCELLANEOUS DETAILS
A6	MISCELLANEOUS DETAILS
A7.1	INTERIOR ELEVATIONS
A7.2	INTERIOR ELEVATIONS
A8	LAB SECTIONS AND EQUIPMENT SCHEDULE
D1	FINISH PLAN
D2	FURNITURE PLAN

PLUMBING

P0	PLUMBING INDEX SHEET
P1	GROUND FLOOR PLAN - UNDERGROUND DRAINAGE
P2	NOT USED
P3	GROUND FLOOR PLAN - DRAINAGE
P4	NOT USED
P5	GROUND FLOOR PLAN - SERVICE PIPING
P6	NOT USED
P7	SCHEDULES AND DETAILS
P8	SCHEDULES AND DETAILS

MECHANICAL

H0	INDEX SHEET
H1	DUCTWORK
H2	PIPING
H3	ROOF PLAN
H4	EQUIPMENT SCHEDULE
H5	EQUIPMENT SCHEDULES
H6	FLOW DIAGRAMS AND DETAILS
H7	DETAILS
H8	ATD DIAGRAMS

ELECTRICAL

E0.1	ELECTRICAL COVER SHEET
E0.2	SINGLE LINE DIAGRAM - NORMAL POWER
E0.3	SINGLE LINE DIAGRAM - EMERGENCY PO
E2.1	FIRST FLOOR PLAN - POWER AND SIGNA
E2.2	FIRST FLOOR PLAN - LIGHTING
E2.3	ROOF PLAN - POWER, SIGNALS AND LIG
E4.1	LIGHTING FIXTURE AND PANELBOARD SCH
E4.2	PANEL BOARD SCHEDULED

CHNOLOGIES INC.
NEW JERSEY

ORPORATE CENTER
PARK BLVD.
NEW JERSEY

ARCHITECTURAL ABBREVIATIONS

@	at	EL	elevation (grade, floor)	LAV	lavatory	SAN	sanitary
&	and	ELEC	electrical	LB	lag bolt, wood screw	SB	splash block
#	pound	ELEV	elevation (ext), elevator	LLH	long leg horizontal	SCHED	schedule
'	foot	EMBED	embedment	LLV	long leg vertical	SECT	section
"	inch	EMER	emergency	LP	light proof, low pressure, low point	SECY	secretary
℄	centerline	ENCL	enclosure	LTG	lighting	SF	square feet
		ENGR	engineer(ing)	LVR	louver	SG	single
@	anchor bolt	ENTR	entrance			SH	shelf
ABV	above	EP	electrical panelboard			SHR	shower
ADH	adhesive	EQ	equal	M	male	SHT	sheet(ing)
AC	air conditioning	EQUIP	equipment	MACH	machine	SHTHG	sheathing
ACC	access(ible)	ES	each way	MAS	masonry	SIM	similar
ACOUS	acoustical	EWC	electric water cooler	MATL	material	SK	sink
ACT	acoustical ceiling tile	EXH	exhaust	MAX	maximum	SL	slotted
AD	area drain	EXIST	existing	MB	marker board	SLF	slope
ADH	adhesive	EXP	expansion	MBR	member	SMLS	seamless
ADJ	adjacent, adjustable	EXT	exterior	MECH	mechanical	SP	spacing
AFF	above finished floor	EYEW	eyewash	MEMB	membrane	SPEC	specification
AGGR	aggregate			MET	metal	SPKR	speaker
AL	aluminum			MEZZ	mezzanine	SPR	sprinkler
ALT	alternate	FA	fire alarm	MFR	manufacturer	SQ	square
AP	access panel	FCBB	fiberglass cement backer board	MH	manhole	SR	service recessed
APC	architectural precast concrete	FCO	fan coil unit	MIN	minimum	SS	service sink
APPROX	approximate	FD	floor drain	MIR	mirror	SST	stainless steel
ARCH	architect(ural)	FDC	fire department connection	MISC	miscellaneous	STA	station
		FDN	foundation	MJ	movement joint (in masonry)	STAGE	staggered
BD	board	FE	fire extinguisher	MLDG	molding	STC	sound transmission class
BETW	between	FEC	fire extinguisher cabinet	MLWK	millwork	STD	standard
BO	bumper guard	FF	finish floor	mm	millimeter	STRUC	structural
BTLW	babyshoe(ing)	FGL	fiberglass	MO	masonry opening	STL	steel
BLK	backer	FIN	finish	MTD	mounted	STOR	storage
BLDG	building	FL	flashing	MTG	mounting	STR	structure
BLK	block	FLDG	folding	MULL	mullion	SUSP	support
BLKG	blocking	FLR	floor			SURF	surface
BLW	below	FLUOR	fluorescent			SUSPEN	suspended
BM	beam, benchmark	FOC	face of conc	N	north	SYM	symbol
BOT	bottom	FOF	face of finish	NA	not applicable	SYM	symmetrical
BP	base plate	FOM	face of masonry	NF	near face	SYS	system
BR	bearing	FOW	face of wall	NIC	not in contract		
BRKG	bracing	FP	frost proof	NO	number		
BRZ	bronze	FPRF	fireproofing	NOM	nominal	T	tread, flush mounted telephone
BRK	brick	FR	frame	NRC	noise reduction coefficient	TBE	tongue and groove
BRKT	bracket	FRH	fire retardant treated	NS	near side	TB	tackboard, towel bar
BS	both sides	FS	far side, full size	NTS	not nessary feet	TEL	telephone
BSMT	basement	FSPC	fire spacing	NTS	not to scale	TEMP	temperature
BUR	built up roof	FTG	fire stand pipe			TEMP	tempered
		FT	feet, foot, frost line	OA	overall	TERR	terrazzo
C/C	center to center	FTG	footing	OC	on center	THK	thickness
CAB	cabinet	FTR	finned tube radiation	OD	outside diameter	TOB	top of beam
CB	catch basin, chalkboard, cashbox box	FURN	furniture	OF	outside face	TOC	top of curb, concrete
CBF	composite building panel	FURR	furring	OFF	office	TOF	top of parapet
CCTV	closed circuit television	FUT	future	OH	opposite hand, overhead	TOS	top of slab
CEM	cement	FWC	fabric wall covering	OPNG	opening	TOS	top of stair
CG	corner guard	FXTR	fixture	OPP	opposite	TOW	top of wall
CH	ceiling height					TR	toilet room
CI	cast iron			PAR	parallel	TV	television
C.J.	control joint	GA	gauge	PASS	passage, passenger	TYP	typical
CL	center line, closet	GALV	galvanized	PB	push button		
CLG	ceiling	GC	general contractor	PBD	particle board	UC	undercounter
CLR	clear	GFRC	glass fiber reinforced concrete	PC	precast (structural)	UH	unit heater
CMU	concrete masonry unit	GFRG	glass fiber reinforced gypsum	PED	pedestal	UNFIN	unfinished
COL	column	GL	glass	PERIM	perimeter	UNO	unless noted otherwise
COMM	communication	GR	grade	PERP	perpendicular	UP	urinal
COMP	compressible	GRA	grade	PGBD	pegboard	UTL	utility
CONC	concrete	GRTG	grating	PL	plate, property line		
CONF	conference	GSF	gross square feet	PLAM	plastic laminate	VAR	varies
CONST	construction	GSM	gypsum wallboard	PLAS	plaster	VB	vinyl base
CONST J	construction joint	GYP	gypsum	PLAT	platform	VCT	vinyl composition tile
CONT	continuous	H	high	PLBG	plumbing	VERT	vertical
CONTR	contractor	HC	handicapped	PLF	plant	VEST	vestibule
CONN	connector	HCT	handicapped accessible toilet	PLWD	plywood	VIF	verify in field
COORD	coordinate	HD	head	PNEU	pneumatic	VP	vinyl
CORR	corridor, corrugated	HDBD	hardboard	PNL	panel	VTR	returns
CPT	carpet	HDWD	hardwood	PNT	paint	W	water, wash
CRS	course	HDWE	hardware	PREFAB	prefabricated	WC	water closet
CSK	countersink	HFT	half full box	PRELIM	preliminary	WD	wood
CT	computer	HGT	height	PSF	pounds per square foot	WF	wide flange
CTR	center, centered	HM	hollow metal	PSI	pounds per square inch	WHC	wheelchair
CTS	counter(top)	HORIZ	horizontal	PT	paint, pressure treated (for moisture)	WP	weatherproof
CTSK	countersink	HP	high point, high pressure, horse power	PTD	painted	WPT	waterproof
CT	ceramic tile	HR	hour	PTN	partition	WR	wall rail
CTR	center	HW	hardware			WSCT	wainscot
CTS	countertop, sink	HVAC	heating, ventilation, air conditioning	QT	quarry tile	W/O	without
CUB	cubicle					WR	white board
CUH	cabinet unit heater	I.D.	inside diameter	R	riser	WC	water closet, wheelchair
		IF	inside face	RAD	radius	WD	wood
DBL	double	IN	inch	RBR	rubber	WF	wide flange
DEMO	demolition	INCL	including	RCP	reflected ceiling plan	WIN	window
DEPT	department	INS	insulation	RD	roof drain	WP	working point, waterproof
DET	detail	INT	interior	REC	recessed	WPRTG	waterproofing
DF	drinking fountain	INV	invert	RECEPT	receptacle	WR	water resistant, waste receptor
DIA	diameter			RECT	rectangular	WS	waste strip
DIM	dimension	JAN	janitor	REF	reference	WTCT	nonskid
DISP	dispenser	JB	junction box	REFR	refrigerator	WT	weight
DMPR	dampproofing	JCT	junction	REG	register	X'substrate'.dwg 1/8"	
DN	down	JST	joist	REINF	reinforce(d) (ing) (ment)		
DO	ditto	J	joint	RESIL	resilient		
DR	door			RET	retained		
DS	downspout	K	key	REV	reverse, return		
DW	dishwasher, dustless water	KIT	kitchen	RFG	roofing		
DWG	drawing	KO	knock out	RJ	rubber(ized) joint		
DX	duct	KPL	kick plate	RLG	railing		
DWR	drawer			RM	room		
DWTR	durometer	L	long	RO	rough opening, reverse osmosis water		
		LAB	L'oratory	RS	resilient stool		
E	each	LAM	lam. (ination)	RT	resilient tile		
EB	expansion bolt	LAV	lavatory	RWC	raw water conductor		
EF	each face	LB	pound				
EFS	exterior insulation and finish system	LIN	linear				
EJ	expansion joint						

PROJECT MANAGER — HOWARD SKOKE
PROJECT ARCHITECT — ANTHONY J. MAZZA
INTERIOR DESIGNER — CLAIRE CLIFFI

general notes

key plan

no.	by	description	date

revisions

Ewing Cole Cherry Brott
Architects · Engineers · Interior Designers · Planners
Philadelphia, PA 19106 — [illegible], VA 22033

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.
CRANBURY, NEW JERSEY

project title

TITLE SHEET

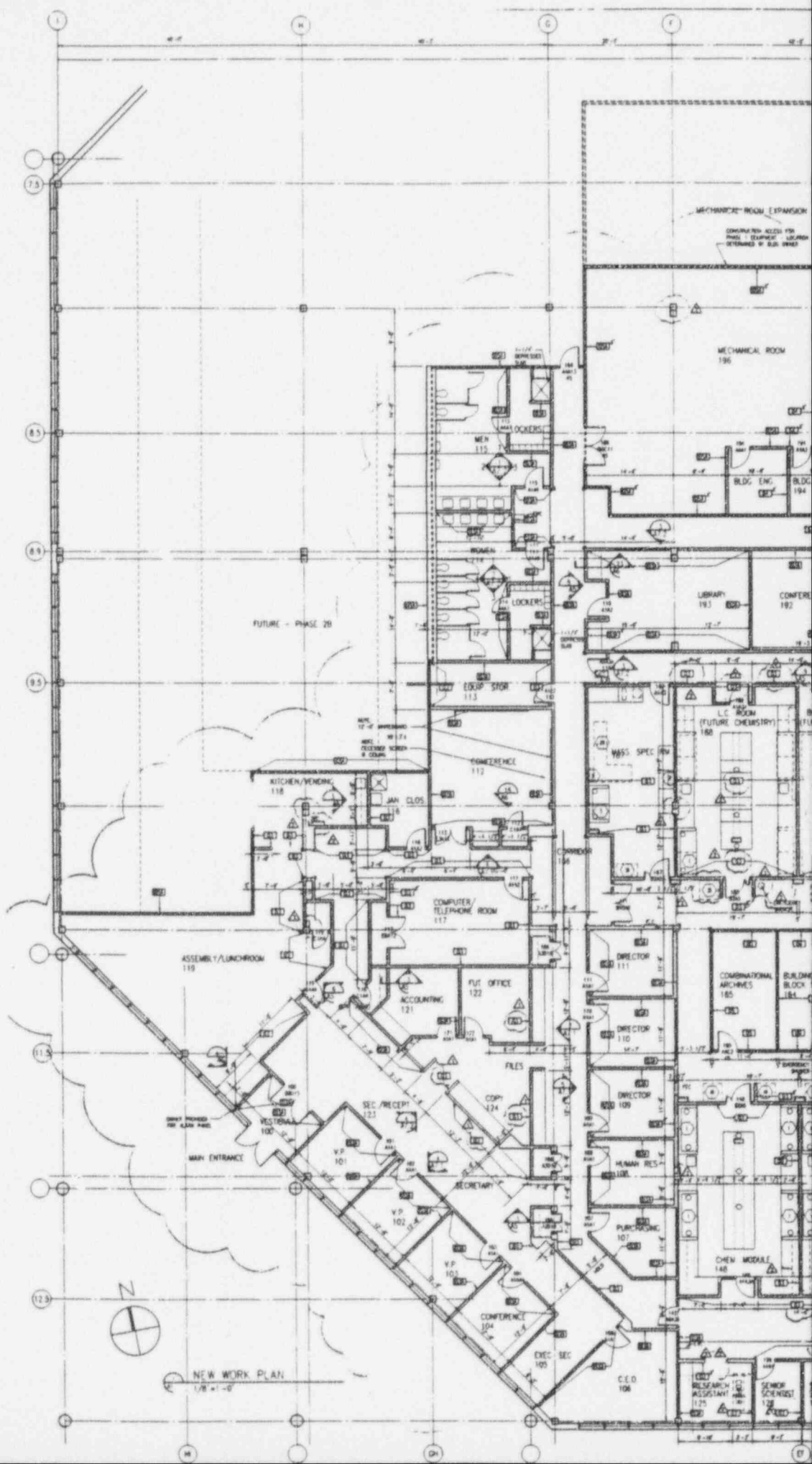
drawing name

scale NOT TO SCALE — date 10/24/94
reference files — drawn by SJM
project no. 9806J
floor/section A0 — drawing no.

