

030-29725

L-1 = 27943

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

U.S. NUCLEAR REGULATORY COMMISSION  
APPROVED BY O-18  
3150-0120  
Expires: 5-31-87

## APPLICATION FOR MATERIAL LICENSE

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

## FEDERAL AGENCIES FILE APPLICATIONS WITH:

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

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

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

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

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

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

## IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- ☒ A. NEW LICENSE  
☐ B. AMENDMENT TO LICENSE NUMBER \_\_\_\_\_  
☐ C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

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

Organogenesis, Inc.  
83 Rogers Street  
Cambridge, MA 02142

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

Organogenesis Inc.  
75 Rogers Street  
Cambridge MA 02142

Organogenesis Inc.  
79 Rogers Street  
Cambridge MA 02142

Organogenesis Inc.  
83 Rogers Street  
Cambridge MA 02142

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. John P. Daley

TELEPHONE NUMBER

(617) 577-1717

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

## 5. RADIOACTIVE MATERIAL

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

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

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

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

9. FACILITIES AND EQUIPMENT

See attached

10. RADIATION SAFETY PROGRAM

See attached

11. WASTE MANAGEMENT

See attached

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

FEE CATEGORY 3M AMOUNT ENCLOSED \$ \$700.

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

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

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, §2 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

*Crispin B. Weinberg* Crispin B. Weinberg and Treasurer Director of Research 1-16-87

## 14. ANNUAL RECEIPTS

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

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)

<\$250K  
\$250K-500K  
\$500K-750K  
\$750K-1M

\$1M-3.5M  
\$3.5M-7M  
\$7M-10M  
>\$10M

c. NUMBER OF BEDS

YES

NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

ML18

106705

DATE

2/5/87

PRIVACY ACT STATEMENT ON THE REVERSE

8710070292 870407  
REG1 LIC30  
20-27945-01 PDR

OFFICIAL RECORD COPY

JAN 28 1987

5. The following radioisotopes will be used under this license:

a. <u>Element/mass number</u>	b. <u>Chemical/physical form</u>	c. <u>Possession limit</u>
Carbon-14	Liquid and solid	50 millicuries
Hydrogen-3	Liquid and solid	100 millicuries
Iodine-125	Liquid	50 millicuries
Iodine-131	Liquid	50 millicuries
Sulphur-35	Liquid and solid	50 millicuries
Phosphorus-32	Liquid and solid	50 millicuries
Chromium-51	Liquid and solid	50 millicuries
Sodium-22	Liquid and solid	2 millicuries
Chlorine-36	Liquid and solid	10 millicuries
Technetium-99m	Liquid and solid	50 millicuries

6. All radioisotopes will be used to label biological molecules in research and development studies. Some animal use of trace amounts of radioisotopes is anticipated.

7. Dr. John Paul Daley will be the radiation safety officer. Please see his attached curriculum vitae for his training and experience. Dr. Crispin Weinberg will be the back-up RSO. His curriculum vitae is also attached.

8. All persons working in or frequenting restricted areas will be given radiation protection training by the RSO. See attached list of material to be covered during a training session. Also our training program is explained in our Radiation Protection Program.

9. Facilities and equipment: See attached floor plan and explanation of facilities where radioisotopes will be handled and stored. The following radiation detection equipment will be available at the facilities:

a. Three Ludlum Model III radiation survey instruments equipped with either end window GM detectors and/or NaI scintillation detectors.

b. One LKB liquid scintillation counter.

c. One LKB gamma counter.

10. Radiation Safety Program: Please see attached.

11. Waste Management: Whenever possible, we will limit the amount of radioactive material that has to be disposed of as low level radioactive waste. Whenever this waste needs to be disposed we will contract with Radiac Research Corporation or another licensed waste disposal contractor. All radioactive waste that can be held for decay storage ( $T_{1/2} < 65$  days) will be disposed of as regular trash after a.) the material is held for a minimum of 10 half lives, and, b.) the material is thoroughly surveyed before disposal and there is no detectable radioactivity above background. For low level aqueous liquid waste, we will use the sanitary sewage system in accordance with 10 CFR 20.303 whenever possible.

# ORGANOGENESIS INC.

83 Rogers Street  
Cambridge, MA 02142  
(617) 577-1717

## RADIOACTIVITY EXPERIENCE

John P. Daley -- Radiation Safety Officer

1980 -- Ph.D. in Radiation Biology  
State University at Buffalo

1971-1974 -- As an instructor of Biology at the State University College at Buffalo I participated in the teaching of a radiation biology and radioisotope tracer course. In this course we taught students how to safely handle and detect several radioisotopes including:  $^3\text{H}$ ,  $^{14}\text{C}$ ,  $^{32}\text{P}$ . We also used a sealed  $^{60}\text{Co}$  source. As an instructor I handled millicurie quantities of the above nuclides.

