

UNITED STATES ATOMIC ENERGY COMMISSION  
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing, upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee is assessed. (See Note in Instruction Sheet)

1. (a) NAME AND STREET ADDRESS OF APPLICANT. (Institution, firm, hospital person, etc. Include ZIP Code and telephone number.)  Mallinckrodt, Inc. Mallinckrodt/Nuclear 675 Brown Road Hazelwood, Missouri 63042	(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. (If different from 1(a), include ZIP Code.)  2703 Wagner Place Maryland Heights, Mo. 63043
2. DEPARTMENT TO USE BYPRODUCT MATERIAL  Mallinckrodt/Nuclear Maryland Heights Facility	3. PREVIOUS LICENSE NUMBER(S). (If this is an application for renewal of a license, please indicate and give number.)  U.S. NRC License No. 24-04206-01 (Renewal)
4. INDIVIDUAL USER(S). (Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)  Radiation Safety Committee D. W. Soldan, Chairman See attached Items 8 and 9	5. RADIATION PROTECTION OFFICER. (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)  D. W. Soldan, Chief Radiological Safety Officer See attached Items 8 and 9

6. (a) BYPRODUCT MATERIAL. (Elements and mass number of each.)  A. Any byproduct material with Atomic Numbers 1 through 83 inclusive B. Molybdenum C. Technetium-99m D. Iodine-131 E. Selenium-75	(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. (If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.) <table border="0"><tr><td>A. Any chemical or physical form</td><td>A. Not to exceed 100 curies of each radionuclide except as follows:</td></tr><tr><td>B. Any chemical or physical form</td><td>B. 10000 curies</td></tr><tr><td>C. Any chemical or physical form</td><td>C. 10000 curies</td></tr><tr><td>D. Any chemical or physical form</td><td>D. 250 curies</td></tr><tr><td>E. Any chemical or physical form</td><td>E. 200 curies</td></tr></table>	A. Any chemical or physical form	A. Not to exceed 100 curies of each radionuclide except as follows:	B. Any chemical or physical form	B. 10000 curies	C. Any chemical or physical form	C. 10000 curies	D. Any chemical or physical form	D. 250 curies	E. Any chemical or physical form	E. 200 curies
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B. Any chemical or physical form	B. 10000 curies										
C. Any chemical or physical form	C. 10000 curies										
D. Any chemical or physical form	D. 250 curies										
E. Any chemical or physical form	E. 200 curies										

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for "fusion use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)

The radionuclides will be used in the production and testing of products marketed by Mallinckrodt, Inc. (in accordance with the provisions of 10 CFR 30.2) and the transport of licensed material, or delivery of licensed material to a carrier for transport (in accordance with the provisions of 10 CFR 71.5) and for distribution to authorized recipients.

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**TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4** (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	See Attached Items 8 and 9		Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments	See Attached Items 8 and 9		Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity	See Attached Items 8 and 9		Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

**9. EXPERIENCE WITH RADIATION.** (Actual use of radioisotopes or equivalent experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See Attached Items 8 and 9		

**10. RADIATION DETECTION INSTRUMENTS.** (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm <sup>2</sup> )	USE (Monitoring, surveying, measuring)
See Attached Item 10					

**11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.**

See Attached Item 14 RADIATION PROTECTION PROGRAM

**12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED.** (For film badges, specify method of calibrating and processing, or name of supplier)

See Attached Item 14 RADIATION PROTECTION PROGRAM  
Current Supplier - Radiation Detection Company

**INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE**

13. **FACILITIES AND EQUIPMENT.** Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) ☒ Yes ☐ No See attached Item 13, **FACILITIES AND EQUIPMENT**
14. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source. See attached Item 14, **RADIATION PROTECTION PROGRAM**
15. **WASTE DISPOSAL.** If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. Nuclear Engineering Co., Inc.