Revision No. [illegible] 1/4/95

9706240062-04

124531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WOMEN
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CONFERENCE
112
KITCHEN/VENDING
118
JAN CLOS
COMPUTER/
TELEPHONE ROOM
117
ASSEMBLY/LUNCHROOM
119
ACCOUNTING
121
FVC OFFICE
122
FILES
SEC./RECEPT.
123
COPY
124
VESTIBULE
100
MAIN ENTRANCE
V.P.
101
SECRETARY
V.P.
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V.P.
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CONFERENCE
104
EXEC. SEC.
105
C.E.O.
106
LIBRARY
193
LC ROOM
(FUTURE CHEMISTRY)
160
MASS SPEC RM
DIRECTOR
111
DIRECTOR
110
DIRECTOR
109
COMBINATIONAL
ARCHIVES
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HUMAN RES.
PURCHASING
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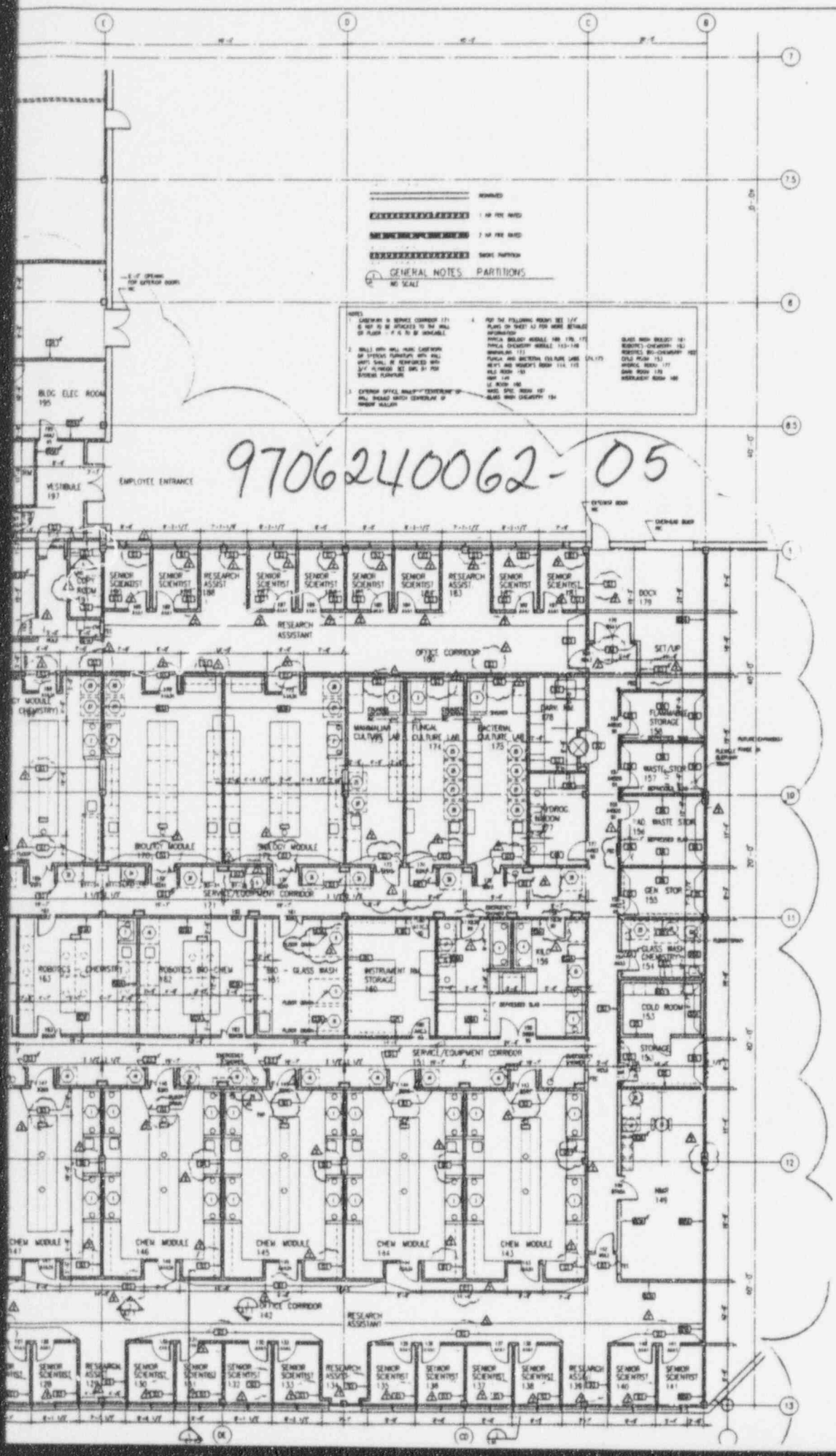
CHEM MODULE
148
BLDG. ENG.
N
NEW WORK PLAN
1/8" = 1'-0"



PROJECT MANAGER — HOWARD SIKORE
PROJECT ARCHITECT — ANTHONY J. MAZZA
INTERIOR DESIGNER — ELAINE CIUFO

general notes

1	JM	ADDENDUM #1	12/5/96
2	JM	REVISIONS	10/24/96
no.	by	description	date

consultants

Ewing Cole Cherry Brott

Architects · Engineers · Interior Designers · Planners

Philadelphia, PA 19103 — Wilmington, DE 19801

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

COLUMBUS, OHIO

project title

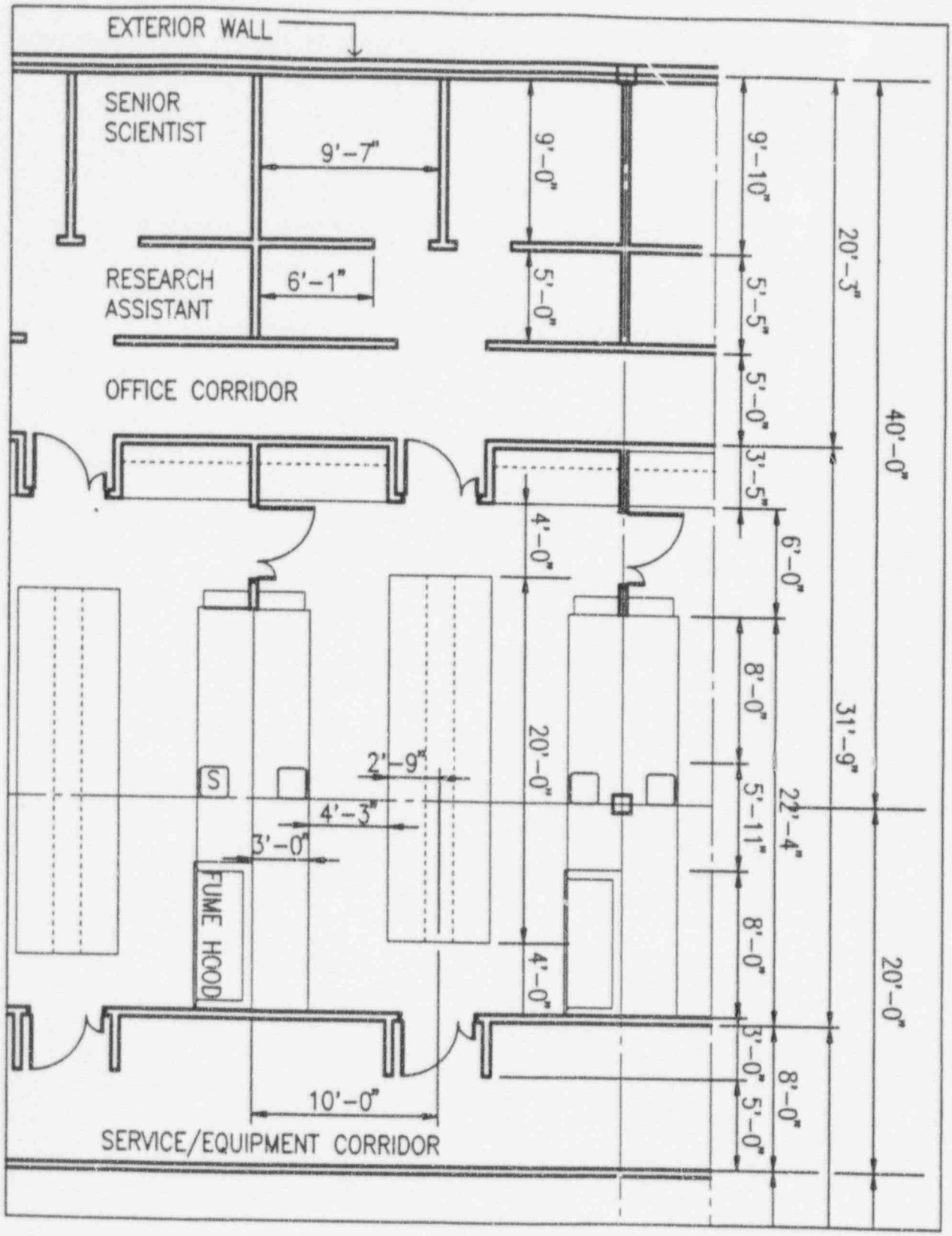
NEW WORK PLAN

drawing name

scale	1/8" = 1'
date	10/24/96
drawn by	AM/DJ
project no.	96061
reference files	
floor	1
	A1

Attachment 2-3

Typical Lab Module Plan



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TRANSCELL TECH

124531 BIOLOGY MODULE

7.17.98 W:\96065\ARCH\TRAPA.DWG

Attachment 2-4

Exhaust Ventilation System

Abbreviations

AD	access door
AFF	above finished floor
AFS	air flow measuring station
AHU	air handling unit
AL	acoustic lining
AP	access panel
ATC	automatic temperature control
AVB	air volume control box
AWT	average water temperature
BDD	backdraft damper
BHP	brake horsepower
BT	bucket trap
℄	centerline
CC	cooling coil
CD	ceiling diffuser
CDR	ceiling diffuser, round
CFM	cubic feet per minute
CUH	cabinet unit heater
CVE	constant volume exhaust
CVR	constant volume return
CVS	constant volume supply
DB	dry bulb
DFD	dynamic fire damper with access door
DN	down
DV	drain valve
(E)	existing to remain
EAT	entering air temperature
EGG	egg crate grille
EG	exhaust grille
EJ	expansion joint
EJB	expansion joint, bellows type
EJO	expansion joint, offset type
EL	elevation
ER	exhaust register
EWT	entering water temperature
EXH	exhaust
°F	degree Fahrenheit
FC	flexible connection
FCU	fan coil unit
F.D.	floor drain
FD	fire damper with access door
FDB	flat on bottom
FDT	flat on top
F&T	float & thermostatic trap
FTR	finned tube radiation
GPM	gallons per minute
GR	grille
GRV	gravity roof vent
HC	heating coil
HP	horsepower
LAT	leaving air temperature
LB	pound
LBD	linear bar diffuser
LBG	linear bar grille
LFD	laminar airflow diffuser
LLD	linear louver diffuser
LLG	linear louver grille
LSD	linear slot diffuser
LSG	linear slot grille
LTR	light troffer return
LTS	light troffer supply
LVD	linear variable volume diffuser
LVG	linear variable volume grille
LWT	leaving water temperature
LF	linear [illegible]
[illegible]	[illegible]
MOD	motor operated damper
(N)	new
NC	normally closed
NIC	not in contract
NO	normally open
NTS	not to scale
OA	outside air
OAI	outside air intake
OBD	opposed blade damper
PD	panel diffuser
PFD	perforated face diffuser
PFG	perforated face grille
PHC	preheat coil
PRV	pressure reducing valve
PSI	pounds per square inch
(R)	remove existing
RA	return air
RG	return grille
RFD	rectangular filter grille
RH	relative humidity
RHC	reheat coil
RPM	revolutions per minute
RR	return register
RVDP	rectangular variable air volume diffuser, pneumatic
RVDS	rectangular variable air volume diffuser, self-contained
SA	supply air
SAT	sound attenuator
SD	smoke damper with access door
SD/FD	combination smoke/fire damper with access door
SG	supply grille
SR	supply register
SS	stainless steel
SV	steam vent
TC	terra cotta
TG	transfer grille
TT	thermostatic trap
TYP	typical
UH	unit heater
V	vent
VAV	variable air volume
VD	volume damper
VI	vibration isolator
VVE	variable volume exhaust
VVF	variable volume fan powered
VVR	variable volume return
VVS	variable volume supply
WB	wet bulb

Piping Symbols & Nomenclature

	air or steam vent
Ø	diameter
	direction of flow
	expansion joint, bellows
	expansion joint, offset
	expansion loop
M	flow meter
H	humidistat
	pipe anchor
	pipe guide
	pitch of pipe, down
	pressure gauge and valve
	pressure/temperature plug
	reducer, concentric
	reducer, eccentric straight crown
	reducer, eccentric straight invert
	riser or elbow down
	riser up and down, elbow up
	steam trap
	strainer
	strainer w/gate valve
	w/nipple & cap
	thermometer
	thermometer well
T	thermostat
	union or flanged connection
	valve, automatic flow control
	valve, balancing
	valve, check
NS	valve, check non-slam
	valve, drain w/nipple & cap
	valve, needle
	valve, pressure regulating
	valve, relief (safety)
	valve, shut-off
	valve, shut-off lock shield
S	valve, solenoid
	valve, throttling
	valve, three-way control
	valve, two-way control
BBD	boiler blow down
CHF	chemical feed
CHWR	chilled water return
CHWS	chilled water supply
CWR	condenser water return (to tower)
CWS	condenser water supply (from tower)
CZR	controlled zone return
CZS	controlled zone supply
D	drain line
DTR	duct temperature return
DTS	duct temperature supply
FOF	fuel oil fill
FOG	fuel oil gauge
FOR	fuel oil return
FOS	fuel oil supply
FOV	fuel oil vent
FW	boiler feed water
GR	glycol return
GS	glycol supply
HPC	high pressure condensate
HPS	high pressure steam
HRR	heat recovery return
HRS	heat recovery supply
HTWR	high temperature water return
HTWS	high temperature water supply
HWR	heating water return
HWS	heating water supply
LCHWR	low temperature chilled water return
LCHWS	low temperature chilled water supply
LPC	low pressure condensate
LPS	low pressure steam
MPC	medium pressure condensate
MPS	medium pressure steam
MU	make-up water (from domestic cold water)
PCHWR	primary chilled water return
PCHWS	primary chilled water supply
PC	pumped condensate
RG	refrigerant hot gas
RHR	reheat water return
RHS	reheat water supply
RL	refrigerant liquid
RS	refrigerant suction
SCHWR	secondary chilled water return
SCHWS	secondary chilled water supply
V	vent, atmospheric

Alteration/Demolition Symbols

	point of connection, new to existing
	termination of demolition, removal
(E)	existing to remain
(E)	existing to remain
(R)	existing to be removed
(R)	existing to be removed

Air Di
Symbo

Branch
Single

Note: Refer
and constru

ibution, General & Nomenclature.

transfer duct, see detail

transfer duct, see detail w/return/exhaust grille/register

transfer duct, see detail w/return/exhaust grille/register

air cushion, 12" long min.

air cushion, 12" long min.

volume damper

volume damper

damper (type as indicated, MOD, FD, SD/FD, VD, etc.)

damper

diameter

door louver (free area in sq. feet)

door undercut

duct drop (sloping)

duct drop (90°)

duct rise (sloping)

duct rise (90°)
note rise and drop in direction of air flow

duct mounted smoke detector

flexible connection

flexible ductwork

flexible ductwork

humidifier (duct mounted)

humidifier (duct mounted)

humidistat

thermostat

turning vanes

nnections in e Ductwork

sification for type of branch connection.

tangular proportional split off bottom

tangular proportional split off side

tangular proportional split off top

nch off bottom

nch off side

nch off top

Branch Connections off Risers in Single-Line Ductwork

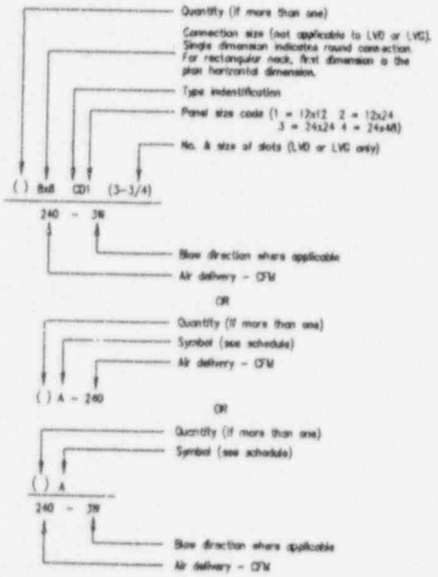
45° SMACNA exit/entry

45° round Y

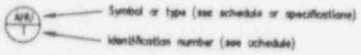
round tee

proportional split

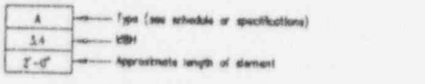
Register, Grille and Diffuser Nomenclature



Equipment Identification



Radiation Nomenclature



Drawing Index

PROJECT MANAGER — HOWARD SMOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLAGOJEVIC

general notes

1. All abbreviations and symbols may not appear on the drawings.
2. Refer to schedule drawings for symbols of scheduled equipment.
3. Refer to architectural reflected ceiling drawings for exact locations of ceiling registers, grilles, diffusers and other air distribution devices.
4. Locate all piping in or at ceiling unless indicated otherwise.
5. All branch piping connections 3/4" in size unless noted otherwise.

key plan

no.	by	description	date

revisions

Ewing Cole Cherry Brott
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TRANSCELL TECH. INC.