1974-1975 -- Graduate Assistant in Radiation Biology responsible for the teaching of a radioisotopes techniques course. In this course I taught the safe handling of several radionuclides including:  $^{14}\text{C}$ ,  $^3\text{H}$ ,  $^{32}\text{P}$ ,  $^{51}\text{Cr}$ ,  $^{125}\text{I}$ ,  $^{35}\text{S}$ ,  $^{24}\text{Na}$  and  $^{45}\text{Ca}$ . I was also responsible for the safe use of a GM x-ray machine as well as a sealed  $^{60}\text{Co}$  source. Most of the latter isotopes were handled in millicurie amounts.

1980-1984 -- During my first postdoctoral fellowship in cellular immunology, since my PhD was in radiation biology, I was asked to be the radiation safety officer for a laboratory of thirteen people. In this capacity, I handled several millicurie quantities of  $^{137}\text{Cs}$ ,  $^{51}\text{Cr}$ ,  $^{59}\text{Fe}$ ,  $^{131}\text{I}$  and  $^{111}\text{In}$ . I developed and maintained, in conjunction with the Radiation Protection Department, isotope inventories, and a radiation survey program.



# ORGANOGENESIS INC.

83 Rogers Street  
Cambridge, MA 02142  
(617) 577-1717

## RADIOACTIVITY EXPERIENCE

CRISPIN B. WEINBERG

- 1972-73      M.S. in Physics, University of Chicago  
              -Course work in nuclear and quantum physics  
              -Laboratory handling of sealed sources in experimental techniques course
- 1973-80      Graduate training in neurobiology, Harvard Medical School (Division of Medical Sciences) and University of California at San Francisco (neuroscience Dept.)  
              -used [ $^3\text{H}$ ], [ $^{14}\text{C}$ ], [ $^{32}\text{P}$ ], [ $^{125}\text{I}$ ], and [ $^{131}\text{I}$ ] as tracers (amounts up to 10 mCi or less depending on isotope).  
              -Performed iodinations of proteins (Chloramine-T and Bolton-Hunter methods) using 10 mCi of [ $^{125}\text{I}$ ] or 10 mCi of [ $^{131}\text{I}$ ] per iodination.
- 1981-85      Research Fellow at M.I.T.  
              -used [ $^3\text{H}$ ], [ $^{14}\text{C}$ ], and [ $^{35}\text{S}$ ] as tracers (up to 10 mCi).



# ORGANOGENESIS INC.

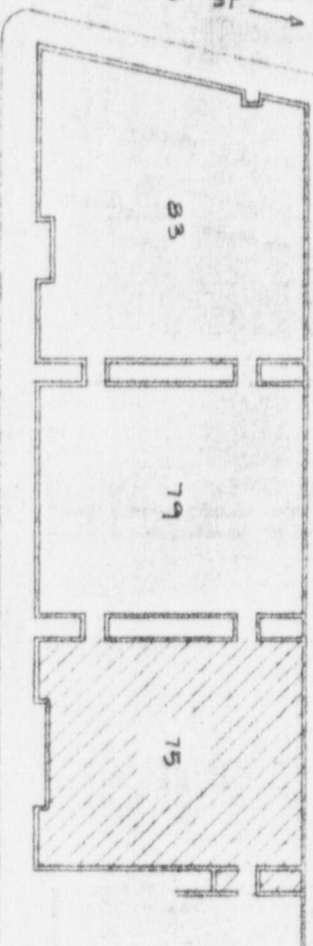
83 Rogers Street  
Cambridge, MA 02142  
(617) 577-1717

## SITE PLANS for RADIOACTIVITY USE

- PLAN #1 Overall site plan.
- PLAN #2 Laboratory area of of 83 Rogers Street  
Room #25 is for radioactivity storage & handling.  
The fume hood will be equipped with a charcol filter  
in the duct and air sampling equipment.  
Room #31 will contain a gamma counter and liquid scitntillation  
counter, and samples for counting.  
Radioactive tracers may be used in romm #31 on  
infrequently (expected to less than 1 day per month).
- PLAN #3 & #4 79 Rogers Street  
Radioactive tracers will be used in rooms #37 and #50.  
Radioactive tracers may infrequently be used in room #41.
- Plan #5 Laboratory area of 75 Rogers Street  
Tracers will be used in the main laboratory area,  
rooms #57-59.  
Radioactive waste will be stored in drums in the  
locked loading area, room #53.

4-UP TRANSITION W/ FRAMES

3RD ST



ROGERS ST.

KEY PLAN  
No SCALE



PLAN #1

ISSUED FOR TRANSITIONAL LAB (PHASE 1) SEPT. 10, 1986  
SUBSEQUENT REVISIONS FOR PERMANENT LAB (PHASE 2)

FLOOR PLAN - 75 ROGERS ST.

ORGANOGENESIS INCORPORATED

75-79-83 ROGERS STREET

CAMBRIDGE

MASSACHUSETTS

WILLIAM B. MERRY & ASSOCIATES, INC. ENGINEERS  
LAKE SIDE OFFICE PARK, WAKEFIELD, MASS. 01880

A1

PROJECT NO.  
88-120

DATE  
SEPTEMBER 10, 1986

DRAWN  
DBA RNA

DRAWING NO.



