



BioTechnica International, Inc.

85 Bolton St. Cambridge, Massachusetts 02140 (617) 864-0040

RECEIVED BY LFMB	
Date...	3/8/85
Leg...	March 7 <sup>th</sup>
By...	Brown
Orig. To...	
Action Compl...	3/11/85

Telex: 705219  
Cable: BIOTECH

February 26, 1985

U.S. Nuclear Regulatory Commission  
631 Park Avenue  
King of Prussia, Pennsylvania 19406

RE: Materials License #20-20506-01

Applicant...	6730
Check No...	6730
Amount/Fee Category...	\$120/3M
Type of Fee...	Amendment
Date Check Recd...	3/8/85
Received By...	Brown

Dear Sir or Madam:

I am writing to request an amendment to our materials license #20-20506-01, issued December 3, 1981. The enclosed materials (in duplicate) outline the changes which have been made to our physical facilities and to our radiation protection program, which were previously described in our original application dated August 26, 1981 (updated November 5, 1981) and our first amendment application dated July 20, 1983 (updated October 17, 1983). All other statements found in the above documents that are not referred to in this amendment application, are still in effect.

All items are discussed in accordance with the pertinent section of the original application. References to the original 1981 application and 1983 amendment have been made whenever possible.

Enclosed is a check for one hundred twenty dollars (\$120.00) to cover the current amendment fee. Please address all questions and comments regarding this request to me. Thank you for your time and consideration.

Sincerely,

*Karen A. April*

Karen A. April  
Deputy Director  
Laboratory Services

Enclosures

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20-20506-01 PDR

MAR 05 1985

Request for an Amendment to Materials License #20-20506-01

February 26, 1985

Section 3. Name and Title of Person to be Contacted Regarding  
This Application.

Karen A. April, Radiation Protection Officer

Telephone Number: 617-864-0040, x182

Section 6. Individual(s) Who Will Use or Directly Supervise  
the Use of Licensed Material.

Karen A. April....Radiation Protection Officer;

Deputy Director, Laboratory Services

David J. Glass....Director, Patents and Regulatory  
Affairs

Andrea Jeffrey....Director, Laboratory Services

Section 7. Radiation Protection Officer.

Karen A. April

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## Section 8. Licensed Material

Since the 1983 amendment, additions to the scientific staff have resulted in an increased demand for Phosphorus-32; this demand is sure to increase with the completion of Phase III.

Our current license authorizes BioTechnica to possess a maximum of "200 millicuries" of Phosphorus-32 at any one time. We wish to amend Section 8, line 3D to "500 millicuries" of this isotope, to ensure that our radioisotope needs are met while keeping within the limits of the license.

## Section 10. Radiation Detection Instruments

Approximately 8 GM survey meters will be purchased for use in Phase III. Five of these meters will be identical to the ones currently used in Phase I and II (Reference Section 10, line 1 of 1981 application). The type and model of both instruments are listed below. No additional detection instrumentation is planned for Phase III.

### GM Survey meter

Manufacturer: Mini Instruments, Ltd.

Model: #5-10EB

Radiation detected: beta / gamma

Sensitivity range: 2400 cpm

# available for Phase III: 5

### Alarm Rate Meter

Manufacturer: Ludlum Measurements, Inc.

Model: #177

Radiation detected: beta / gamma

Sensitivity range: 500,000 cpm

# available for Phase III: 3

A Beckman LS/1800 scintillation counter and a Beckman Gamma 5500 Radiation Counter are located in Phase II. These instruments will more than adequately accommodate the additional personnel located in Phase III as they are currently underutilized.

### Section 13. Description of Facilities

As noted in the 1981 application and 1983 amendment, Phases I and II of our laboratories are located on the first floor of the facility at 85 Bolton Street. Phase II construction ended early in 1984 and the labs were fully occupied by March, 1984. We wish to amend our license to include 1) another series of laboratories currently under construction on the second floor of our building, which will be occupied in July, 1985, and 2) a greenhouse facility located on the first floor level.

#### Phase III Laboratories.

The attached floor plan (P-III,A) details the location and layout of Phase III, which will occupy approximately 7000 square feet of floor space. Also located on the second floor are the administrative and management offices, employee lunchroom, library, and conference rooms. The black, dotted line indicates the division between Phase III and these areas. The structural wall separating Phase III from the employee lunchroom is solid up to the metal decking in the underside of the roof. Doors (highlighted in blue) have been installed to restrict access across this division. Absolutely no activities involving radioisotopes will be allowed in any of the non-laboratory areas.