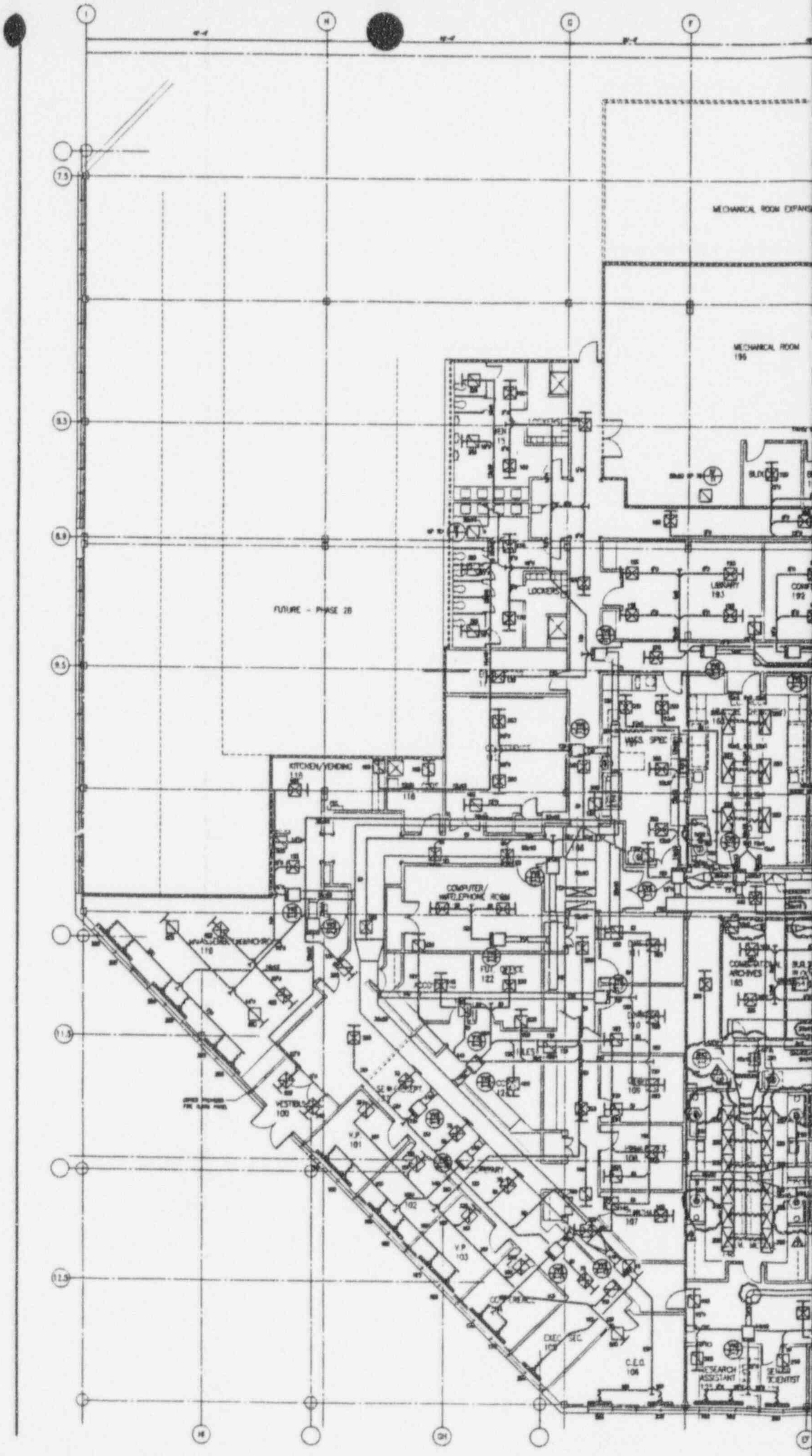
TRANSCELL TECH. INC.

project title
INDEX SHEET
HVAC
drawing name

scale	date 10/26/99
reference files	drawn by CB
	project no. 9809.1
	floor/section H0 drawing no.

9706240062-06

124531



MECHANICAL ROOM
196
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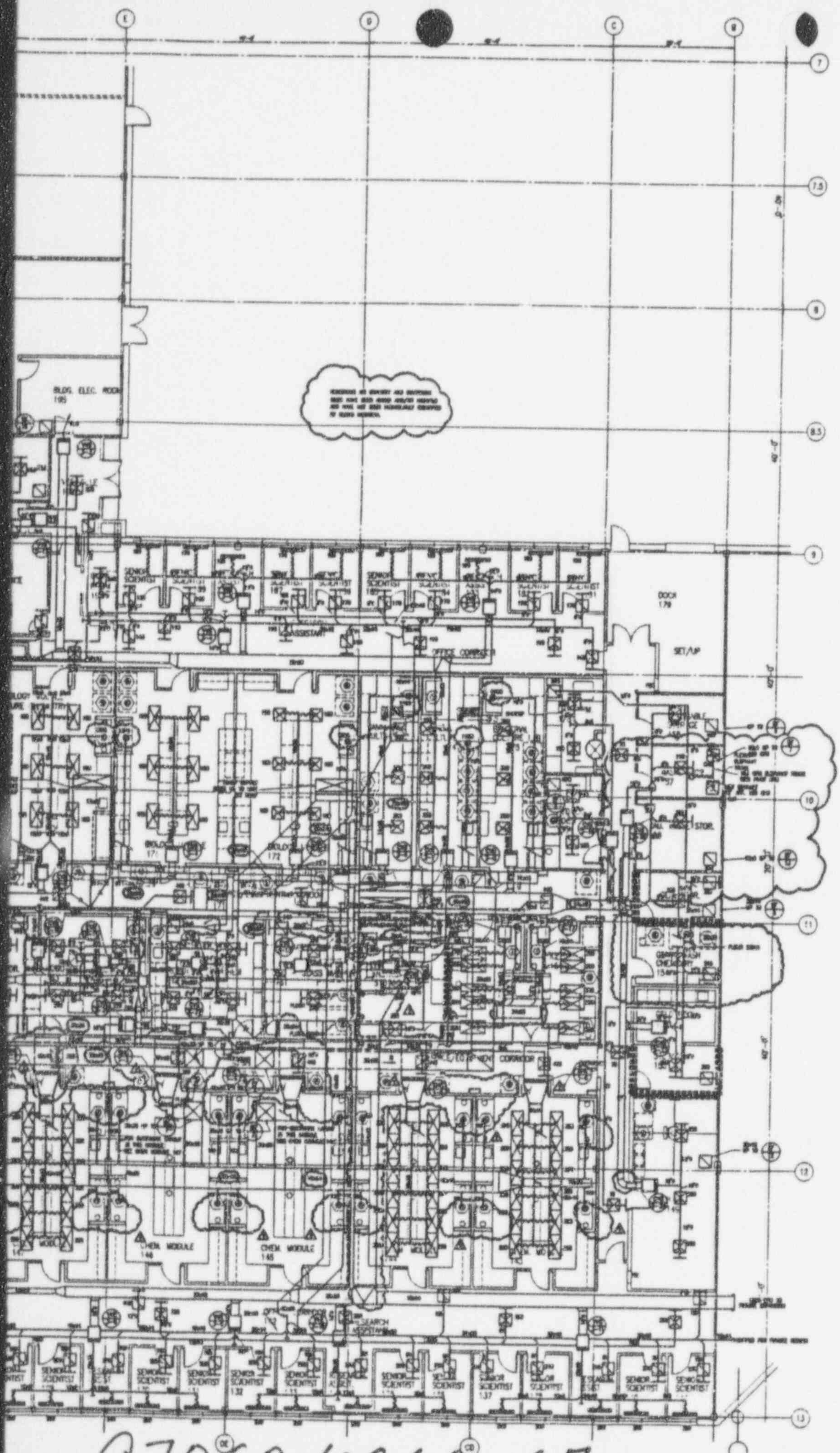

PROJECT MANAGER — HOWARD SNOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL SLABOJEVIC

general notes

1. PROVIDE VOLUME DAMPER IN ALL RETURN AIR AND EXHAUST AIR BRANCH DUCTWORK AND IN ALL SUPPLY DUCTWORK DOWNSTREAM OF AIR VOLUME CONTROL BOXES.

2. INLET SIZES FOR SUPPLY AIR DIFFUSERS SHALL BE AS FOLLOWS:

key plan

no.	by	description	date
⚠	BD	ADDENDUM NO. 2	12/13/96

revisions

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TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title

DUCTWORK
HVAC WORK

drawing name

scale

reference files

date 10/24/96

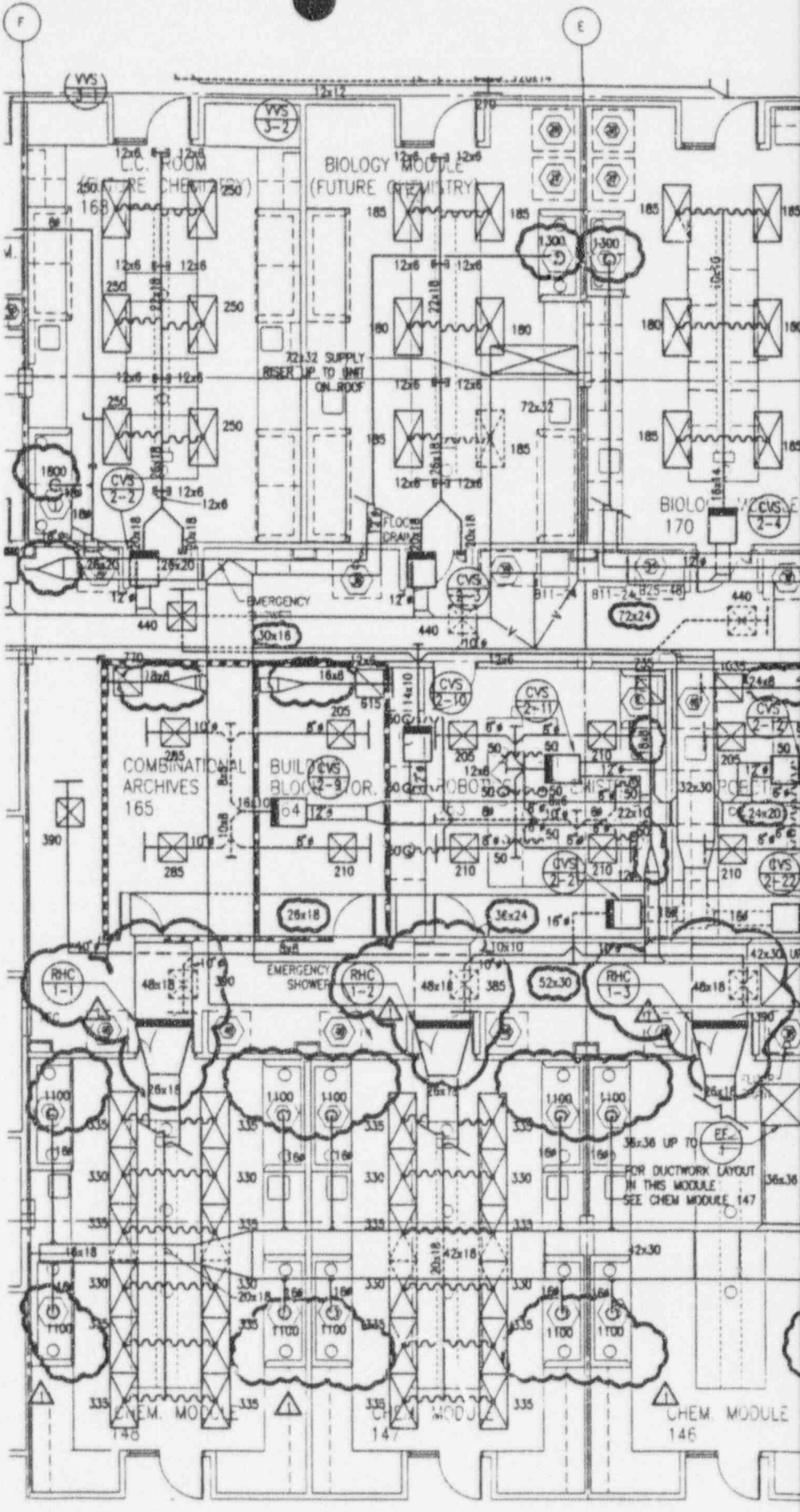
drawn by CP

project no.

floor/section

H1
drawing no.