CAKPEB 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2411 2412 2413 2414 2415 2416 2417 2418 2419 2420 2421 2422 2423 2424 2425 2426 2427 2428 2429 2430 2431 2432 2433 2434 2435 2436 2437 2438 2439 2440 2441 2442 2443 2444 2445 2446 2447 2448 2449 2450 2451 2452 2453 2454 2455 2456 2457 2458 2459 2460 2461 2462 2463 2464 2465 2466 2467 2468 2469 2470 2471 2472 2473 2474 2475 2476 2477 2478 2479 2480 2481 2482 2483 2484 2485 2486 2487 2488 2489 2490 2491 2492 2493 2494 2495 2496 2497 2498 2499 2500 2501 2502 2503 2504 2505 2506 2507 2508 2509 2510 2511 2512 2513 2514 2515 2516 2517 2518 2519 2520 2521 2522 2523 2524 2525 2526 2527 2528 2529 2530 2531 2532 2533 2534 2535 2536 2537 2538 2539 2540 2541 2542 2543 2544 2545 2546 2547 2548 2549 2550 2551 2552 2553 2554 2555 2556 2557 2558 2559 2560 2561 2562 2563 2564 2565 2566 2567 2568 2569 2570 2571 2572 2573 2574 2575 2576 2577 2578 2579 2580 2581 2582 2583 2584 2585 2586 2587 2588 2589 2590 2591 2592 2593 2594 2595 2596 2597 2598 2599 2600 2601 2602 2603 2604 2605 2606 2607 2608 2609 2610 2611 2612 2613 2614 2615 2616 2617 2618 2619 2620 2621 2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 2632 2633 2634 2635 2636 2637 2638 2639 2640 2641 2642 2643 2644 2645 2646 2647 2648 2649 2650 2651 2652 2653 2654 2655 2656 2657 2658 2659 2660 2661 2662 2663 2664 2665 2666 2667 2668 2669 2670 2671 2672 2673 2674 2675 2676 2677 2678 2679 2680 2681 2682 2683 2684 2685 2686 2687 2688 2689 2690 2691 2692 2693 2694 2695 2696 2697 2698 2699 2700 2701 2702 2703 2704 2705 2706 2707 2708 2709 2710 2711 2712 2713 2714 2715 2716 2717 2718 2719 2720 2721 2722 2723 2724 2725 2726 2727 2728 2729 2730 2731 2732 2733 2734 2735 2736 2737 2738 2739 2740 2741 2742 2743 2744 2745 2746 2747 2748 2749 2750 2751 2752 2753 2754 2755 2756 2757 2758 2759 2760 2761 2762 2763 2764 2765 2766 2767 2768 2769 2770 2771 2772 2773 2774 2775 2776 2777 2778 2779 2780 2781 2782 2783 2784 2785 2786 2787 2788 2789 2790 2791 2792 2793 2794 2795 2796 2797 2798 2799 2800 2801 2802 2803 2804 2805 2806 2807 2808 2809 2810 2811 2812 2813 2814 2815 2816 2817 2818 2819 2820 2821 2822 2823 2824 2825 2826 2827 2828 2829