The Radiation Protection and Laboratory Services office (highlighted in pink) is located at the far end of the second floor laboratories within easy access to all the laboratories and hot room.



Design and construction of the Phase III laboratories are identical to that used in Phase I and II (See Fig. P-III,B), and meet the same physical plant descriptions previously filed in 1981 and 1983, respectively. (Reference Section 13, pp. 1-2 of 1981 application; Section A, pp. 1-3 of 1983 amendment). One functional improvement has been the installation of epoxy resin bench tops in all the Phase III laboratories. This material is impervious to all acids, bases, and solvents. It does not crack when exposed to a varying degree of high temperatures.

The radioisotope room or "hot" lab is located at the far end of the main corridor, intentionally removed from heavy traffic areas (See Fig. P-III,A, highlighted in yellow). Figure P-III,C illustrates the design and safety features in this lab which are identical to that described for the Phase I and II hot labs (Reference Section 13, pp. 3-4 of 1981 application; Section A, pp. 3-4 of 1983 amendment). Bench tops are stainless steel with spill-containing lips. The sink is stainless steel with foot-operated faucets. The floor consists of a sealed, impermeant molded covering and the walls will be painted with impermeant paint. The safety hood in this room is a stainless steel topped, four-foot wide chemical fume hood with an individual charcoal filtered exhaust (identical to the safety hood in Phase II). Although Phosphorus-32 is the primary radioisotope to be used in this hot room, Sulfur-35,

Hydrogen-3, Carbon-14, and low levels of Iodine-125 may also be handled. All work with high levels of Iodine-125 will remain on the first floor in the Phase I hot room which is currently used for Iodine-125 work.

Access to Phase III from the first floor laboratories and the shipping/receiving area is provided by a stairway (See Fig. P-III,A highlighted in green). Safe transport of incoming shipments of radioisotopes will be insured by hand-carrying all items to their destination in Phase III.

#### Greenhouse Facility.

Completed in August 1984, the greenhouse at BioTechnica is located on the southern side of the building at 85 Bolton Street, occupying an area of 18x30 square feet (See Fig. P-II,A). It is composed of an internal aluminum frame and an outer skin of polycarbonate Exolite. Polycarbonate Exolite was chosen specifically for the following characteristics: 1) unbreakable and shatterproof, 2) the inert material is not attractive to rodents or insects.

The greenhouse sits on a 4 ft. high concrete slab. The floor is broom-swept concrete which slopes towards the floor drains.

Heating is provided by a thermostatically controlled gas heater. Air cooling is provided by an evaporative cooling system. This system is composed of a large pad from which cool

water is allowed to evaporate into the air, thus reducing the internal greenhouse temperature. Air ventilation is provided by finely screened vents along both walls and on the roof; the windows to these vents are controlled thermostatically by an automated system. Plumbing provides cold water to the greenhouse for watering, and hot and cold water to the potting room. 1500 foot-candles of light are provided by 12 high pressure sodium bulbs which are controlled by simple time clocks.

The benches in the greenhouse are composed of expanded metal mesh and are 3 ft. in width, 29 ft. in length, and 3 ft. in height.

The greenhouse structure is attached at its north end to the building, and is accessible through only two doorways. One leads to the potting room inside the building, the other leads to the Phase I and II laboratories. No doors can be opened to the outside from within the greenhouse.

A number of security measures have been implemented to protect the greenhouse from vandalism and unauthorized entry. A 15 ft. high, chain-link fence surrounds the greenhouse with 12 inches of barbed wire present on the top perimeter. An extensive alarm system has been installed, including motion detectors to prevent unauthorized entry to the greenhouse from any location. All entry/exit doors have been tied into the master security system which monitors the entire building.



#### Section 14. Waste Disposal

All radioactive compounds with half-lives of one-hundred (100) days or less are held for ten (10) half-lives for on-site decay and are non-detectable when surveyed with a portable GM survey meter before disposal. All other radioisotopes are handled as described in Section 13, pg. 5, part C of the 1981 application, and Section B, pg. 5, part 4 of the 1983 amendment.

The 1981 application designates Interex, Inc. of Natick, Massachusetts as our commercial waste disposal service. At this writing, no radioactive waste has ever been shipped from the BioTechnica facility. Since we have yet to do business with Interex and are unfamiliar with its policies, we wish to amend Section 14,a to read, "Interex, Inc., 3 Strathmore Road, Natick, MA 01760 OR any other licensed low-level disposal service".