9706240062-07


F
E
BIOLOGY MODULE
(FUTURE CHEMISTRY)
168
72x32 SUPPLY RISER UP TO UNIT ON ROOF
170
EMERGENCY SHOWER
COMBINATIONAL ARCHIVES
165
BUILDING COR.
ROBOTICS LABORATORY
RHC 1-1
RHC 1-2
RHC 1-3
EMERGENCY SHOWER
36x36 UP TO
FOR DUCTWORK LAYOUT IN THIS MODULE SEE CHEM MODULE 147
CHEM. MODULE
146
CHEM. MODULE
147
CHEM. MODULE
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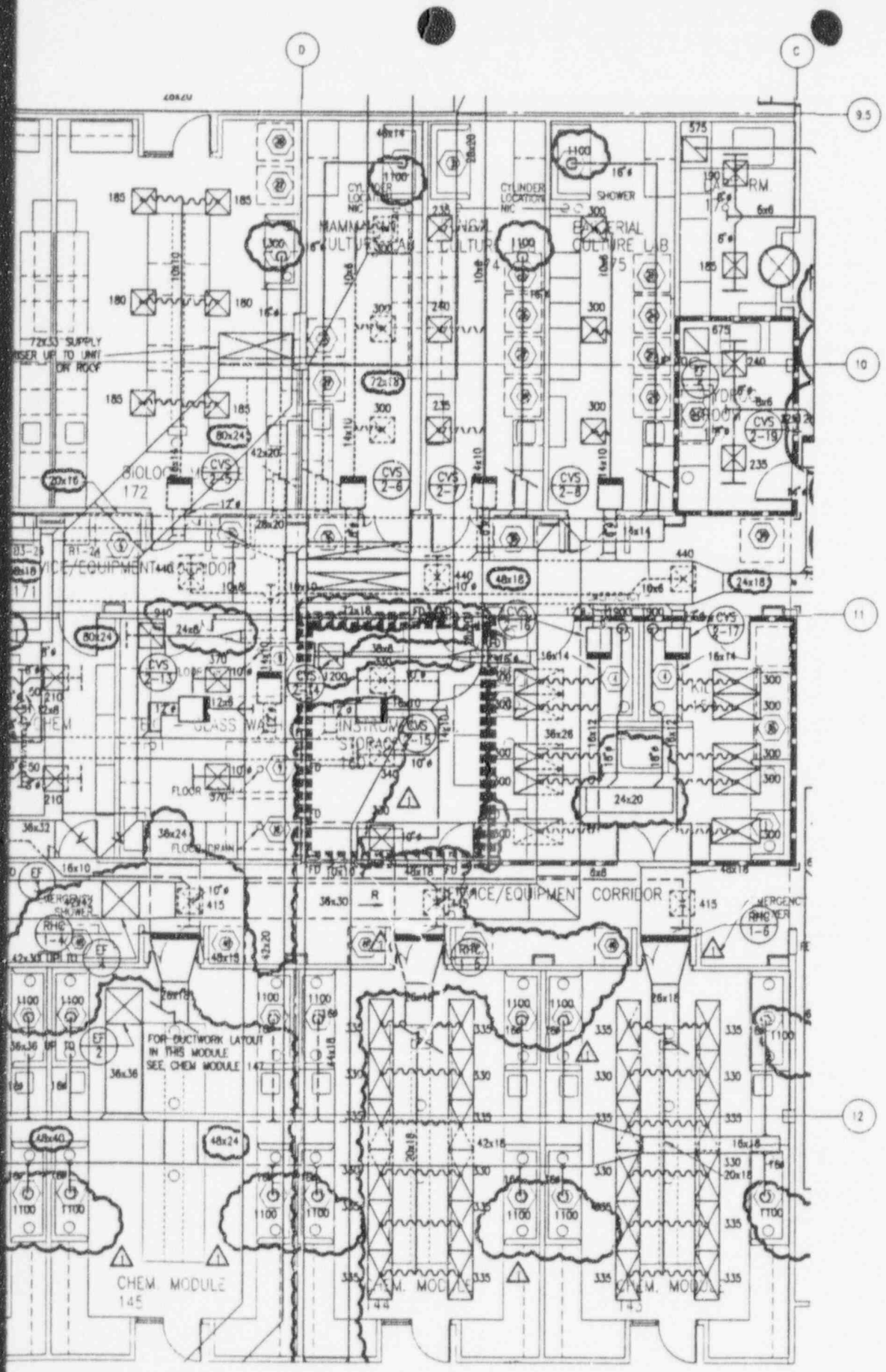


PROJECT MANAGER — HOWARD SROKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLAGOJEVIC

general notes

key plan

no.	by	description	date
1	RD	ADDENDUM NO. 2	12/13/94

revisions

Ewing Cole Cherry Brott
Architects · Engineers · Interior Designers · Planners

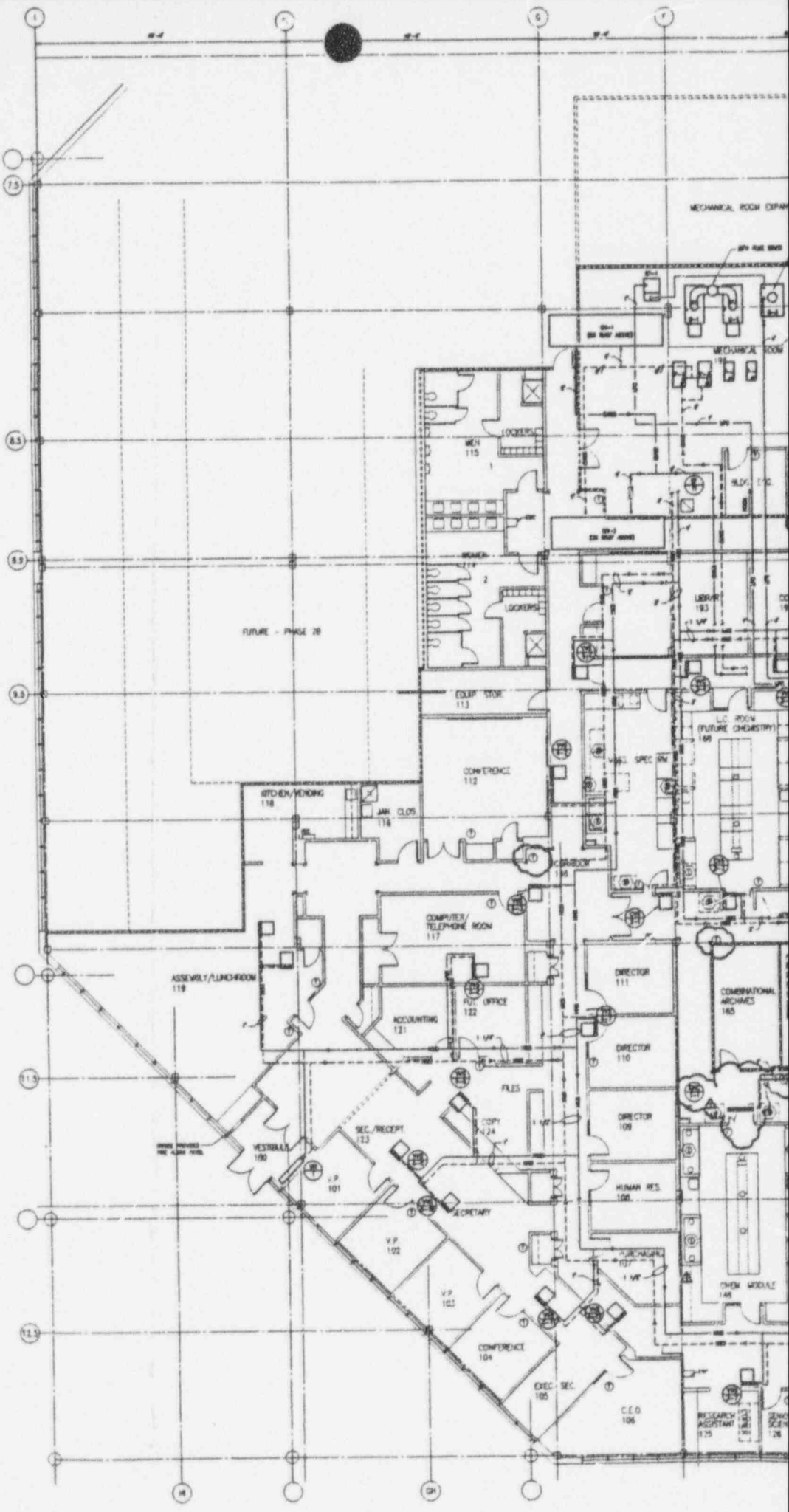
TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title
DUCTWORK - LABS
HVAC WORK
drawing name

scale 1/8" = 1'-0" — date 10/26/94
reference files — drawn by CB
project no. 94051
floor/section — H1A drawing no.

9706240062-08


FUTURE - PHASE 2B
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CONFERENCE 112
KITCHEN/SERVING 118
JAN CLOS 116
COMPUTER/ TELEPHONE ROOM 117
ASSEMBLY/LUNCHROOM 119
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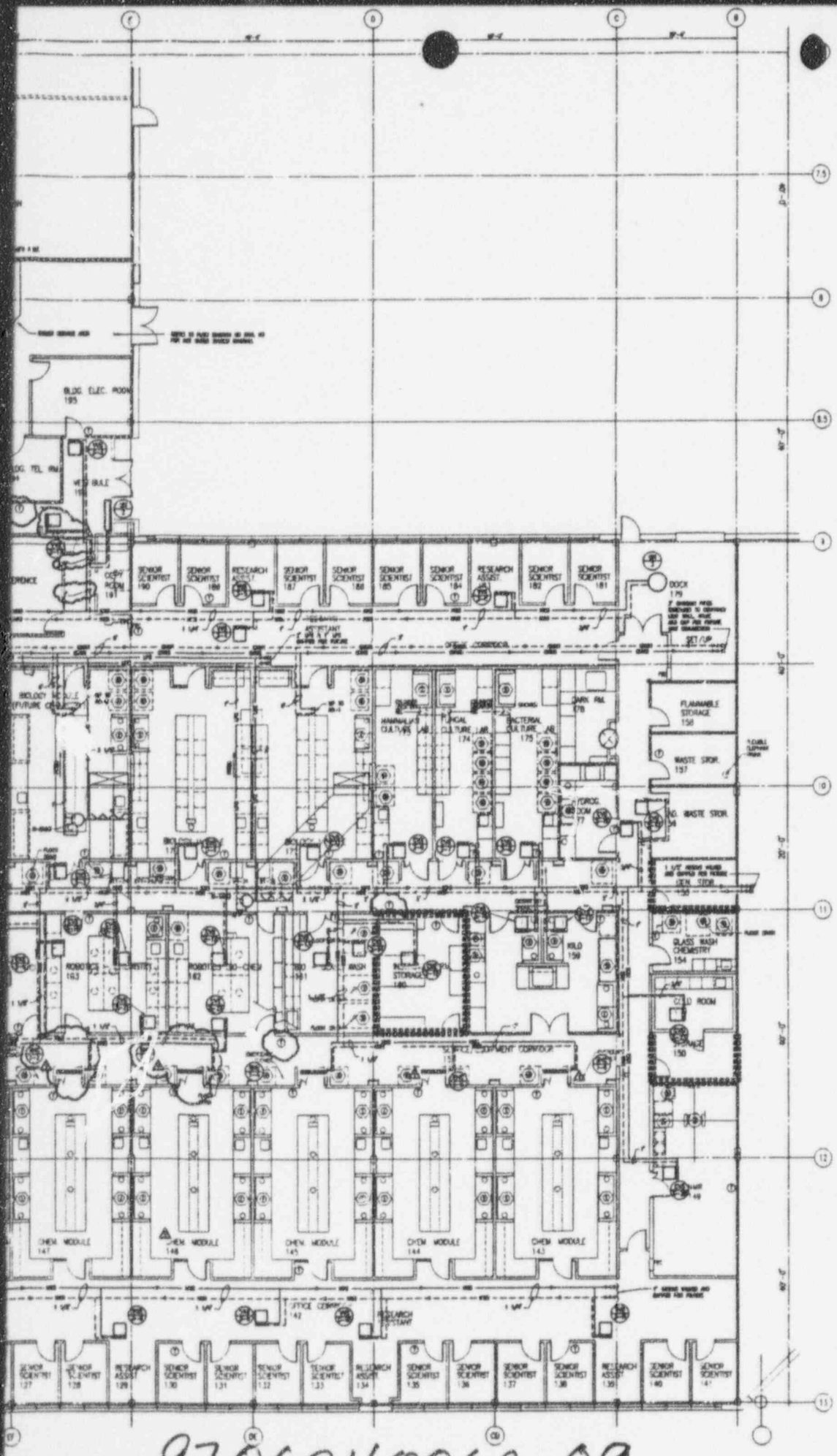

9706240062-09

PROJECT MANAGER — HOWARD SPOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLADDAEMC

general notes

1. ALL SENSOR PIPING CONNECTIONS TO BE 3/4" IN SIZE UNLESS OTHERWISE NOTED.

key plan

no.	by	description	date
1	BD	ADDENDUM NO. 1	12/13/96

revisions

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TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