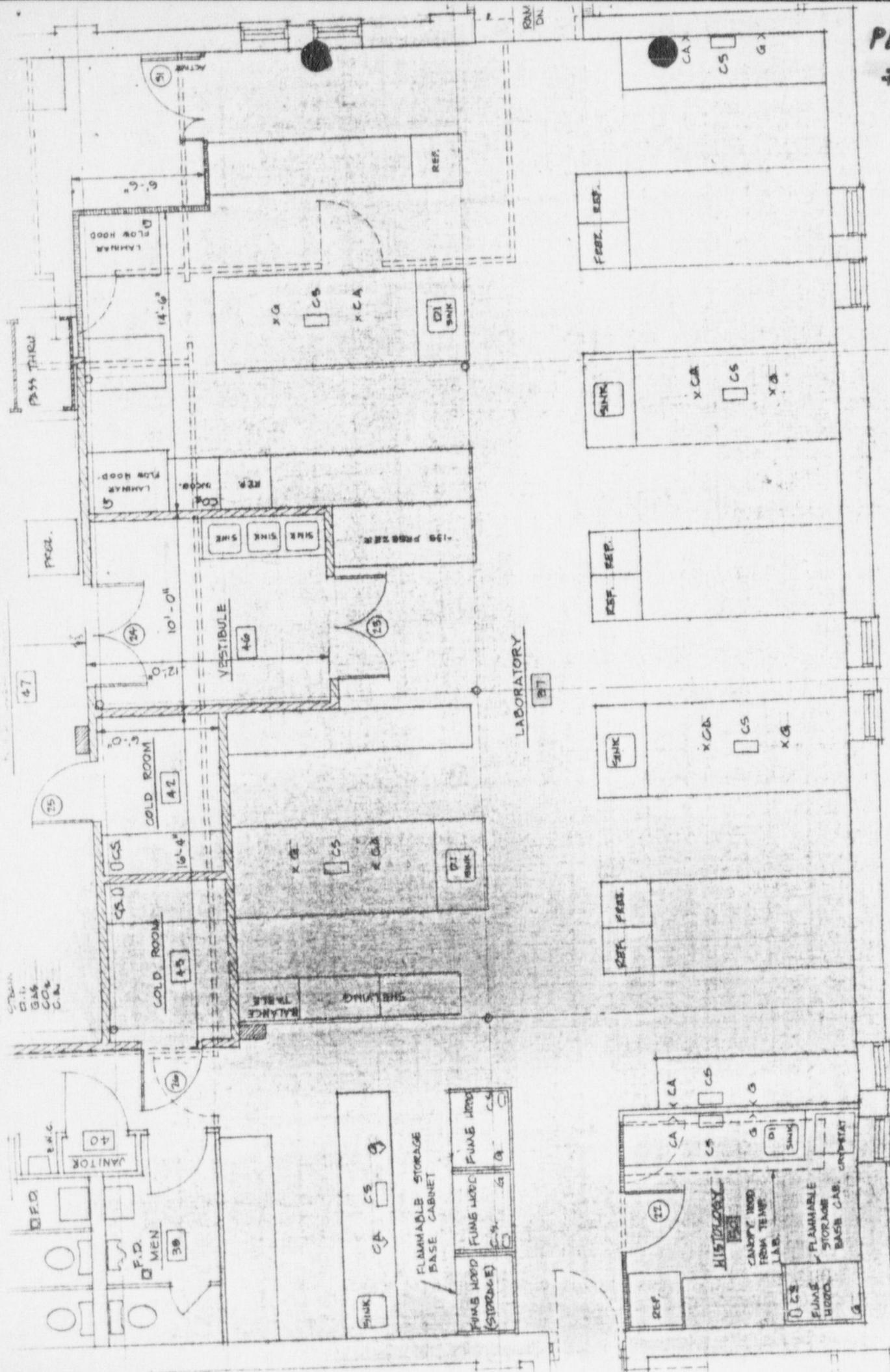


RELOCATE EXISTING ROLL UP



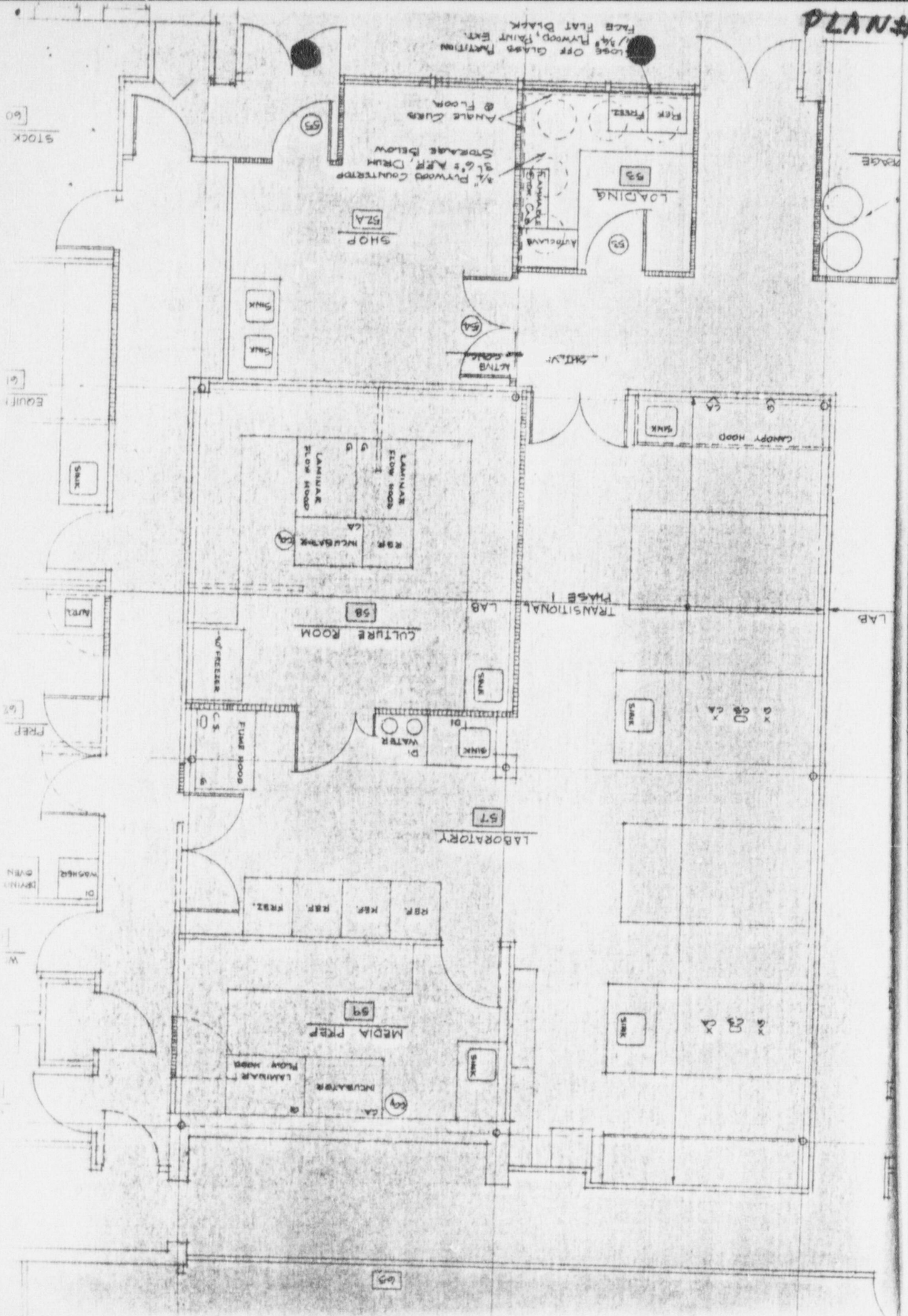
PLAN  
#3

Called  
North











## RADIATION PROTECTION TRAINING PROGRAM

### Outline Of Subject Material

1. Concepts of ionizing radiation.
2. Units and definitions:
  - A. Exposure dose
  - B. Absorbed dose.
  - C. Dose equivalent
  - D. Dose rate
  - E. Units for amount of radioactivity.
  - F. Half life.
3. Biological effects of radiation:
  - A. History of radiation exposure.
  - B. Acute exposure values and effects.
  - C. Chronic exposure and effects.
  - D. Threshold versus linear relation between dose and effect.
  - E. Balancing risks versus benefits.
  - F. Regulatory Guide 8.29.
4. Maximum permissible exposures:
  - A. Current MPE values.
  - B. Concept of ALARA.
  - C. Regulatory Guide 8.13.
5. Control of radiation exposure:
  - A. Control of external exposure (time, distance, shielding)
  - B. Control of internal exposure.
6. Monitoring procedures.
  - A. Wipe tests.
  - B. Radiation monitoring equipment (survey instruments).
7. Handling radiation emergencies or incidents.
8. Compliance with regulations.
  - A. NRC regulations
  - B. DOT regulations
  - C. Commonwealth of Massachusetts regulations.

Appropriate reference material will be distributed at the time of the training lectures to further reinforce the above concepts.

ORGANOGENESIS

RADIATION PROTECTION PROGRAM

## TABLE OF CONTENTS

### I. INTRODUCTION

#### • A. PURPOSE

#### B. RADIATION PROTECTION OFFICER RESPONSIBILITIES

### II. RADIATION PROTECTION PROGRAM

#### A. REGISTRATION AND INSTRUCTION OF RADIATION WORKERS

#### B. CONTROL OF RADIATION EXPOSURES

#### C. PERSONEL MONITORING OF INTERNAL AND EXTERNAL RADIATION EXPOSURES

#### D. ENVIRONMENTAL RADIATION MONITORING

#### E. RADIATION SURVEYS OF RADIOSOTOPE LABORATORIES