**CERTIFICATE (This item must be completed by applicant)**

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Licenses Fee Category \$ \_\_\_\_\_

Fee Enclosed \$ \_\_\_\_\_

Date September 29, 1977

Mallinckrodt, Inc.  
Applicant named in Item 1  
By: John J. Toomey  
Director of Operations  
Title of certifying official

Items 8 and 9

The membership of the Radiation Safety Committee is:

- A. Soldan, Donald W., Chairman  
Supervisor, Health/Physics  
The Corporate Radiation Safety Officer for Mallinckrodt for a period of 12 years has a total of 21 years experience in the field of radiation safety. He has had experience in the handling or control of megacuries of radioactive materials under Type A specific licenses of broad scope. He is also Chairman of the Radiation Safety Committee for Mallinckrodt, Inc. under the NRC license number 24-17450-01. Mr. Soldan is a member of the American National Standards Institute Committee N14.7 on the packaging of radioactive materials.
- B. Adams, John R., Vice Chairman  
Supervisor, Safety and Maintenance  
Mr. Adams has been a Mallinckrodt/Nuclear Health/Safety Supervisor for a period of nine years. He has approximately 21 years experience in the field of occupational safety, industrial hygiene and health radiation physics. He has approximately 15 years radiation safety supervisory experience while working in the Uranium Division, an AEC contract operation conducted by Mallinckrodt, and Mallinckrodt/Nuclear. Mr. Adams is a member of the American Society of Safety Engineers and a certified safety professional. He is a graduate of the University of Missouri and Iowa State University with an associate degree and a B.S. degree in Science.
- C. Nuelle, Ralph, Secretary  
Physicist  
Mr. Nuelle has a B.S. in E.E. from the University of Missouri School of Mines and Metallurgy. During World War II, Mr. Nuelle was Product Engineer on the Navy's proximity fuse project. Following the war, he had five years experience as a Cyclotron Engineer for the Department of Physics at Washington University, St. Louis, Missouri. Mr. Nuelle has been employed at Mallinckrodt for 26 years and has conducted considerable research and study on radiation damage and effects. At the present time he is a member of our Quality Control Assay Department in conjunction with NBS traceable sources and equipment calibration program.
- D. Becker, Victor J.  
Production Manager, In Vivo Radioactive Pharmaceuticals  
Mr. Becker obtained B.S. and M.S. degrees from the University of Missouri-Rolla in 1969 and 1971, with a major in nuclear chemistry. His graduate studies included trace element analysis via neutron activation analysis. He was in

charge of a radiation laboratory at the University of Missouri-Rolla from 1970 to 1973. He accepted a position with Mallinckrodt, Inc. in 1973 in the R&D Section, concerned with In Vivo radioactive pharmaceuticals. His experience has included handling over a dozen isotopes ranging from microcurie to kilocurie levels of activity.

E. Green, Kenneth J.

Manager, Radiopharmaceutical Distribution

Mr. Green has been employed in the transportation of radioactive materials for 15 years. He is knowledgeable in the packing, transportation and radiation safety regulations codified in Titles 10 and 49 of the Federal Register. Mr. Green has been a member of the Atomic Industrial Forum Committee on Radioisotopes Production and Distribution and the American National Standards Institute Committee N 14.7 on the packaging of radioactive materials.

F. Hatakeyama, James S.

Manager, Process Technology and Health Physics

Mr. Hatakeyama received a B.S. degree in Pharmacy from the University of Colorado. He had four years experience at the University of Chicago Clinics, Argonne Cancer Research Hospital as an Isotope Pharmacist engaged in preparation, assay and testing of dosage forms of radioisotopes for use in patients and animals. He spent six years as Manager of Production of Radiopharmaceutical Products and was also involved in quality control and developmental work at Volk Radiochemical Company. Mr. Hatakeyama has been with Mallinckrodt for a total of 12 years in various managerial positions in Radiopharmaceutical manufacturing.

G. Robb, William P.

Manager, Quality Control

Mr. Robb received a B.S. degree in Pharmacy from the St. Louis College of Pharmacy. Mr. Robb's industrial experience in the field of Radiopharmaceuticals extends over a period of 11 years and he is familiar with the Title 10 of the Code of Federal Regulations as applied to a "Type A" specific license of broad scope.

H. Toomey, John

Director of Operations

Mr. Toomey received his B.S. and M.S. degrees in Pharmacy from Philadelphia College of Pharmacy & Science. He has 16 years experience in the pharmaceutical industry, with responsibilities in manufacturing, quality control, distribution and plant management.