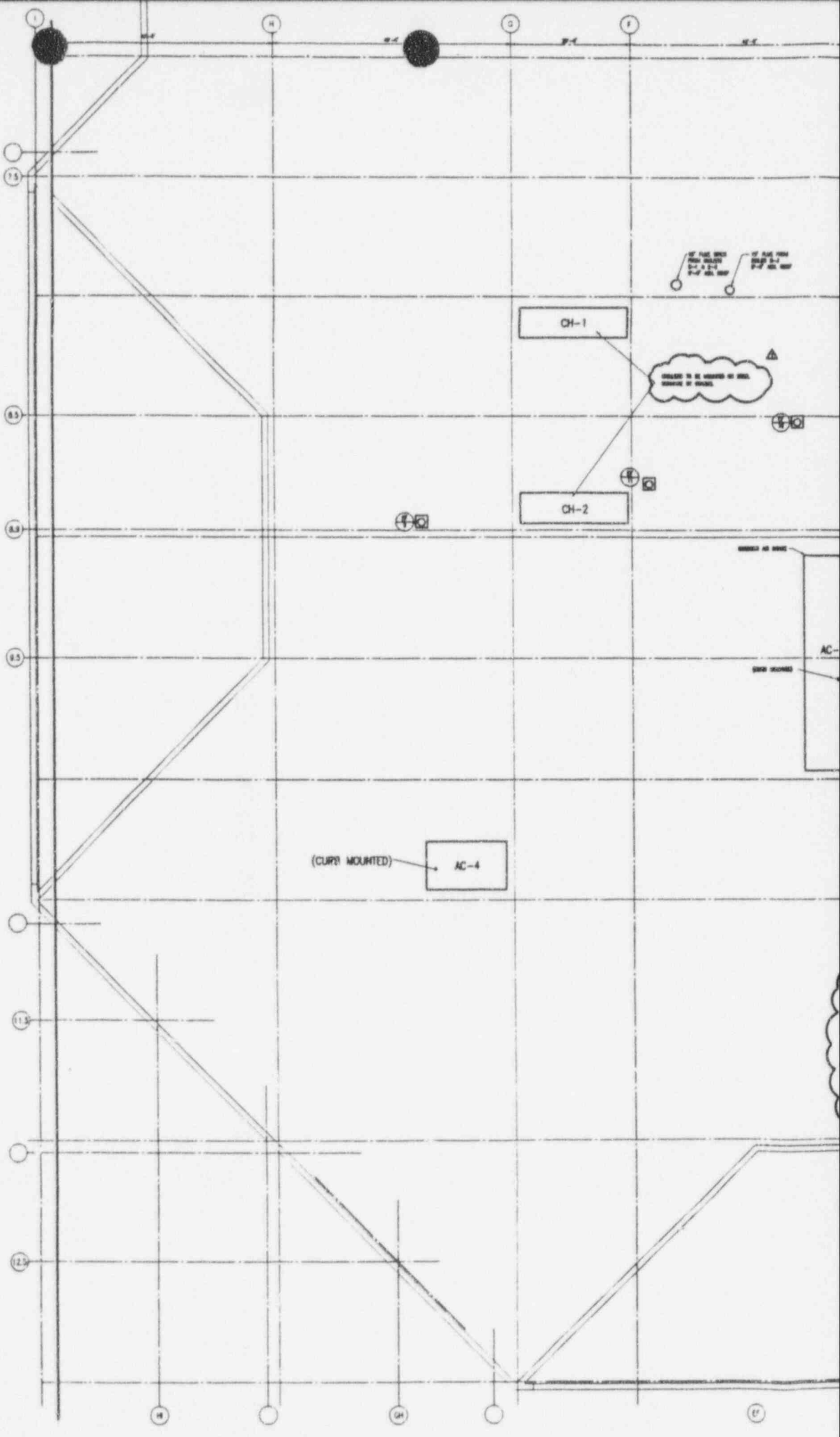
project title

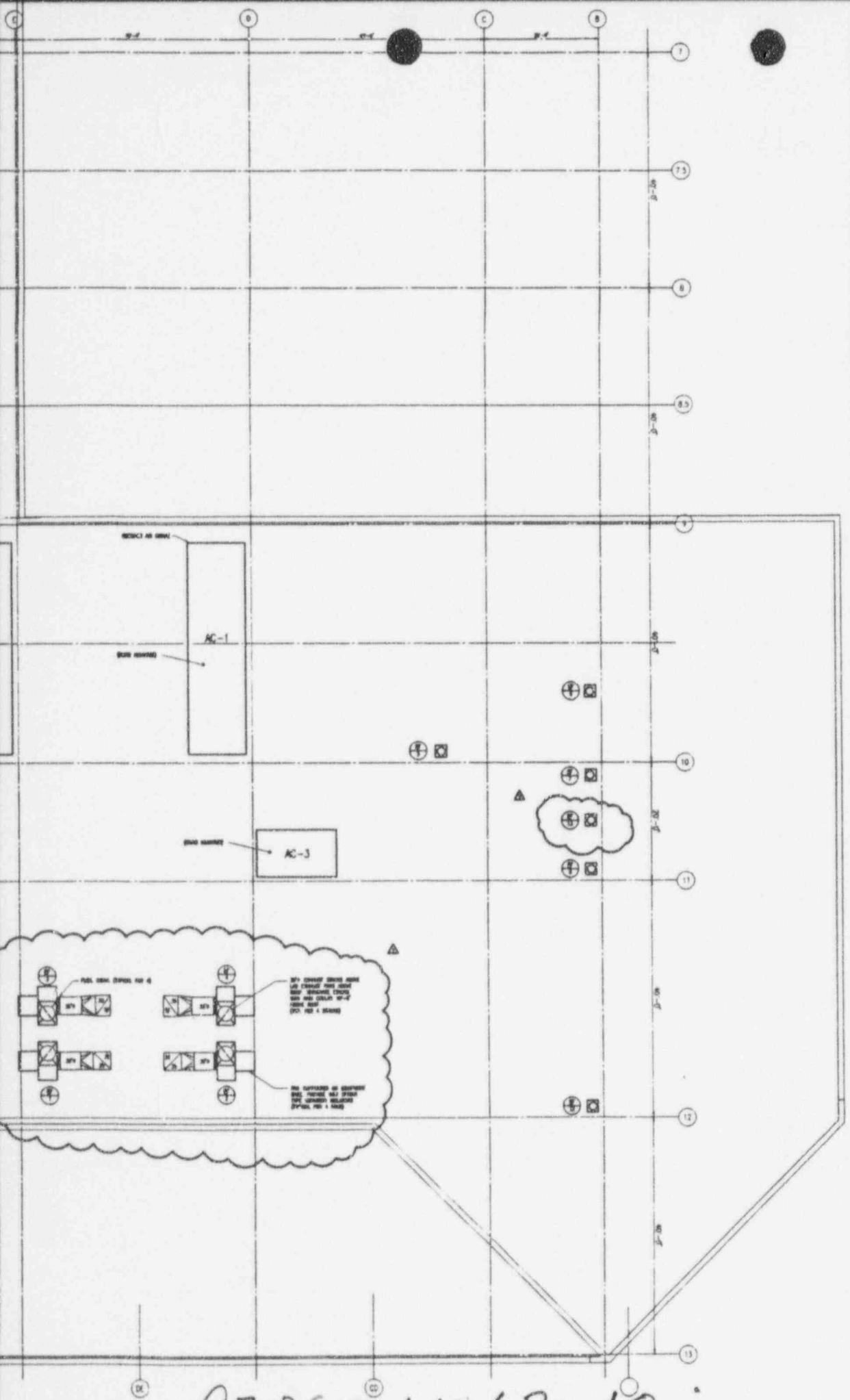
PIPING

HVAC WORK

drawing name

scale	date 10/25/96
reference files	drawn by CB
	project no. 95065
	floor/section H2 drawing no.


CH-1
CH-2
(CURB MOUNTED)
AC-4



PROJECT MANAGER — HOWARD SMOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLAGOJEVIC

general

key plan

no.	by	description	date
1		ADDENDUM	12/13/96

revisions

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Architects · Engineers · Interior Designers · Planners

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title

ROOF PLAN

drawing name

scale	1/8"=1'-0"
reference files	
drawn by	CB
project no.	96062
floor/section	
drawing no.	H3

date: 12/13/96

9706240062-10

AIR [illegible]

SYMBOL	TYPE	SERVICE	LOCATION	TOTAL CFM	MIN. OA CFM	SP/IN. EXT.	[illegible]	FAN TYPE	HP	ELECT. SERVICE	EAT °F DB	EAT °F WB	LAT °F DB	LAT °F WB	MBH TOT.	MBH SENS.	FACE VEL. FPM	SP/IN. WG	EWT °F	GPM	PD/FT. WG	MIN. ROWS
AC-1	ROOFTOP CURB [illegible]	EMERGENCY LAB SUPPLY	ROOF	24,000	24,000	1.75	8.0	AF [illegible]	40	460/3/60	91	75	50.0	53.4	1740	980	464	1.07	44	387	16.0	10
AC-2	ROOFTOP CURB [illegible]	LAB AND LAB SUPPORT	ROOF	38,000	38,000	3.0	6.10	AF [illegible]	50	460/3/60	91	75	53.3	53.2	2483	1333	441	1.02	44	387	16.0	10

NOTE 1. TOTAL SP IS AN ESTIMATED VALUE BASED ON INFORMATION OF ONE MANUFACTURER OF AHUS. ADJUST TOTAL AS REQUIRED BASED ON ACTUAL UNIT AND COIL LOSSES AND SPECIFIED EXTERNAL AND FINAL FILTER SP.
NOTE 2. P= PREHEAT LOCATION R= HEATING OR REHEAT LOCATION
NOTE 3. PF= PREFILTER LOCATION AF= AFTERFILTER LOCATION
NOTE 4. SEE DIAGRAM BELOW FOR ADDITIONAL ACCESSORY AND ARRANGEMENT INFORMATION.
NOTE 5. SELECT COOLING COILS USING 30% WT. PROPYLENE GLYCOL.

PACKAGED ROOF TOP GAS HEATI[NG]

SYMBOL	TYPE	SERVICE	TOTAL CFM	MIN. OA CFM	FAN DATA SERVICE	FAN DATA ESP IN. WG	FAN DATA HP	DISCHARGE LOCATION	RETURN LOCATION	COOLING EAT °F DB	COOLING EAT °F WB	COOLING LAT °F DB	COOLING LAT °F WB	COOLING MBH TOT.	COOLING MBH SENS.	HEATING EAT °F	HEATING LAT °F	INPUT MBH	OUTPUT MBH	STAGES	FILTERS SP/IN. WG INIT.	FILTERS SP/IN. WG FIN.	FILTERS EFF. %	FILTERS TYPE
AC-3	PACKAGED ROOFTOP	OFFICE AREAS	12,000	3000	460/3/60	-	15	VERTICAL DOWN	VERTICAL DOWN	80	67	58	-	380	360	-	-	-	-	-	0.53	1.0	35	[illegible]
AC-4	PACKAGED ROOFTOP	OFFICE AREAS	12,000	3000	460/3/60	-	15	VERTICAL DOWN	VERTICAL DOWN	83	67	58	-	380	360	-	-	-	-	-	0.53	1.0	30	[illegible]

NOTE 1. ESP DOES NOT INCLUDE ACCESSORY AND DIRTY FILTER LOSSES. ADJUST TOTAL AS REQUIRED BASED ON ACTUAL UNIT, ACCESSORY AND COIL LOSSES AND SPECIFIED FINAL FILTER SP.
NOTE 2. CA=CIRCUIT AMPS (FOR WIRE SIZING) OCP=MAXIMUM OVERCURRENT PROTECTION AMPS.
NOTE 3. SEE DIAGRAM BELOW FOR ADDITIONAL ACCESSORY AND ARRANGEMENT INFORMATION.

AIR COOLE[D]

SYMBOL	TYPE	LOCATION	CAPACITY TONS	GPM	PD/FT. WG	EWT °F	LWT °F	NO. OF PASSES	MAX. VEL. FPS	REF.	MIN. SUCT. TEMP. °F	FOUL. FAC.
CH-1	PACKAGED AIR COOLED	ROOF	144.0	280	8.7	56.0	44	-	-	R22	-	[illegible]
CH-2	PACKAGED AIR COOLED	ROOF	144.0	280	8.7	56.0	44	-	-	R22	-	[illegible]

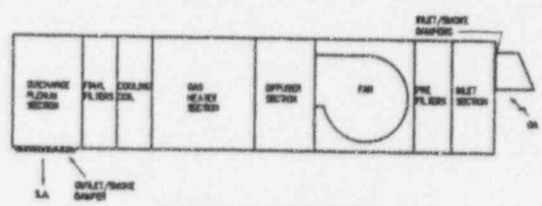
NOTE 1. CHILLER SELECTED TO OPERATE WITH 30% WT. PROPYLENE GLYCOL.
ADJUST FINAL RATINGS TO REFLECT CORRECTION FACTORS FOR GLYCOL.

HUMIDIFIER SCHEDULE

SYMBOL	LOCATION	SERVICE	DISCHARGE LBS. STM/HR	STEAM SUPPLY PSIG	ABSORPTION DISTANCE (IN.)	NO. OF MANIFOLDS	APPROX. DUCT WxH (IN.)	REMARKS	BASIS OF DESIGN [illegible]
H-1A	AC-1 SUPPLY DUCT	AC-1	167	5	24	1	72092	1/3 CAPACITY	MODEL [illegible]
H-1B	AC-1 SUPPLY DUCT	AC-1	334	5	24	2	72022	2/3 CAPACITY	MODEL [illegible]
H-2A	AC-2 SUPPLY DUCT	AC-2	200	5	24	1	72090	1/3 CAPACITY	MODEL [illegible]
H-2B	AC-2 SUPPLY DUCT	AC-2	417	5	24	2	72033	2/3 CAPACITY	MODEL [illegible]

SYMBOL	LOCATION	TYPE	BOILER HP
B-1	MECHANICAL EQUIPMENT RM. [illegible]	FLEX TUBE	40
B-2	MECHANICAL EQUIPMENT RM.	FLEX TUBE	40
B-3	MECHANICAL EQUIPMENT RM. [illegible]	FLEX TUBE	30

PROVIDE BOILERS WITH LEAD LAG CONTROL, MODULATING [illegible]
COMBUSTION SAFETY CONTROLS, ALARM BELL, AND [illegible]



COMPONENT ARRANGEMENT
AC-1 AND AC-2

SOUND ATTENUATOR SCHEDULE

SYMBOL	TYPE	SERVICE	LOCATION	CFM	OVERALL SIZE (IN.) W	OVERALL SIZE (IN.) H	OVERALL SIZE (IN.) L	SP/IN. WG	REMARKS	BASIS OF DESIGN IAC
SA-1S	-	AC-1 SUPPLY	-	24,000	72	90	[illegible]	.25	CLEAN FLOW FILL PROTECTED	TYPE 3-HL
SA-2S	-	AC-2 SUPPLY	-	38,000	72	36	60	.60	CLEAN FLOW FILL PROTECTED	TYPE 3-HL
SA-1E	-	EF-1 & 2	EF-1&2 EXHAUST DUCT	13,500	36	30	60	.47		TYPE 3-LFM
SA-2E	-	EF-1 & 2	EF-1&2 EXHAUST DUCT	13,365	36	30	60	.47		TYPE 3-LFM
SA-3E	-	EF-3 & 4	EF-3&4 EXHAUST DUCT	14,000	42	30	60	.27		TYPE 3-LFM
SA-4E	-	EF-3 & 4	EF-3&4 EXHAUST DUCT	14,000	42	30	60	.27		TYPE 3-LFM

UNIT HEATER SCHEDULE

SYMBOL	TYPE	LOCATION	FAN CFM	FAN HP	FAN ELECT. SERVICE	FAN RPM	HEATING MBH	EAT °F	GPM	PD/FT. WG	EWT °F	REMARKS	BASIS OF DESIGN STERLING
UH-1	CABINET	VESTIBULE 109	300	1/40	120/1/60	675	16.0	60	3.0	.30	160		MODEL [illegible] SIZE [illegible]
UH-2	CABINET	VESTIBULE 107	300	1/40	120/1/60	675	16.0	60	3.0	.30	160		MODEL [illegible] SIZE [illegible]
UH-3	VERTICAL PROPELLER	LOADING DOCK [illegible]	2500	1/50	[illegible]	1600	53.0	60	4.2	.30	160		MODEL [illegible]

[illegible] HANDLING UNIT SCHEDULE

[illegible]	GAS HEATER CAPACITY: LOC.	EAT °F	LAT °F	INPUT MBH	OUTPUT MBH	STAGES	INLET PRESS.	FILTERS (SEE NOTE 2): LOC.	SP (IN. WG) INIT.	SP (IN. WG) FIN.	NO.	SIZE	EFF. %	TYPE	REMARKS (SEE NOTE 4)	BASIS OF DESIGN YORK
[illegible]	[illegible]	[illegible]	[illegible]	1500	1250	MODULATING	7.0 IN WG	PF	[illegible]	[illegible]	-	2" DEEP	[illegible]	PLEATED	SUPPLY FAN MOTORS TO BE PROVIDED WITH INLET VANES. PROVIDE UNITS WITH GAS FURNACE SECTIONS.	CUSTOPAK MODEL OF [illegible]
								AF	[illegible]	[illegible]	-	-	[illegible]	CARTRIDGE		
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	MODULATING	7.0 IN WG	PF	[illegible]	[illegible]	-	2" DEEP	[illegible]	PLEATED	SUPPLY FAN MOTORS TO BE PROVIDED WITH INLET VANES. PROVIDE UNITS WITH GAS FURNACE SECTIONS.	CUSTOPAK MODEL OF [illegible]
								AF	[illegible]	[illegible]	-	-	[illegible]	CARTRIDGE		

[illegible]S/ELECTRIC COOLING AIR HANDLING UNIT SCHEDULE

CONDENSING SECTION: AMB. AIR °F [illegible]	AMB. AIR °F DSGN.	COND. TEMP. °F	COMPRESSION: NO.	KW EA.	STEPS	FAN: NO.	HP EA.	EER	IPLV	UNIT POWER SUPPLY (NOTE 3): ELECT. SERVICE	CA	OCP	SUPPORT TYPE	REMARKS (NOTE 3)	BASIS OF DESIGN YORK
[illegible]	40	[illegible]	1	[illegible]	3	[illegible]	1/2	-	-	460/3/60	[illegible]	[illegible]	CURB	PROVIDE WITH SOLID STATE O.A. ECONOMIZER	[illegible]
[illegible]	40	[illegible]	1	[illegible]	3	[illegible]	1/2	-	-	460/3/60	[illegible]	[illegible]	CURB	PROVIDE WITH SOLID STATE O.A. ECONOMIZER	[illegible]
															[illegible]