Section 15. Radiation Protection Officer

We are amending Item #6, lines a,b,c, of the the 1983 amendent in order to reflect changes within the BioTechnica Radiation Safety Program. (Reference Section 15, 16, 17, of 1981 application; Section B, pp. 4-6 of 1983 amendment).

Continued growth at BioTechnica reflected a need for a full-time Safety Officer. Ms. Karen A. April was appointed to the position of Deputy Director of Laboratory Services in July, 1984 after working for one year as an Assistant Scientist in the BioTechnica laboratories. It is as Deputy Director that she has been named the Radiation Protection Officer, and therefore supervises the Radiation Protection Program and all use of radioisotopes at BioTechnica. In working closely with the Director of Laboratory Services, Ms. April maintains a high degree of visibility in her daily interaction with the scientific staff, the laboratories, shipping/receiving and stockroom activity. Since early September, 1984, Ms. April has been responsible for all day-to-day activities involved with Radiation Protection. A detailed list of these responsibilities is included as Appendix 1. A copy of her curriculum vitae is attached.

Dr. David J. Glass, who previously held the position of Radiation Protection Officer, from Summer 1981 to September 1984, has spent the last six months transferring his responsibilites in Radiation Protection to Ms. April.

Dr. Glass will continue to maintain a high degree of contact with Ms. April and the Radiation Protection Office, in an advisory and consultative role. It is in this capacity that he has been named as the "alternate" Radiation Protection Officer.

Ms. Andrea Jeffrey, the Director of Laboratory Services, is listed in item c as the second "alternate". Being ultimately responsible for all aspects of laboratory management at BioTechnica, Ms. Jeffrey is highly involved in building construction, laboratory design, and laboratory policy. As the direct supervisor for the Deputy Director, Ms. Jeffrey is active in many of the Radiation Safety issues confronting BioTechnica.

## List of Appendices

Appendix 1. "Duties of the Radiation Protection Officer"

Curriculum vitae for Karen A. April

Figure P-III,A. "Laboratory and Facilities: Phase III"

Figure P-III,B. "Standard Two-bay Laboratory: Phase III"

Figure P-III,C. "Radioisotope (Hot) Lab: Phase III"

Figure P-II,A. "Greenhouse facility: Location, Design,  
Proximity to Phase II"

## Appendix 1. Duties of the Radiation Protection Officer

All of the duties outlined in the original 1981 application (Sections 15, 16, 17) and in the 1983 amendment (Section B) remain the responsibility of the Radiation Protection Officer. A general outline of these duties has been compiled from the two previous applications and is included for the purpose of completeness.

### I. Radiation Safety

- a. conduct regular surveys of laboratory areas.
  - monthly wipe tests
  - laboratory spot checks.
- b. administer personnel monitoring program
  - film badges
  - bioassays when required
- c. conduct training sessions for all personnel (technical and non-technical)
  - instruct on how to use and dispose radioisotopes properly and safely.
- d. monitor all incoming shipments of radioactivity.
  - package inspections/wipe tests
- e. supervise and implement emergency procedures when necessary.
- f. responsible for all regulatory requirements for radiation use and safety; liaison with the Nuclear Regulatory Commission, etc.

### II. Radiation Materials Management

- a. responsible for supervising and maintaining records for the following items:
  - incoming shipments of radioisotopes/package surveys
  - inventory of radioisotopes on the premises
  - self-monitoring of employees
  - film badge exposure records/personnel files
  - purchasing of radioisotopes
  - radioactive waste storage and disposal procedures
  - calibration of monitoring instruments
  - employee training sessions
  - regularly scheduled housekeeping and maintenance of laboratories for high levels of radiation use.
  - air monitoring procedures



KAREN ANN APRIL

83 Lexington Street  
Belmont, MA 02178  
(617) 489-4913  
Born: August 30, 1959

Education: M.S. Plant Physiology, May, 1983. Rutgers University, New Brunswick, NJ. Investigation: "Biochemical Changes in mRNA Production and Protein Biosynthesis During Cyst Formation in Euglena gracilis."

B.A. Biology, May, 1981. Saint Anselm College, Manchester, NH.

Career History:

Deputy Director of Laboratory Services, July 1984 - present.

Biotechnica International, Inc., Cambridge, MA.  
A supervisory/management position which involves responsibility as the Safety Officer for all safety related programs and regulations, and assisting in the coordination of all laboratory operations and services.