#### F. PROCUREMENT AND MONITORING OF RADIOACTIVE SHIPMENTS

#### G. OPENNING RADIOACTIVE PACKAGES

#### H. CALIBRATION OF RADIATION SURVEY INSTRUMENTS

#### I. RADIOACTIVE WASTE DISPOSAL

#### J. RADIATION EMERGENCIES

#### K. GENERAL LABORATORY RULES

#### L. REGULATORY GUIDE 8.13

#### M. REGULATORY GUIDE 8.29



## ORGANOGENESIS

### RADIATION PROTECTION PROGRAM

#### I. Introduction

##### A. Purpose

It is the policy of Organogenesis to provide the necessary training, facilities, equipment, and personnel to maintain levels of radiation exposure to its employees and to the general public and environment as low as reasonably achievable. Organogenesis is committed to ensuring that radioactive materials are possessed, used, transported, and disposed in accordance with the conditions of its license along with applicable regulations of the U.S. Nuclear Regulatory Commission, the Department of Transportation, and the Commonwealth of Massachusetts.

##### B. Radiation Protection Officer's Responsibilities

The Radiation Protection Officer is responsible for the following:

- (1) The establishment and continuing review of an adequate Radiation Protection Program.
- (2) Compliance with radiation protection regulations promulgated by governmental agencies.
- (3) Reviewing proposed uses of radioactive materials.
- (4) Providing new and current employees with proper training and information regarding radiation health and safety.
- (5) Reviewing reports of infractions of any rules or regulations and implementing corrective actions.
- (6) Maintaining all records as required by the Organogenesis Radiation Protection Program.
- (7) Supplying reports, if necessary, to the Nuclear Regulatory Commission or to employees as required by 10 CFR 19 and 20.
- (8) Supervising any radiation emergencies or special decontamination procedures.