[illegible] WATER CHILLER SCHEDULE

*SHORT CIRCUIT AMPS RMS SYMETRICAL

COMP. SIZE	CONDENSING SECTION: AMB. AIR °F DSGN.	AMB. AIR °F MIN.	COND. TEMP. °F	COMPRESSOR: NO.	KW (TOT)	STEPS	FAN: NO.	HP EA.	EER	IPLV	UNIT POWER SUPPLY (NOTE 3): ELECT. SERVICE	UNIT KW	UNIT EER	CA	OCP	FOUND. TYPE	REMARKS	BASIS OF DESIGN YORK
[illegible]	[illegible]	[illegible]	-	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	-	[illegible]	460/3/60	[illegible]	[illegible]	-	-	ROOF MOUNTED	OPERATING WEIGHT-[illegible] LBS.	MODEL YCA[illegible]
[illegible]	[illegible]	[illegible]	-	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	-	[illegible]	460/3/60	[illegible]	[illegible]	-	-	ROOF MOUNTED	OPERATING WEIGHT-[illegible] LBS.	MODEL YCA[illegible]

BOILER SCHEDULE

DESIGN PRESS. PSIG	SQ. FT. OF SURFACE	INPUT MBH	GROSS OUTPUT: MBH	STEAM LBS HR	WATER: GPM	LWT °F	RELIEF VALVE: NO.	SIZE	GAS BURNER: CFH	BTU/CU. FT.	INLET PRESS. IN. WG	BLOWER H.P.	SMOKE VENT SIZE	ELECT. SERVICE	FOUND. TYPE	REMARKS	BASIS OF DESIGN [illegible] BOILERS
[illegible]	[illegible]	[illegible]	[illegible]	-	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	7.0	3/4	14	120/1/60	CONC. PAD	FORCED DRAFT GAS FIRED-FLEXIBLE TUBE HOT WATER BOILER	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	-	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	7.0	3/4	14	120/1/60	CONC. PAD	FORCED DRAFT GAS FIRED-FLEXIBLE TUBE HOT WATER BOILER	MODEL [illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	-	-	1	[illegible]	[illegible]	[illegible]	7.0	-	16	120/1/60	CONC. PAD	ATMOSPHERIC GAS FIRED-FLEXIBLE TUBE LOW PRESSURE STEAM BOILER	MODEL [illegible]

[illegible] BURNERS TO MEET [illegible] INSURANCE CARRIER REQUIREMENTS.
[illegible]

FAN SCHEDULE

SYMBOL	TYPE	LOCATION	SERVICE	CFM	SP/IN. WG	ROOF OPNG. [illegible] IN.	WHEEL DIA. IN.	RPM	DRIVE	HP	ELECT. SERVICE	REMARKS	BASIS OF DESIGN
EF-1	[illegible] CENTRIF.	ROOF	CHEMISTRY LAB EXHAUST	[illegible]	3.0		[illegible]	[illegible]	BELT	15	460/3/60	UPBLAST FAN ON CURB WITH OUTLET TRANSITION TO [illegible] STACK. TOP OF STACK [illegible] ABV. ROOF. PROVIDE WITH INLET VANES.	BAYLEY SIZE B - [illegible]
EF-2	[illegible] CENTRIF.	ROOF	CHEMISTRY LAB EXHAUST	[illegible]	3.0		[illegible]	[illegible]	BELT	15	460/3/60	UPBLAST FAN ON CURB WITH OUTLET TRANSITION TO [illegible] STACK. TOP OF STACK [illegible] ABV. ROOF. PROVIDE WITH INLET VANES.	BAYLEY SIZE B - [illegible]
EF-3	[illegible] CENTRIF.	ROOF	BIOLOGY LAB FUME HOOD EXHAUST	[illegible]	3.0		[illegible]	[illegible]	BELT	[illegible]	460/3/60	UPBLAST FAN ON CURB WITH OUTLET TRANSITION TO [illegible] STACK. TOP OF STACK [illegible] ABV. ROOF. PROVIDE WITH INLET VANES.	BAYLEY SIZE B - [illegible]
EF-4	[illegible] CENTRIF.	ROOF	BIOLOGY LAB FUME HOOD EXHAUST	[illegible]	3.0		[illegible]	[illegible]	BELT	15	460/3/60	UPBLAST FAN ON CURB WITH OUTLET TRANSITION TO [illegible] STACK. TOP OF STACK [illegible] ABV. ROOF. PROVIDE WITH INLET VANES.	BAYLEY SIZE B - [illegible]
EF-5	PRV	ROOF	[illegible]	[illegible]	[illegible]	[illegible]	-	[illegible]	BELT	1/2	120/1/60		PENN VENTILATOR [illegible]
EF-6	PRV	ROOF	FLAMMABLE STORAGE	[illegible]	[illegible]	[illegible]	-	1530	BELT	1/4	120/1/60		PENN VENTILATOR [illegible]
EF-7	PRV	ROOF	WASTE STORAGE	[illegible]	1.0	[illegible]	-	1340	BELT	1/2	460/3/60		PENN VENTILATOR [illegible]
EF-8	PRV	ROOF	GENERAL EXHAUST STORAGE AREAS	1740	[illegible]	[illegible]	-	[illegible]	BELT	3/4	460/3/60		PENN VENTILATOR [illegible]
EF-9	PRV	ROOF	TOILET ROOMS	[illegible]	1.0	[illegible]	-	[illegible]	BELT	3/4	460/3/60		PENN VENTILATOR [illegible]
EF-10	PRV	ROOF	ELECTRICAL ROOM	[illegible]	[illegible]	[illegible]	-	[illegible]	BELT	1/3	120/1/60		PENN VENTILATOR [illegible]
EF-11	PRV	ROOF	MECHANICAL ROOM	[illegible]	[illegible]	[illegible]	-	[illegible]	BELT	1	460/3/60		PENN VENTILATOR [illegible]
EF-12	PRV	ROOF	[illegible] ROOM	[illegible]	[illegible]	[illegible]	-	[illegible]	BELT	1/3	120/1/60		PENN VENTILATOR [illegible]
EF-13	PRV	ROOF	RADIOACTIVE WASTE	[illegible]	[illegible]	[illegible]	-	[illegible]	BELT	1/4	120/1/60		PENN VENTILATOR [illegible]

PUMP SCHEDULE

SYMBOL	TYPE	LOCATION	SERVICE	GPM	TOTAL HEAD FT. WG	MAX. NPSH FT. WG	OPER. TEMP. °F	SIZE IN. SUCT.	SIZE IN. DISCH.	EFF. %	RPM	HP	ELECT. SERVICE	FOUND. TYPE	REMARKS	BASIS OF DESIGN
P-1	END SUCTION	MECH. RM. [illegible]	GLYCOL COOLING	[illegible]	[illegible]	-	[illegible]	4	3.0	[illegible]	1750	[illegible]	460/3/60	1		BELL & GOSSETT MODEL 1510 3 1/2 AB
P-2	END SUCTION	MECH. RM. [illegible]	GLYCOL COOLING	[illegible]	[illegible]	-	[illegible]	4	3.0	[illegible]	1750	[illegible]	460/3/60	1		BELL & GOSSETT MODEL 1510 3 1/2 AB
P-3	END SUCTION	MECH. RM. [illegible]	HEATING/REHEAT	[illegible]	[illegible]	-	[illegible]	3	3	[illegible]	1750	3	460/3/60	1		BELL & GOSSETT MODEL 1510 3 BB
P-4	END SUCTION	MECH. RM. [illegible]	HEATING/REHEAT	[illegible]	[illegible]	-	[illegible]	3	3	[illegible]	1750	3	460/3/60	1	P-4 USED FOR SPARE	BELL & GOSSETT MODEL 1510 3 BB
P-5	IN-LINE	MECH. RM. [illegible]	PRIMARY HOT WATER	[illegible]	[illegible]	-	[illegible]	2	2	[illegible]	1750	1	460/3/60	-		BELL & GOSSETT SERIES 80 "[illegible]"
P-6	IN-LINE	MECH. RM. [illegible]	PRIMARY HOT WATER	[illegible]	[illegible]	-	[illegible]	2	2	[illegible]	1750	1	460/3/60	-		BELL & GOSSETT SERIES 80 "[illegible]"
BF-1	CENTRIF.	MECH. RM. [illegible]	BOILER FEED UNIT	[illegible]	[illegible]	[illegible]	[illegible]	1	1		[illegible]	1/3	120/1/60	1		[illegible] [illegible]

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PROJECT MANAGER — HOWARD SKOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLAGOJEVIC

general notes

key plan

no.	by	description	date
	[illegible]	ADDENDUM NO. [illegible]	12/13/94

revisions

Ewing Cole Cherry Brott
Architects · Engineers · Interior Designers · Planners
Philadelphia, PA 19103 · [illegible]

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.
[illegible]

project title
COMPONENT SCHEDULES

drawing [illegible]

scale N.T.S. | date [illegible]
reference files | drawn by CB
project no. [illegible]

floor/section | drawing no. H4

file-dwg: [illegible]
plot date

EXHAUST AIR VOLUME CONTROL BOX SCHEDULE

SYMBOL	ROOM SERVED	SIZE IN.			MIN CFM (NOTE 1)	MAX NC (NOTE 3)	ARC SCHEDULE	NORM DAMP POS.	REMARKS	EMER. POWER REQUIRED BY DIV. 16	BASIS OF
VAV 1-1	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-2	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-3	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-4	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-5	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-6	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-7	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-8	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-9	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-10	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-11	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-12	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-13	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-14	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-15	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-16	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-17	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-18	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-19	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-20	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-21	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-22	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-23	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 1-24	OHSU MODULE	10	1900	380	0.20	30	A	8.0		YES	
VAV 2-1	MASS SPEC TRANS. ROOM	14	1750	875	0.25	35	B	8.0		YES	
VAV 2-2	L.C. ROOM	12	1650	960	0.30	35	B	8.0		YES	
VAV 2-3	BIOLOGY MODULE	12	1350	450	0.35	30	B	5.0		YES	
VAV 2-4	BIOLOGY MODULE	12	1350	680	0.50	30	B	8.0		YES	
VAV 2-5	BIOLOGY MODULE	12	1350	850	0.50	30	B	8.0		YES	
VAV 2-6	WARM ROOM CULTURE LAB	10	1900	550	0.25	30	B	8.0		YES	
VAV 2-7	FUNGAL CULTURE LAB	10	1900	800	0.25	35	B	8.0		YES	
VAV 2-8	BACTERIAL CULTURE LAB	10	1900	550	0.30	30	B	8.0		YES	
VAV 2-9											
VAV 2-10											
VAV 2-11											
VAV 2-12											
VAV 2-13											
VAV 2-14											
VAV 2-15	ZOOM. ARCHIVES	8	770	440	0.25	30	C	8.0		YES	
VAV 2-16	GLASS BLK STORAGE	7	660	330	0.25	30	C	8.0		YES	
VAV 2-17	ROBOTICS (CHEMISTRY	8	730	330	0.25	30	C	8.0		YES	
VAV 2-18	ROBOTICS BIO-CHEM	8	1035	460	0.35	30	C	8.0		YES	
VAV 2-19	BIO-GLASS WASH		840	370	0.25	30	C	8.0		YES	
VAV 2-20	INSTRUMENT ROOM	10	1355	720	0.25	30	C	8.0		YES	
VAV 2-21	MAIN	14	1950	900	0.30	30	B	8.0		YES	
VAV 2-22	[illegible]	14	1800	900	0.25	30	B	8.0		YES	

△

[illegible] ARE NOT USED

REHEAT COIL SCHEDULE

SYMBOL	SERVICE OR LOCATION	CFM	COIL H x L/IN. NOMINAL	MBH	EAT °F	LAT °F	SP/ IN. WG	MIN ROWS	FINS	EWT °F	GPM	PD/ FT. WG	TYPE ATC VALVE	BRANCH PIPE SIZE/IN.	REMARKS	BASIS OF DESIGN
RHC 1-1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]
RHC 1-2	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]
RHC 1-3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]
RHC 1-4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]
RHC 1-5	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]
RHC 1-6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1		[illegible]

NOTE: [illegible]

SUPPLY AIR VOLUME CONTROL BOX

SYMBOL	ROOM SERVED	INLET SIZE IN.	CFM RANGE MAX.	CFM RANGE MIN.	MAX. OPER. SP/ IN. WG	MAX NC @1.5 SP INLET	ATC SCHEME	NORMAL DAMP POS.	MBH	EAT °F	WATER COIL GPM	WATER COIL PD/FT.	TYPE ATC VALVE	REMARKS	BASIS OF DESIGN
CVS 3-1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-2	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-5	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-7	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-8	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-10	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-11	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-12	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-13	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-14	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-15	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-16	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-17	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-18	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-19	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-20	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-21	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-22	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
CVS 3-23	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-1	LIBRARY	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-2	CONFERENCE	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-5	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-7	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-8	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-10	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-11	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 3-12	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-2	CONFERENCE	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-3	HALL	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-5	VESTIBULE	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-7	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-8	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-10	VP OFFICES	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-11	CONFERENCE	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
VVS 4-12	CEO	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]

1. [illegible]
2. [illegible]
3. [illegible]
4. [illegible]

PROJECT MANAGER — HOWARD SKOKE
Project Engineer — HOWARD WALKER
Project Designer — CAROL BLAGOJEVIC

general notes

ANSTEC APERTURE CARD

Also Available on Aperture Card

key plan

△	RD	ADDENDUM NO. 2	12/13/96
no.	by	description	date

revisions

Ewing Cole Cherry Brott

Architects · Engineers · Interior Designers · Planners

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title

EQUIPMENT SCHEDULES

drawing name

scale N.T.S. | date 10/24/96 | drawn by CB | project no. 95063

H5

drawing no.