- Radiation Protection;

Employee training seminars  
Radioactive waste disposal  
on-site storage  
disposal procedures and records  
NELRAD  
NRC regulations  
Liaison to NRC  
Personnel monitoring  
film badges  
air sampling  
employee health records  
Lab area monitoring  
Monitoring of incoming shipments  
Radioisotope inventory and  
purchasing records

Biosafety

Liaison to Cambridge Biohazards Committee  
BTI Biosafety Committee  
Employee training  
Maintain project registration files  
Autoclave testing

Occupational Safety  
Chairman, Occupational Safety Committee;

Hazardous Waste Management  
On-site storage and disposal procedures  
Employee Training

Other

Update and revision of BTI safety manuals  
Massachusetts Right to Know Law  
OSHA regulations and recordkeeping  
All permits or regulations pertaining to  
laboratory areas or laboratory functions.

Training Programs

Massachusetts Right-To-Know Law: Compliance and  
Management. Bewick Associates & Smaller  
Business Association of New England. July 26,  
1984.

Hazardous Waste Management. Applied  
Environmental Technologies Corporation.  
November 28, 1984.

Occupational & Environmental Radiation  
Protection. Harvard University School of  
Public Health. Scheduled to be taken, March  
25-29, 1985.

Laboratory Services responsibilities include:

Managing and supervising personnel in  
media preparation and glassware washing  
facility; training personnel in the use  
of all equipment. Assists in supervision  
and management of stockroom activities,  
shipping and receiving. Oversees upkeep  
and maintenance of research facilities;  
arranges for cleaning, repairs and  
servicing of all equipment as well as  
purchasing and stocking of all supplies.

Assistant Scientist, June 1983 - July 1984.

BioTechnica

International, Inc., Cambridge, MA. Performed a  
wide range of molecular genetics techniques  
such as gene cloning, restriction mapping,  
preparation of cosmid gene banks,  
pulse-labelling procedures, de-repression of  
nitrogen fixation genes.

The following radioisotopes were used at the levels indicated:

Sulfur-35 up to 10 millicuries

Carbon-14 up to 10 millicuries

Phosphorous-32 up to 5 millicuries

Graduate Assistant, 1981-83. Dept. of Biological Sciences, Rutgers University. Research experience included the following:

DNA, RNA isolation/purification; cell free protein translation; agarose gel electrophoresis, autoradiography, fluorography

Protein/enzyme extraction and purification; ion exchange chromatography; PAGE-SDS, urea, and gradient gel electrophoresis

Sterile technique; media preparation and growth maintenance for both plant and animal cell tissue culture.

Electron microscopy, including sample preparation up to final processing of prints. Operated Sorvall, LKB ultramicrotomes; Siemens Elmiskop 1A TEM.

Received training in the safe handling of radioactive materials, units of measurement of radioactivity, and the biological effects of radiation at Rutgers University, September 1981.

The following radioisotopes were used at the levels indicated:

Sulfur-35 up to 30 millicuries

Carbon-14 up to 10 millicuries

Phosphorous-32 up to 5 millicuries

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 1

1. APPLICATION ATTACHED

Applicant/Licensee: BioTechnica International, Inc.

Application Dated: 2/26/85

Control No.: 03494

License No.: 20-20506-01

2. FEE ATTACHED

Amount: \$ 120.00

Check No.: 6730

3. COMMENTS

Signed Brenda Platchek

Date 3/6/85

11/30/86  
3M  
B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M #120

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

Amendment ✓

Renewal \_\_\_\_\_

License \_\_\_\_\_

Signed Frances Brown

Date 3/8/85

by  
3/14/85

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BIOTECHNICA INTERNATIONAL, INC.

85 BOLTON STREET  
CAMBRIDGE, MA 02140

6730

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February 15, 19 85

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ORDER OF U. S. Nuclear Regulatory Commission

\$ 120.00

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THE FIRST NATIONAL BANK OF BOSTON