## II. Radiation Protection Program

### A. Registration and Instruction of Radiation Workers

Prior to working with radioactive materials, all radiation workers are:

(1) Given a lecture and hand-out material on the mechanics of radioactivity and radiation protection practices. Our consultants, Bolton & Galanek, Inc., will assist the Radiation Protection Officer in the training of radiation workers (see the attached outline of the subject material to covered). Periodic retraining seminars will be held as needed.

(2) Provided with a copy of the Organogenesis radiation protection program as accepted by the Nuclear Regulatory Commission (NRC).

(3) Instructed that all laboratory rules and safety procedures outlined in this program must be complied with and that failure to do so may result in disciplinary action.

(4) Informed of the relevant portions of NRC regulations in 10 CFR 19 and 20. Copies of these regulations will be maintained by the RPO for review by interested workers.

(5) Required to sign the following statement confirming that the above information has been conveyed to them and they have been afforded an opportunity to ask any questions.

#### ORGANOGENESIS

##### Statement of Training in Radiation Protection

" I have been provided with a copy of the Organogenesis Radiation Protection Program as well as any additional material and information necessary to understand the radiation protection practices that are outlined in the program. I have been afforded the opportunity to ask questions concerning radiation safety and the safe use of radioactive material, I am aware of the NRC regulations in 10 CFR 19 & 20 pertaining to radiation safety, and I understand my responsibility to comply with applicable regulations."

Signature \_\_\_\_\_

Date \_\_\_\_\_

(6) Training will also be provided for ancillary personnel (custodians, security, etc.).

## B. Control of Radiation Exposures

- (1) External and internal exposures to ionizing radiation shall be kept as low as reasonably achievable (ALARA).
- (2) Occupational external and internal exposures from radioactive material shall be controlled such that no individual can receive a radiation dose in excess of the values listed in Table 1.

Table 1.  
OCCUPATIONAL DOSE VALUES

- (a) Maximum permissible exposures for occupational external radiation

	<u>Rems per calendar quarter</u>	<u>Rems per year</u>
Whole body; head and trunk; active blood forming organs; lens of eye; gonads	1.25	5.0
Skin of whole body	7.50	30.0
Hands and forearms; feet and ankles	18.75	75.0

- (b) Maximum permissible dose for minors and non-radiation workers:  
50Cmrem per year.
- (c) Maximum permissible dose to pregnant women: The Radiation Safety Officer instructs all pregnant women to follow the NRC guidelines established in Regulatory Guide 8.13.



## C. Personnel Monitoring of Internal and External Exposures

### (1.a) Thyroid Monitoring:

All new radiation workers who will routinely handle unsealed quantities of radioiodine will have a baseline thyroid burden measurement before beginning work. Persons handling unsealed quantities of radioiodine greater than 100 microcuries will have thyroid burden measurements performed within 24 - 48 hours after handling the material. Thyroid monitoring will be performed 'in-house' using a Ludlum Model 3 instrument equipped with a properly calibrated scintillation detector. Action levels along with corrective actions taken will be those outlined in Item 5 of Regulatory Guide 8.20.

### (1.b) Urinalysis:

Persons routinely handling 10 millicuries or greater of tritium will be required to submit urine specimens to the RSO for tritium analysis. Action levels along with corrective actions taken will be those outlined in Item 5 of Regulatory Guide 8.

Additional bioassays may be performed on designated individuals at the discretion of the RSO. As is required by 10 CFR 20.401, records of bioassay results for all employees are maintained.

### (2) Whole body dosimeters:

Radiation workers who handle radioisotopes or are routinely present in the areas where the radioisotopes are stored and used will be required to wear a whole body film badge.

### (3) Extremity dosimeters:

Persons who routinely handle millicurie quantities of radioisotopes that can result in hand exposures will be required to wear wrist badges and/or finger ring dosimeters in conjunction with their whole body badges.

Dosimeters will be supplied by R.S. Landauer and will have a monthly exchange frequency. Records of personnel exposures will be maintained by the Radiation Protection Officer.

## D. Environmental Monitoring

(1) Any hood in which radioiodine is stored and used will be equipped with a charcoal filter system. Monitoring stations will be established to determine if any radioiodine is being released to the environment. If released amounts exceed the Maximum Permissible Concentration as listed in Part 20, further engineering controls will be established to reduce these exposures to as low as reasonably achievable.

(2) Laboratory air sampling and/or breathing zone sampling will be performed during iodination procedures.