9706240062- 12

124531

Attachment 2-5

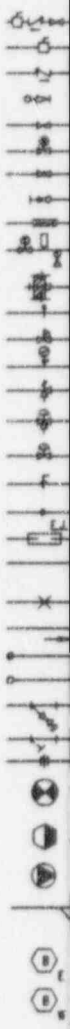
Facility Sinks and Floor Drains

ABBREVIATIONS

A	compressed air
ABV	above
AFF	above finished floor
AD	area drain
AP	access panel
AR	argon
ATMOS. V.	atmospheric vent
AV	acid resistant vent
AW	acid resistant waste
BFP	back flow preventer
BSMT	basement
BT	bathtub
BWV	backwater valve
CB	catch basin
CFS	cubic feet per second
CI	road iron
CLW	clothes washer
CLG	ceiling
CO	cleanout
CO_2	carbon dioxide
CONC.	concrete
CONN.	connection
CONT.	construction
CP	concrete pipe
CS	cup sink
CTL	countertop lavatory
CTS	countertop sink
CW	domestic cold water
DIW	deionized water
DIWR	deionized water return
DF	drinking fountain
DN	down
DOM.	domestic
DP	deep
DR.	drain
DSP	dry standpipe
DV	drain valve
DWG	drawing
DWP	domestic water pump
(E)	existing to remain
EL	elevation
EM. SHR.	emergency shower
E.S.	electrical section
EW	eye wash
EWC	electric water cooler
EXP. COMP.	expansion compensator
FA	fresh air inlet
FC	flow control
FD	floor drain
FDV.	fire department valve
FDVC	fire department valve cabinet
FEC	fire extinguisher cabinet
FH	fire hydrant
FHC	fire hose cabinet
FHR	fire hose rack
FIN. FL.	finished floor
FL	floor
FP	fire pump
FS	flow switch
FU	fixture unit(s)
FV	flush valve
G	gas-natural
G.I.	grease interceptor
GPM	gallon per minute
G.S.	general section
H_2	hydrogen
HB	hose bibb
HD	hub drain
HDR.	header
HE	helium
HP	horsepower
HVAC	heating ventilating & air conditioning section
HW	domestic hot water
HWG	hot water generator
HWR	hot water return
HWH	hot water heater
HWRP	hot water recirc. pump
ID	inside diameter
IE	invert elevation
INV	invert
IW	indirect waste
JP	jockey pump
KS	kitchen sink
LAV	lavatory
LS	laboratory sink
MH	manhole
MR	mop receptor
(N)	new
N_2	nitrogen
N_2O	nitrous oxide
NC	normally closed
NIC	not in contract
NO	normally open
N.T.S.	not to scale
OP	open port
O_2	oxygen
OWH	outside wall hydrant
PH	penthouse
PIV	post indicator valve
PRV	pressure reducing valve
P.S.	plumbing service drain
P.S.I.	pounds per square inch
(R)	remove
RCP	reinforced concrete pipe
RD	roof drain
RWC	rain water connector
S	soil
SAN	sanitary
SC. DR.	scupper drain
SHR	shower
SMAL	seamless
SP.	sump
SPD	standpipe
SPR	sprinkler
SS	service sink
S.W.DR.	safe waste drain
T.B.	thrust block
T.E.	top elevation
TW	tempered water
UR	urinal
V	vent
VAC	vacuum
VB	vacuum breaker
VI	vibration isolator
VTR	vent through roof
W	waste
WC	water closet
WCO	wall cleanout
WF	wash fountain
WH	wall hydrant
WHA	water hammer arrestor
WSP	wet standpipe
WW	wall water
ZCV	zone control valve

SYMBOLS

- ———— sanitary drain
- ———— (sanitary) vent pipe
- ———— storm drain
- ———— domestic cold water
- ———— domestic hot water (120) °
- ———— domestic hot water return (120) °
- ——one'——- domestic hot water (temperature as indicated)
- ——one'——- domestic hot water return (temperature as indicated)
- — A (50) — compressed air (p.s.i.)
- —— AR —— argon
- —— AV —— acid resistant vent
- —— AW —— acid resistant drain
- —— CO_2 —— carbon dioxide
- —— DIWR —— deionized water return
- —— DIW —— deionized water
- —— DSP —— dry standpipe
- —— DW —— distilled water
- —— F —— fire line
- —— G —— gas
- —— H_2 —— hydrogen
- —— HE —— helium
- —— IW —— indirect waste
- —— N_2 —— nitrogen
- —— O_2 —— oxygen
- —— PW —— process waste
- —— SPR —— sprinkler piping
- —— T —— tempered hot water
- —— V —— vacuum
- —— W —— domestic water (outside)
- —— WSP —— wet standpipe



GENERAL NOTES

1. ABOVE CEILING CONSTRUCTION OF THIS FLOOR.
2. ABOVE CEILING CONSTRUCTION OF FLOOR BELOW.
3. AT CEILING OF THIS FLOOR.
4. AT CEILING OF FLOOR BELOW.
5. ABOVE FLOOR.
6. BELOW FLOOR.
7. OFFSET AT 45°
8. CAP OR PLUG SERVICE(S) FOR FUTURE EXTENSION.
9. CONTRACTOR SHALL VERIFY LOCATION, MATERIAL, SIZE, DEPTH AND INVERT ELEVATION OF EXISTING UTILITY SERVICE AT THIS POINT. IF ANY DISCREPANCY EXISTS, HE SHALL NOTIFY THE ARCHITECT IMMEDIATELY IN WRITING PRIOR TO PROCEEDING WITH THE WORK.
10. EXISTING FIXTURE, EQUIPMENT, SERVICE, OR FACILITY TO REMAIN.
11. EXISTING FIXTURE, EQUIPMENT, SERVICE, OR FACILITY TO BE REMOVED.
12. EXISTING FIXTURE, EQUIPMENT, SERVICE, OR FACILITY TO BE RELOCATED.
13. EXTEND AND CONNECT TO NEAREST APPROVED SERVICE AS REQUIRED.
14. REMOVE SERVICE(S) & CAP BEYOND FINISHED SURFACE AND CAP.
15. REMOVE EXISTING PIPING BACK TO ACTIVE POINT AND CAP.
16. EXISTING FLOOR DRAIN TO BE PLUGGED, STRAINER REMOVED, AND DRAIN FILLED WITH CONCRETE.
17. EXISTING SERVICE TO BE ABANDONED IN PLACE.
18. REMOVE EXISTING PIPING AS REQUIRED.
19. CONNECT NEW PIPING TO EXISTING SERVICE AS REQUIRED.
20. REMOVE PIPING ABOVE IN CEILING OF FLOOR BELOW.

NOTE: NOT ALL OF ABOVE NOTES MAY APPEAR ON DRAWINGS.

DRAWING INDEX

four balancing system
balancing valve
check valve
fire department valve
shut-off valve
monitored fire valve
throttling valve
valve in drag
pipe guide
monitored sprinkler sectional valve w/flow switch & test valve
outside wall hydrant
post indicator valve
pressure regulating valve
pressure gauge & valve
pressure temperature relief (safety) valve
three-way valve
two-way valve
gas cock
direction of flow
expansion joint
fire department connection (siamese)
pipe anchor
pitch of pipe down
service riser-down
service riser-up
strainer w/gate valve w/nipple & cap
strainer
union or flanged connection
point of connection new to existing
termination of demolition, removal
hot water recirc. pump
cleanout
electric fire alarm bell
water meter gong

PROJECT MANAGER: HOWARD SHORE
Project Engineer: ROBERT LANZZETTA
Project Designer: LEONARD MECCA

general notes

key plan

no.	by	description	date

revisions

Ewing Cole Cherry Brott
Architects • Engineers • Interior Designers • Planners
Philadelphia, PA 19103 | Wilmington, DE 19801

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.
CHANGE OF USE

project title

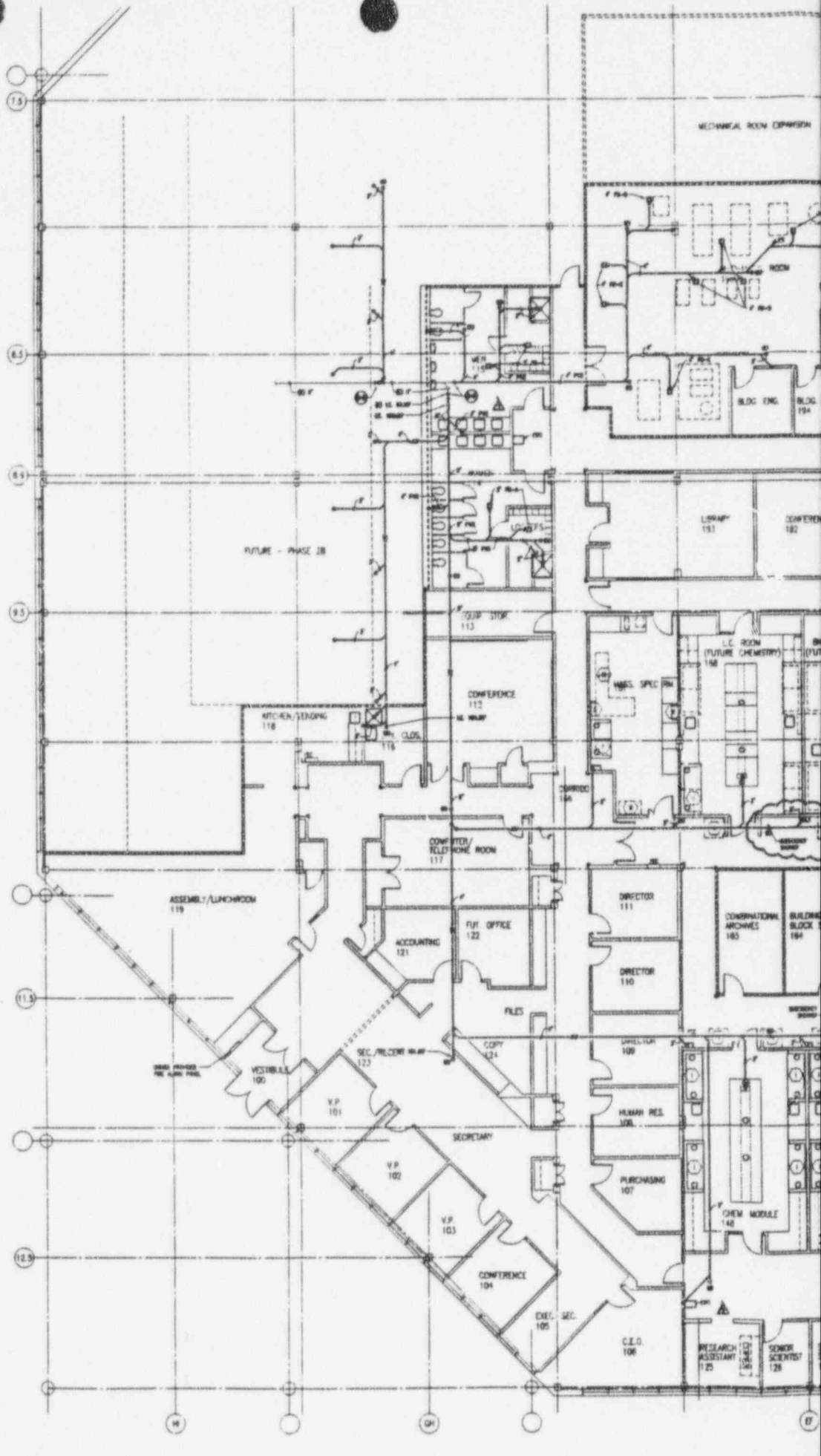
PLUMBING INDEX SHEET

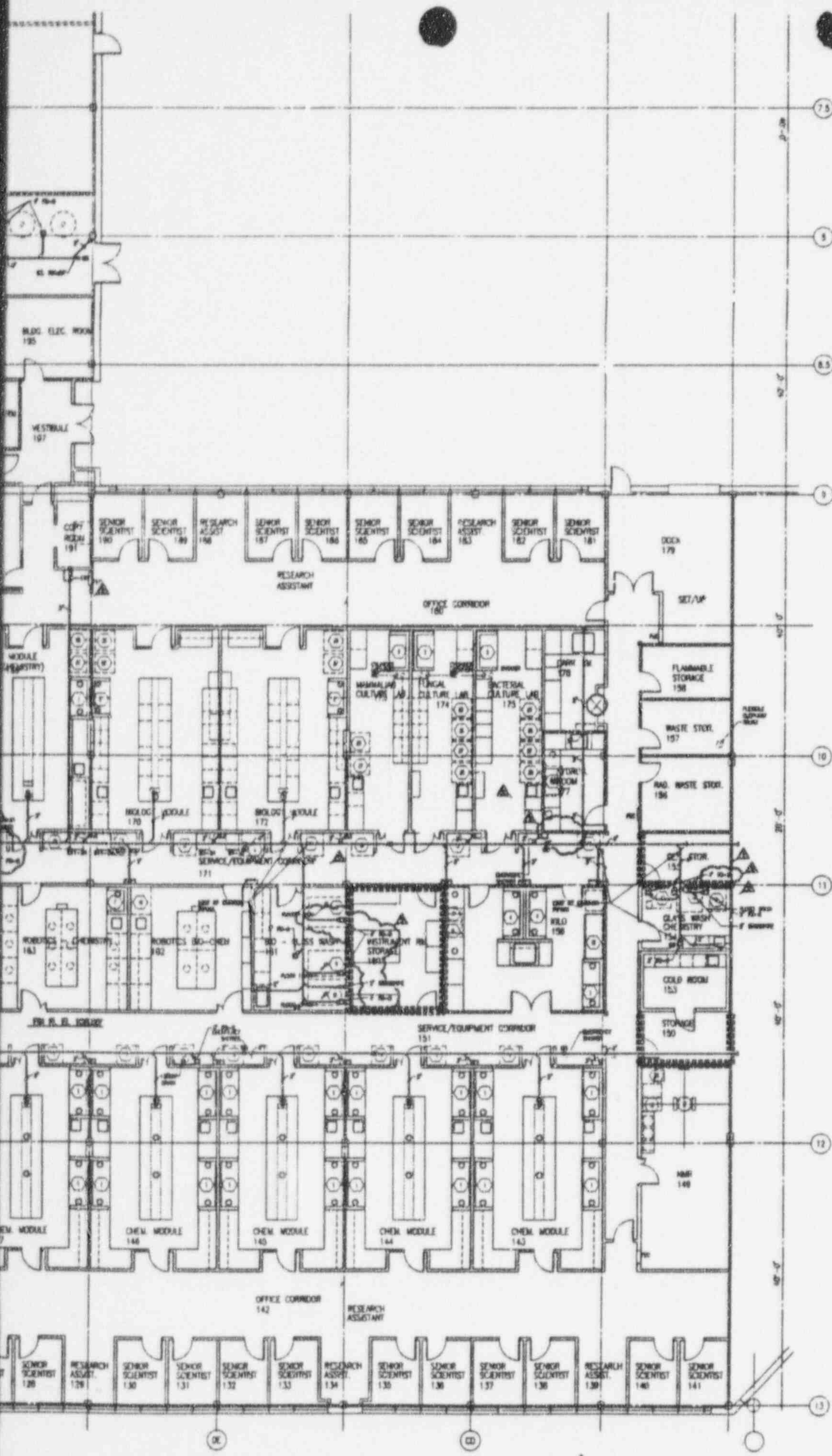
drawing name

scale: NONE | date: 10/25/91
reference files | drawn by: LM | project no. 9106
floor/section | drawing no. P0

file-disc: P1_GROUND_FLOOR_TYPICAL
plot date: 10/25/91

970624 0062 - 13


MECHANICAL ROOM EXPANSION
FUTURE - PHASE 2B
EQUIP. STOR. 113
CONFERENCE 112
KITCHEN/SERVING 118
CLOS. 119
LC ROOM (FUTURE CHEMISTRY) 150
MASS. SPEC RM.
COMPUTER/ TELEPHONE ROOM 117
ASSEMBLY/LUNCHROOM 119
ACCOUNTING 121
FUT. OFFICE 122
FILES
DIRECTOR 111
DIRECTOR 110
CONFIDENTIAL ARCHIVES 183
COPY 124
SEC./RECEPT 123
VESTIBULE 100
V.P. 101
SECRETARY
V.P. 102
V.P. 103
CONFERENCE 104
EXEC. SEC. 105
C.E.O. 106
HUMAN RES. 108
PURCHASING 107
CHEM. MODULE 148
RESEARCH ASSISTANT 125
SENIOR SCIENTIST 126
7.5
8.5
9.5
11.5
12.5
M
GH
E7



9706240062-14

PROJECT MANAGER — HOWARD SNOKE
Project Engineer — ROBERT LANGZETTEL
Project Designer — LEONARD MECCA

general notes

A. AW – ACID WASTE DRAINAGE PIPING BELOW GRADE. ELECTRIC FUSION SCHEDULE 40 POLYPROPYLENE.
B. PVC SCHEDULE 40 FOR UNDERGROUND SANITARY PIPING.
C. DRAINAGE PIPING FOR GLASS WASHING ROOMS TO BE SUBMERGED FOR FIRST 15 FEET.
D. FD-A ...
E. FD-B NOT USED
F. FD-C ...
G. FD-D ...
H. FD-E ...