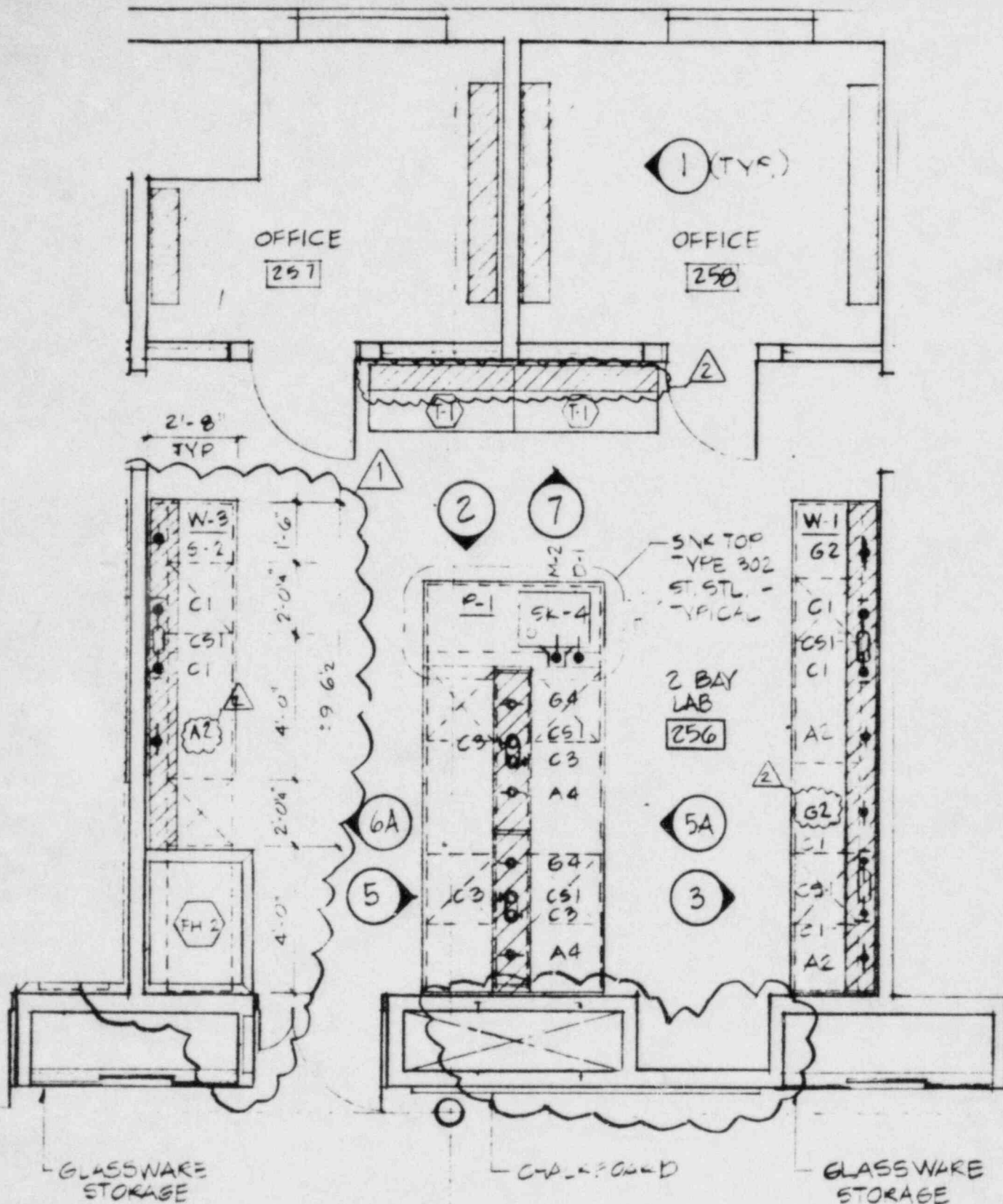
AUTHORIZED SIGNATURE

FOR

*Van- Hui Heng*

⑈006730⑈ ⑆011000390⑆ 540⑈25060⑈

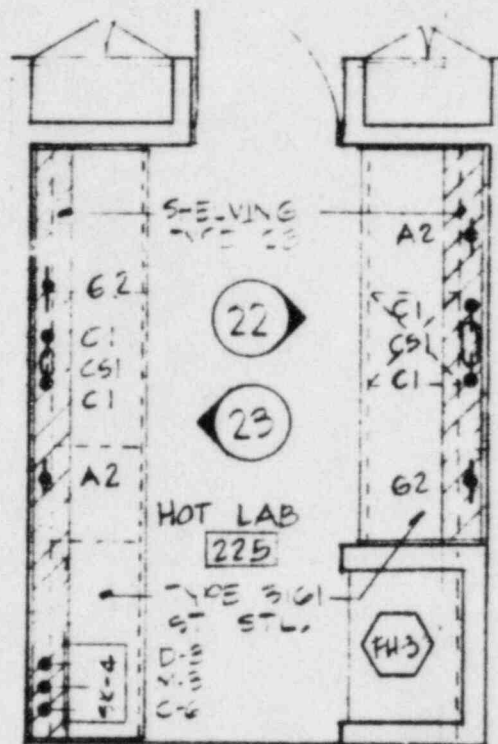




P-III, B. An enlargement of the architectural plan of a typical, Phase III laboratory.