#### E. Radiation Surveys of Radioisotope Laboratories

- (1) All laboratories in which greater than 100 microcuries of radioactivity is handled on a routine basis will be surveyed weekly. These surveys will consist of radiation dose rate measurements at specified locations accompanied by wipe testing for removable contamination.
- (2) All other laboratories will be surveyed on a monthly basis.
- (3) The iodination hood will be surveyed after each day of use.
- (4) Wipe tests will consist of rubbing a 1 inch dry filter disc over an area of approximately  $100\text{cm}^2$ . The wipes will be analysed by liquid scintillation counting. Results of the wipe tests will be recorded in disintegrations per minute per  $100\text{cm}^2$ . Any results greater than 100 dpm/ $100\text{cm}^2$  for I-125 and 200 dpm/ $100\text{cm}^2$  for all other licensed radioisotopes will be decontaminated and resurveyed.
- (5) Daily 'close-down' procedures will be established in all areas in which radioactive materials are stored or used. These procedures will ensure that:
  - (a) Radiation sources are properly labeled, stored, and secured.
  - (b) Survey meter measurements have established that radiation and contamination levels are within permissible limits and as low as reasonably achievable.
  - (c) Each laboratory is secured against unauthorized access.

#### F. Procurement and Monitoring of Radioactive Packages

- (1) The person ordering the radioactive material must forward a purchase order requisition to the Radiation Protection Officer for approval. The radioisotope and amount must appear on the requisition, not just the catalog number.
- (2) The Radiation Protection Officer will sign the requisition after verifying that the material to be ordered is covered by the NRC license and that possession limits for the laboratory are not exceeded.
- (3) Incoming shipments of radioactive material are delivered to the receiving room and then forwarded to the Radiation Protection Officer or his designate. The package will then be logged in and surveyed for radiation dose rates and external contamination.
- (4) Radioactive shipments will only be received during normal working hours. These are 8:00am to 5:00pm, no weekends.
- (5) Check in procedures will include radiation dose rate measurements at the surface of the package and at one meter. If dose rates are greater than 200 mr/hr at the surface or 10 mr/hr at one meter, the package will be isolated and the RSO contacted immediately. The outside surface of the package will be wipe tested to check for removable contamination.

## G. Procedures for Opening Radioactive Material Shipments

- (1) Packages of radioactive material are to be opened only in the designated radioisotope laboratory in the fume hood.
- (2) Wearing protective gloves, open the outer package. Remove the packing slip and inspect it to verify that the shipment is in agreement with what was ordered. If special instructions for opening the isotope container are enclosed, these instructions are to be followed.
- (3) Monitor the inner container with a GM survey instrument. Check the inner packing material for contamination.
- (4) Remove the inner container and place behind appropriate shielding.
- (5) Open the inner container. Monitor and inspect the primary container for leakage (i.e. loss of volume, discoloration of the absorbing material, etc.). Monitor the lead pig for any leakage from the primary container.
- (6) Notify the Radiation Protection Officer if:
  - (a) Contamination or leakage is detected.
  - (b) If readings in excess of expected values are obtained on the survey meter.
  - (c) There is a discrepancy between the material received and that ordered.

## H. Calibration of Radiation Survey Instruments

All radiation survey instruments will be calibrated by our consultants on a six month basis. If instruments are repaired, they will be recalibrated after such work is complete. The following are the procedures used by our consultants, Bolton & Galanek, Inc.:

Radiation survey instruments are calibrated as described in the application for NRC license # 20-13302-01. Calibrations are performed by either Murray M. Bolton or Mitchell S. Galanek. All instruments are checked with an electronic pulser to determine that the instrument is functioning properly. Geiger Mueller (GM) and ionization detectors are calibrated with an N.B.S. certified Radium standard. The source is 46.3 milligrams of  $^{226}\text{Ra}$  - N.B.S. No. 25729 - Test No. 1194552. The standard is certified by N.B.S. with an uncertainty value of less than 0.7 %. The source is raised and lowered via remote electrical controls. The instruments are calibrated at 2 points on each scale using a variable distance technique. The 2 points on each scale are separated by 35 to 50 % of full scale. The low energy gamma scintillation detector used for detection of  $^{125}\text{I}$  is calibrated with an N.B.S. traceable  $^{125}\text{I}$  standard (N.B.S. 4407L-D). The detector efficiency is determined at a fixed distance from the source. Also the detector efficiency for thyroid monitoring is determined with the probe in contact with a thyroid phantom loaded with the  $^{125}\text{I}$  standard.

A calibration record with applicable information is attached to each calibrated instrument.



## I. Radioactive Waste Disposal

- (1) All solids contaminated with radioactive material with a half life of less than 65 days will be put in the waste containers provided in each laboratory. A record of the isotope and amount being disposed will be maintained. When these containers are full, the waste will be transferred to 55 gallon drums and stored for decay. No liquids are to be put in the solid waste containers.
- (2) All other solids contaminated with radioactive material will be disposed of as low level radioactive waste through a licensed disposal company.
- (3) Liquid radioactive waste will be disposed of via the sanitary sewage system in accordance with 10 CFR 20.303 and the applicable concentrations in Appendix B Table II. Any liquids that cannot meet these requirements will be absorbed and disposed of as low level radioactive waste.
- (4) Whenever possible, radioactive material will be stored for radioactive decay and subsequent disposal as non-radioactive waste. All such material will be held for a minimum of 10 half lives and will be surveyed completely before disposal. Survey results must be background before any material is disposed of as normal trash.