ANSTEC APERTURE CARD

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key plan

no.	by	description	date
	LAH	ADDENDUM NO. 2	12/13/90
	LAH	REISSUED	10/16/90
	LAH	GENERAL REVISIONS	8/16/90
	LAH	CP-P1	8/16/90

revisions

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Philadelphia, PA 19160

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title

GROUND FLOOR PLAN
UNDERGROUND DRAINAGE

drawing name

scale 1/8" = 1'-0"

date 10/24/90

drawn by LAH

project no.

reference files

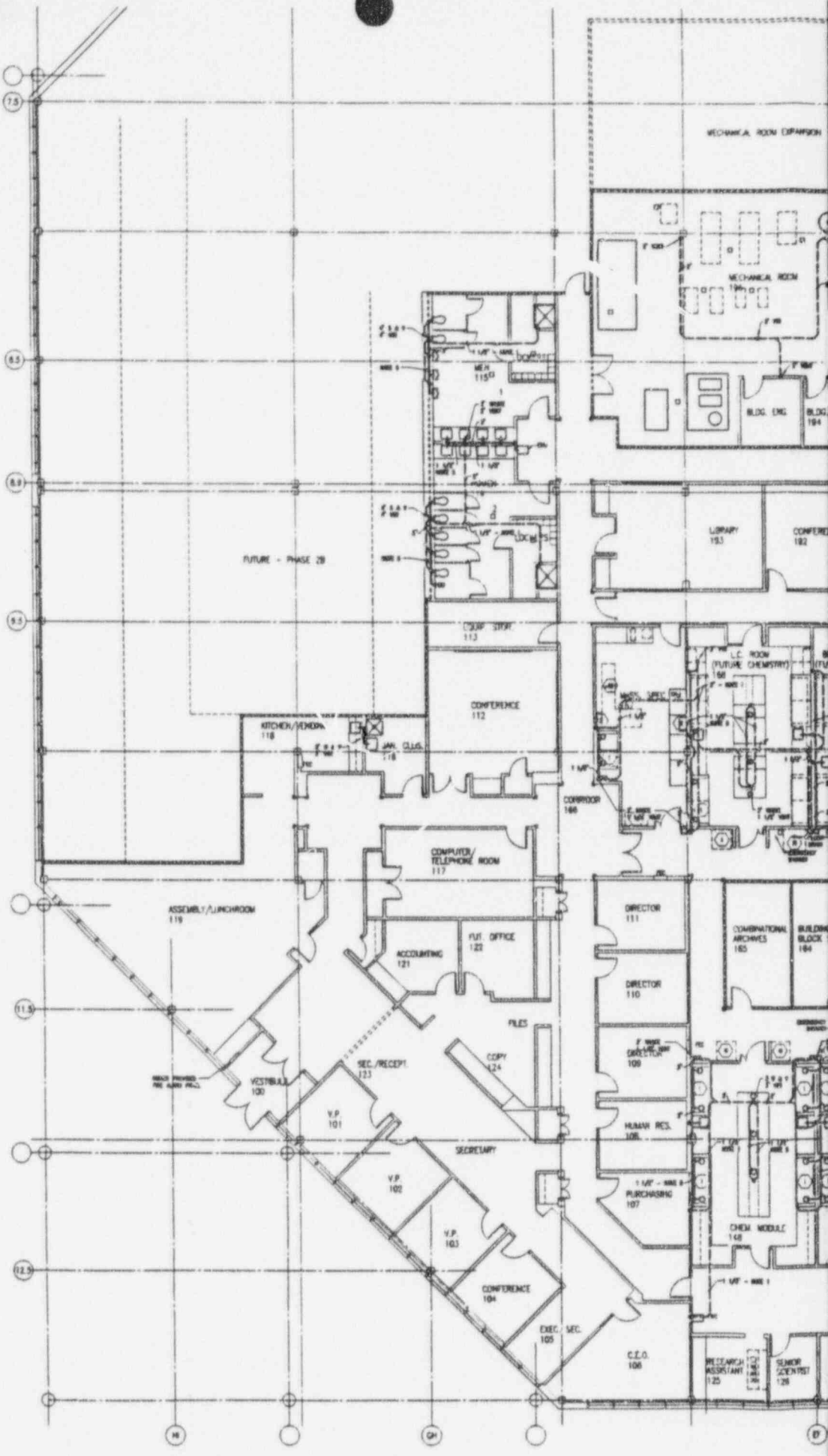
G

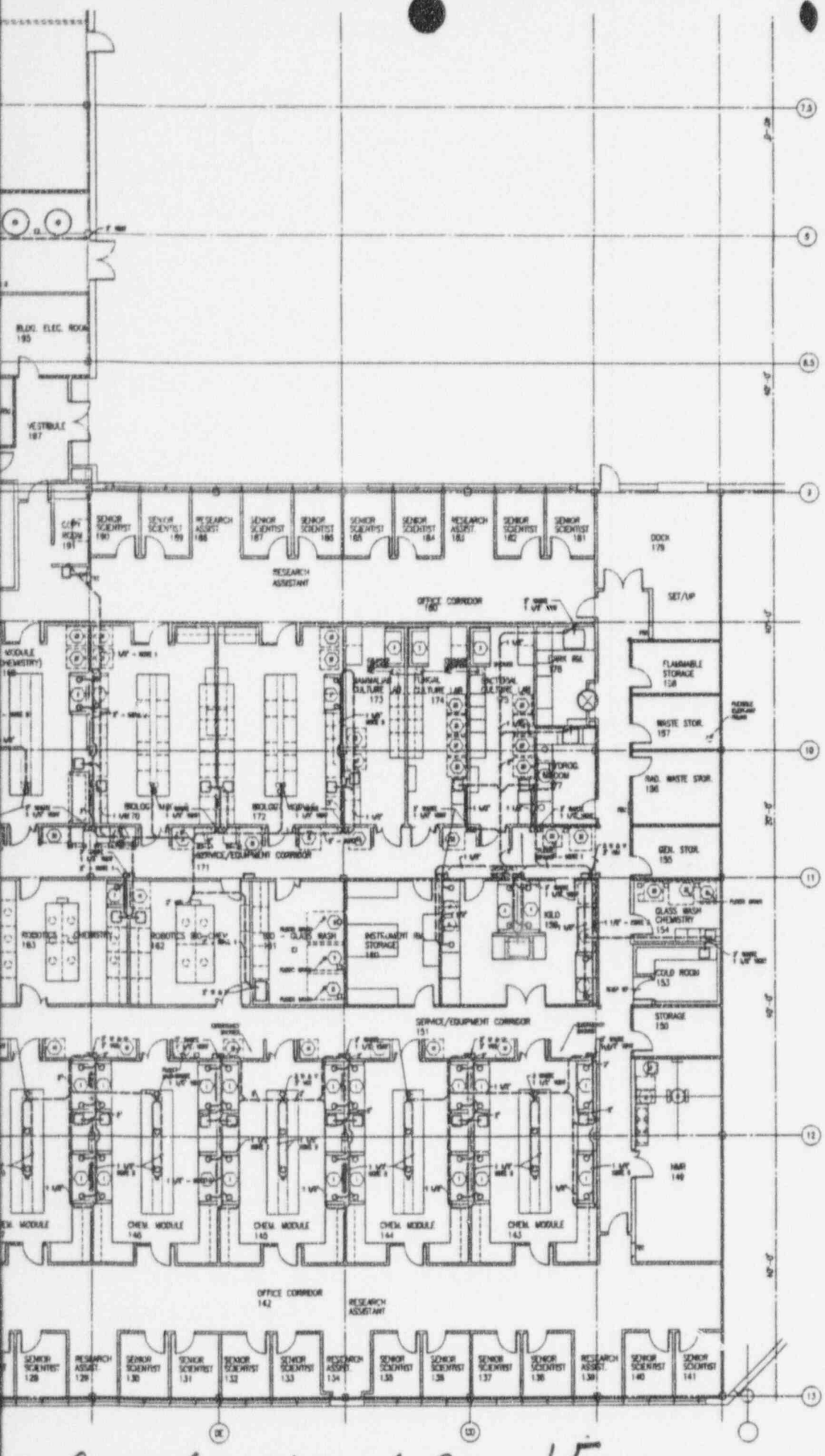
floor/section

P1

drawing no.

plot date 12/11/90


MECHANICAL ROOM EXPANSION
MECHANICAL ROOM
BLDG. ENG.
LIBRARY
FUTURE - PHASE 2B
EQUIP. STOR.
CONFERENCE
KITCHEN/VENDING
L.C. ROOM (FUTURE CHEMISTRY)
CORRIDOR
COMPUTER/ TELEPHONE ROOM
ASSEMBLY/LUNCHROOM
DIRECTOR
ACCOUNTING
FUT. OFFICE
DIRECTOR
FILES
SEC./RECEPT.
COPY
VESTIBULE
V.P.
SECRETARY
HUMAN RES.
PURCHASING
CHEM. MODULE
CONFERENCE
EXEC. SEC.
C.E.O.
RESEARCH ASSISTANT
SENIOR SCIENTIST



PROJECT MANAGER — HOWARD SHUKE
Project Engineer — ROBERT LANGSTEFEL
Project Designer — LEONARD MECCA

general notes

drawing notes

key plan

no.	by	description	date

revisions

Ewing Cole Cherry Brott

Architects · Engineers · Interior Designers · Planners

TRANSCELL TECH. INC.

TRANSCELL TECH. INC.

project title

GROUND FLOOR PLAN
DRAINAGE

drawing name

scale 1/8" = 1'-0" — date 10/24/90

reference files — drawn by LM

project no. 9005

floor/section G — drawing no. P3

9706240062-15

124531

Attachment 3

Letters of Commitment and Intent

TRANSCELL TECHNOLOGIES INC.

2000 Cornwall Road
Monmouth Junction, NJ 08852
(908) 821-0550
(908) 821-4470

April 25, 1997

Mr. Tom McKittrick
Disaster Coordinator
Emergency Medical Service
Princeton Hospital
253 Witherspoon Street
Princeton, NJ 08540

Dear Mr. McKittrick:

Transcell Technologies, Inc. will be conducting various activities to support the research and development of new drug delivery systems requiring the use of a few radionuclides in a limited number of experiments, including H-3, C-14, P-32, P-33, S-35, Cr-51, I-125, and I-131. As part of our contingency plan and requirements with the Nuclear Regulatory Commission and the New Jersey State Department of Environmental Protection and Energy's Bureau of Environmental Radiation, we wish to notify you in case of need for treatment of injuries that might also include residual levels of contamination.

The type of injuries might include chemical burns, skin cuts, punctures, and abrasions. The amount of radioactivity being used will not result in near or lethal doses, but may result in technical over exposure above regulatory limits (i.e., 5 rem/year). Should a patient be brought to the trauma center, Transcell will provide technical assistance in monitoring radioactive levels, give information to the emergency room staff about the nature of the contaminants, and descriptions or cause of the accident.

Should you need additional information, please do not hesitate to contact me at (908) 821-0550.

Sincerely,

Clifford Longley

Clifford Longley, RSO

TRANSCELL TECHNOLOGIES INC.

2000 Cornwall Road
Monmouth Junction, NJ 08852
(908) 821-0550
(908) 821-4470

April 25, 1997

Dr. Gerald Melnick
Robert Wood Johnson Hospital
Emergency Room and Trauma Center
180 Somerset St.
New Brunswick, NJ 08903

Dear Dr. Melnick:

Transcell Technologies, Inc. will be conducting various activities to support the research and development of new drug delivery systems requiring the use of a few radionuclides in a limited number of experiments, including H-3, C-14, P-32, P-33, S-35, Cr-51, I-125, and I-131. As part of our contingency plan and requirements with the Nuclear Regulatory Commission and the New Jersey State Department of Environmental Protection and Energy's Bureau of Environmental Radiation, we wish to notify you in case of need for treatment of injuries that might also include residual levels of contamination.

The type of injuries might include chemical burns, skin cuts, punctures, and abrasions. The amount of radioactivity being used will not result in near or lethal doses, but may result in technical over exposure above regulatory limits (i.e., 5 rem/year). Should a patient be brought to the trauma center, Transcell will provide technical assistance in monitoring radioactive levels, give information to the emergency room staff about the nature of the contaminants, and descriptions or cause of the accident.

Should you need additional information, please do not hesitate to contact me at (908) 821-0550.

Sincerely,

Clifford Longley

Clifford Longley, RSO

The Fire Safety Bureau Authorization Permit for keeping, storage, and use of hazardous Material for Cranbury Township is pending.

TAX ID #.

Lic No 29-30181-01

Docket No 03033700

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

MAY 27 1997

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: 29301810 1 L

NAME: TRANSCELL TECHNOLOGIES, INC.

ADDRESS: ATTN: CLIFFORD B. LONGLEY, RADIATION SAFETY OFFICER

ADDRESS: 2000 CORNWALL ROAD

CITY: MONMOUTH JUNCTION STATE: NJ ZIP: 08852

TRANS CODE: PX

TRANS TYPE: ____	FUND: ____	JOB CODE: ____	AMOUNT: $80.00
TRANS TYPE: IR	FUND: R1435	JOB CODE: INTR	AMOUNT: ____
TRANS TYPE: IR	FUND: R1099	JOB CODE: ADCH	AMOUNT: ____
TRANS TYPE: IR	FUND: R1099	JOB CODE: FINE	AMOUNT: ____

TOTAL REFUND AMOUNT: $80.00

COMMENTS: Lic 29-30181-01/CK 3101/3m AMD OVRPYT

(limit comments to 40 characters, including spaces)

PREPARED BY: Brenda Burns DATE: 5/27/97

AUTHORIZED BY: Sandra Kimberly DATE: 5/28/97

ORIGINAL INV. NO: ____ DATE PAID: ____ AMOUNT: ____

REFUND ENTERED INTO COLLECT BY: ____

REFUND DETERMINED BY: ____ DATE: ____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

May 6 I (97)
Appl dtd 4/30/97
3m Amd Fee is $60
124531

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03620
Status Code: O
Fee Category: 3M
Exp. Date: 20041231
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: TRANSCELL TECHNOLOGIES, INC.
   Received Date: 970501
   Docket No: 3033700
   Control No.: 124531
   License No.: 29-30181-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: $690.00
   Check No.: 3101

3. COMMENTS

Signed Brown, R. J.
Date 5/5/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: 3M $610

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____

Signed _____
Date _____

I (97)

Log Bday 6
Remitter
Check No. 3101
Amount $690 $610 Refunded $80
Fee Category 3M
Type of Fee AMD
Date Check Rec'd 5/07/97
Date Completed BB
By:

97 MAY -7 PM 12:29