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P-III,C. An enlargement of the architectural plan for the Phase III radioisotope laboratory.

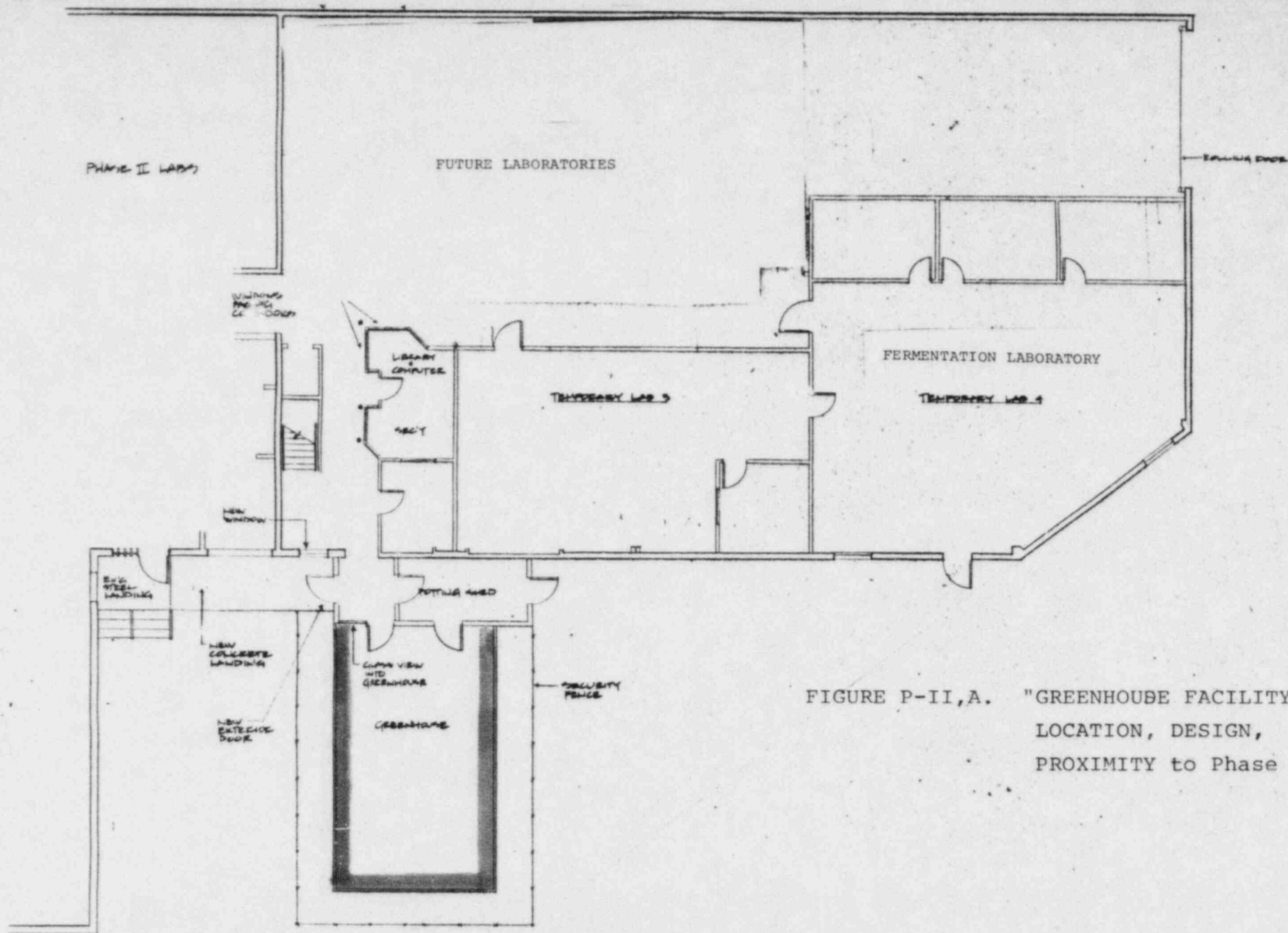


FIGURE P-II,A. "GREENHOUSE FACILITY:  
LOCATION, DESIGN,  
PROXIMITY to Phase II"

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