## J. Radiation Emergencies

In the event of a major spill or accident involving radioactive material, the following procedures should be used:

- (1) The area is quarantined immediately.
- (2) If volatile material is involved, activate the hood if necessary and evacuate personnel from the immediate work area.
- (3) Survey persons involved in accident. If clothing is contaminated, remove and place in a plastic bag.
- (4) If skin is contaminated, begin decontamination procedures and continue until levels are as close to background as possible.
- (5) Decontaminate the work area. Continue with decontamination and resurvey procedures until removable contamination and dose rates are within permissible limits.
- (6) Notify the Radiation Protection Officer

Responsibility for any decontamination procedures rests with the Radiation Protection Officer and the laboratory supervisor. Under no circumstances are these procedures to be performed by members of the maintenance or housekeeping staff. The Radiation Protection Officer will perform a thorough survey of the affected areas to determine if additional action is necessary. The RPO will establish and maintain a log of radiation accident reports and corrective actions taken. Our consultants will be used as needed by the Radiation Protection Officer.

In the event that the accident occurs after hours or on a weekend, the following steps are to be taken:

- (1) Do not attempt to clean up the spill. Quarantine the area as much as possible.
- (2) Notify the Radiation Protection Officer or the Facility Supervisor for specific instructions as to the course of action to be followed.
- (3) Survey yourself for radioactive contamination. Begin decontamination procedures and await help from the RPO.

Responsibility for any decontamination procedures rests with the Radiation Protection Officer and the laboratory supervisor. Under no circumstances are these procedures to be performed by members of the maintenance or housekeeping staff. The Radiation Protection Officer will perform a thorough survey of the affected areas to determine if additional action is necessary. The RPO will establish and maintain a log of radiation accident reports and corrective actions taken. Our consultants will be used as needed by the Radiation Protection Officer.

#### K. General Laboratory Rules

- (1) Lab coats or other designated protective clothing must be worn at all times when working with radioactive materials.
- (2) Mouth pipetting of radioactive material is prohibited.
- (3) There will be no eating, drinking, smoking, storage of food, or application of cosmetics in areas where radioactive materials are stored or used.
- (4) Personnel will wear protective gloves when handling unsealed quantities of radioactive material. Gloves are to be removed and disposed of before leaving the work area.
- (5) Dosimeters as assigned by the Radiation Protection Officer must be worn when in the areas where radioactive materials are stored or used. In addition, personnel must submit bioassay samples or have thyroid burden measurements as requested by the Radiation Protection Officer.
- (6) After hour or weekend work must have the specific approval of the Radiation Protection Officer.
- (7) All equipment and instrumentation containing radioactive material must be properly labeled.
- (8) All radioactive materials not in use will be stored in a safe and approved manner.

(9) All areas where radioactive materials are stored or used must be properly posted.

(10) Work performed on an open bench must be done in a manner such that any spills are contained and spread of contamination is controlled.

(11) At the end of each work day, work areas must be thoroughly surveyed and cleaned if necessary.

(12) Any radiation survey instruments found to be defective or suspected to be malfunctioning will be brought to the attention of the Radiation Protection Officer immediately.

(13) All persons who work with radioactive materials will wash their hands after work is completed and will thoroughly survey their hands and clothing for contamination before leaving the laboratory.

(14) Specific rules for Phosphorus-32:

- (a) Persons handling millicurie quantities will use low density shielding (i.e. plexiglass) to minimize bremsstrahlung radiation production.
- (b) Wear safety glasses or similar protective devices when handling millicurie quantities of P-32
- (c) Thoroughly survey the work area after each use of P-32.
- (d) Perform a dry run prior to any new procedures to preclude unexpected complications.
- (e) Wear wrist or ring badge dosimeters when handling millicurie quantities.
- (f) Use the GM detector when surveying for P-32 contamination.

(15) Specific Rules for Iodine-125:

- (a) Persons performing iodinations with millicurie quantities of I-125 will use appropriate lead shielding and/or leaded acrylic shielding to minimize external exposures.
- (b) All iodinations will be performed in the charcoal filtered hood. Only protein bound I-125 will be removed from the hood.
- (c) Persons performing iodinations will have thyroid burden measurements made within 48 hours of working with the unsealed I-125.
- (d) Perform a dry run prior to any new procedures to preclude unexpected complications.
- (e) Wear wrist or ring badge dosimeters when handling millicurie quantities of I-125.
- (f) Use the NaI scintillation detector when monitoring for I-125 contamination.



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BETWEEN: William O. Miller, Chief  
License Fee Management Branch  
Office of Administration

John E. Glenn, Chief  
Nuclear Materials Section B  
Division of Engineering and  
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Organogenesis, Inc

Application Dated: 1/16/87

Control No.: 106705

License No.: New

2. FEE ATTACHED

Amount: \$ 700.00

Check No.: 1315

3. COMMENTS

Signed Brenda Platchek

Date 1/29/87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M \$ 700

2. Correct Fee Paid. Application may be processed for:

Amendment                     

Renewal                     

License   ✓  

Signed J. Kynleley

Date 2/5/87