## Item 10

Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Picker Nuclear Spectro- scaler III A Model #628433	7	NA	NA	NA	Activity measure- ment, Quality Assurance and Environmental sampling
Harshaw Integral Line NaI Scintillation Detectors - 2" Well Type #6SFS	12	Gamma	NA	NA	Activity measure- ments, Quality Assurance and Environmental sampling - Used with Picker Spectro- scalers III and IV
Harshaw Integral Line Plastic Scintillation Detector - Through Hole Special	1	Gamma	NA	NA	Used with Picker Spectroscaler for capsule activity Quality Control
Harshaw Integral Line NaI Detector 2" x 2"	1	Gamma	NA	NA	Used with Spectro- scaler for activ y analysis
Picker Nuclear Spectro- scalers IV and IV R	5	Gamma	NA	NA	Activity analysis Quality Assurance Environmental sampling
General Radiological "Physics Range" D.C. amplifier (Electrometer) Model 34-503	1	NA	10 <sup>-13</sup> Amps	NA	Used with ioniza- tion chambers - Activity measurement



Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Eberline Instruments "Mini Scalers" Model MS-2	2	Alpha Beta Gamma	NA	NA	Used with Harshaw GSF5 Scintillation Detector and Eberline Gas Flow proportional chamber activity measurement Quality Control
Picker Nuclear "Omniprobe" Thyroid Uptake Systems	2	Gamma	NA	NA	Critical human organ burden measurements
Picker Nuclear Log/Linear Ratemeter #600047	1	NA	0 <sup>-</sup> to 10 <sup>6</sup> c/m	NA	Analog display/alarm for uptake system
Picker Nuclear Labmeter I	1	Beta Gamma	0 to 10 <sup>6</sup> c/m	3.5	Personnel monitoring
Picker Nuclear "Cliniscaler"	2	Beta Gamma	NA	3.5	Contamination wide tests
Nuclear Chicago-Searle Unilux II Liquid Scintillation Counter	1	Beta Gamma	NA	NA	Liquid activity - analysis Environmental
Ludlum Measurements, Incorporated Thn.Wind. Survey Meters, Model 3	8	Beta Gamma	0-200 mr/hr	3.5	Personnel and area radiation monitoring Thin window end - window det.
Ludlum Measurements, Incorporated Survey Meters, Model 3 Metal Det.	10	Beta Gamma	0-200 mr/hr	30	Personnel and area radiation monitoring side window metal det.
Ludlum Measurements, Incorporated - Survey Meters Model 14A with thin end window det.	5	Beta Gamma	0-200	3.5	Personnel and area radiation monitoring

Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Ludlum Measurements Survey Meter - Model 12 with 1 x 1 NaI Detectors	1	Beta Gamma Alpha	0-500,000 Counts/Min.	NA	Area and Personnel Monitoring
Ludlum Measurements, Inc. Survey Meters, Model 14A with Metal GM Detectors Side Type	6	Beta Gamma	0-200 mr/hr	30	Area and Personnel Monitoring
Picker Nuclear Lab Monitors Model 642081 with thin end window detectors	11	Beta Gamma	0-30,000 Counts/Min.	3.5	Area and Personnel Monitoring
Victoreen "Cutie Pie" Model 740D Ionization Chamber Survey Meter	2	Beta Gamma	0-25,000 mr/hr.	2.5	Area and Personnel Monitoring
Eberline Instruments, Inc. Geiger Counter Model PRM-6	1	Beta Gamma	0-200 mr/hr.	3.5	Personnel and Area Radiation Monitoring
Eberline Instruments, Inc. Geiger Counter Model E-510	2	Beta Gamma	0-200 mr/hr.	3.5	Personnel and Ar... Radiation Monitoring
Tracerlab, Inc. Source Calibrator Model 60-56A (Electrometers)	3	Beta Gamma	0-5 mCi	NA	Source Activity Measurement and Quality Assurance
Scherrer Source Calibrator Electrometers	10	Beta Gamma	0-5000 mCi	NA	Source Activity Measurement and Quality Assurance

Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Tracerlab Low Range Ionization Chambers Series 60-65A	12	Gamma	0-5000 mCi	NA	Source Activity Measurement and Quality Assurance
General Radiological Radioisotope Calibration Chambers Model 1383A (Nuclear Associates Model 34-014)	3	Beta Gamma	0-5000 mCi	NA	Source Activity Measurements and Quality Assurance
Packard Instruments Autogamma Spectrometer Automatic 600 Sample Spectrum Analyzer	1	Beta Gamma	NA	NA	Health Physics Environmental Analyses (Air - Water - Loose contamination) Urinalysis
Bendix Dosimeter Charger-Readers	6	NA	Depends on Dosimeters	NA	Personnel monitoring
Victoreen "Vamp" Area Monitors	5	Gamma	0-100 mr/hr	NA	Area Monitoring
Picker Nuclear Magnascaler	1	Gamma	NA	NA	Wipe Tests
Eberline Instruments Hand and Foot Monitor Model HFM2	1	Gamma		0-30	Personnel Monitoring Thin window probe (0-3.5 mg/cm <sup>2</sup> ) on Frisker
Ludlum Measurements Model 25 Scaler Ratemeter	2	Gamma	0-10 c/m	NA	Activity Measurement



Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Nuclear-Chicago Searle - Actigraph III Chromatographic Scanners	2	Beta Gamma	0-10 <sup>6</sup> c/m	1.0 mg/cm <sup>2</sup>	Quality Assurance
Vanguard Inst. Model 930 Auto Scanner (chromatographic) with TLC capability	1	Beta Gamma	0-10 <sup>6</sup> c/m	Windowless	Quality Assurance
Packard Inst. Chromatographic Scanner Model 7200	1	Beta Gamma	0-10 <sup>6</sup> c/m	Windowless	Quality Assurance
Canberra Multichannel Analyzer Model 8100 MCA 4096 Channels - Computer based with Solid State Detector	1	Gamma	NA	NA	Quality Assurance Contamination Analysis
Tracor-Northern Multichannel Analyzer Model TN 1705 2048 Channels with 3 x 3 Harshaw NaI Detector	1	Gamma			Quality Assurance
Packard Instruments Auto-Gamma Scintillation Spectrometer Model 5265 Computer based TTY Readout 600 Sample	1	Gamma	-	-	Quality Assurance
Packard Instruments Autogamma Scintillation Spectrometers - Model 5265 <u>Not</u> computer based - TTY Readout 600 sample	2	Gamma			Quality Assurance

Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Ludlum Measurements Model 40 Hand and Foot Monitors - 6 Channels	2	Beta Gamma		30 mg/cm <sup>2</sup>	Personnel monitoring Note - Frisker 3.5 mg/cm <sup>2</sup> window thickness
Ludlum Measurements Model 177 Area Monitors	10	Beta Gamma	0-5000 c/m	3.5 mg/cm <sup>2</sup>	Area and Personnel Monitoring
Nuclear Chicago Model 2588 Survey Meter Ionization Chamber Type	1	Beta Gamma	0-25R	2 mg/cm <sup>2</sup>	Area Monitoring
Ludlum Measurements, Inc. Model 2200 Scaler Ratemeter	1	Beta Gamma		NA	Activity Measure- ments - Emergency Standby Scaler (Portable - Battery operated)
Pocket Chambers	200	Gamma	0-200 mr	NA	Personnel monitoring
Reactor Experiments, Inc. Digi/Micro Dose	1	Beta Gamma	0-100 mr	-	Area and Personn Monitoring
Reactor Experiments, Inc. Auto Digimaster Exposure Ratemeter	1	Beta Gamma	0-100R/hr	-	Area Monitoring
Reactor Experiments Digimasters Exposure Ratemeters	2	Beta Gamma	0-100R/hr	-	Area Monitoring
Reactor Experiments Digidose exposure	4	Beta Gamma	0-100 mr	-	Area Monitoring

Instrument(s)	Quantity	Radiation Detected	Sensitivity Range (mr/hr)	Window Thickness (mg/cm <sup>2</sup> )	Use
Keithley Instruments Model 35020 Digital Dosimeter with air equivalent ionization chambers	1	Beta Gamma	Rate 0-10R/min.  Dose 0-1R	-	Precision measure- ments - Secondary calibration reference
Victoreen Model 444 Air Ionization Survey Meter	1	Beta Gamma	0-300 R/Hr.	NA	Secondary Reference Inst.
Victoreen Model 555 Radacon Air Ionization Inst.	1	Beta Gamma	Rate 0-10R/M  Dose 100R	-	Secondary Reference Inst.

FACILITIES AND EQUIPMENT

The Mallinckrodt, Inc., Mallinckrodt/Nuclear Maryland Heights Radiopharmaceutical Plant consists of 6 structures designated as Buildings 100 through 600.

Building 500 described in our letter dated March 16, 1976, has been operational since June of 1976.

Building 600 described in our letter dated March 29, 1976, with additional information provided in our letter dated October 18, 1976, is not currently fully operational in that some of the processing of in vivo products is still being performed in Building 100. We anticipate that all in vivo product processing, dispensing and packaging operations will be transferred to Building 600 during the fourth quarter of 1977.

The initial renovation of Building 400 has been completed and is operational for shipping of our products.

Drawings for renovation of our Dispensing Department in Building 300 have been completed. This renovation should begin in late 1977.

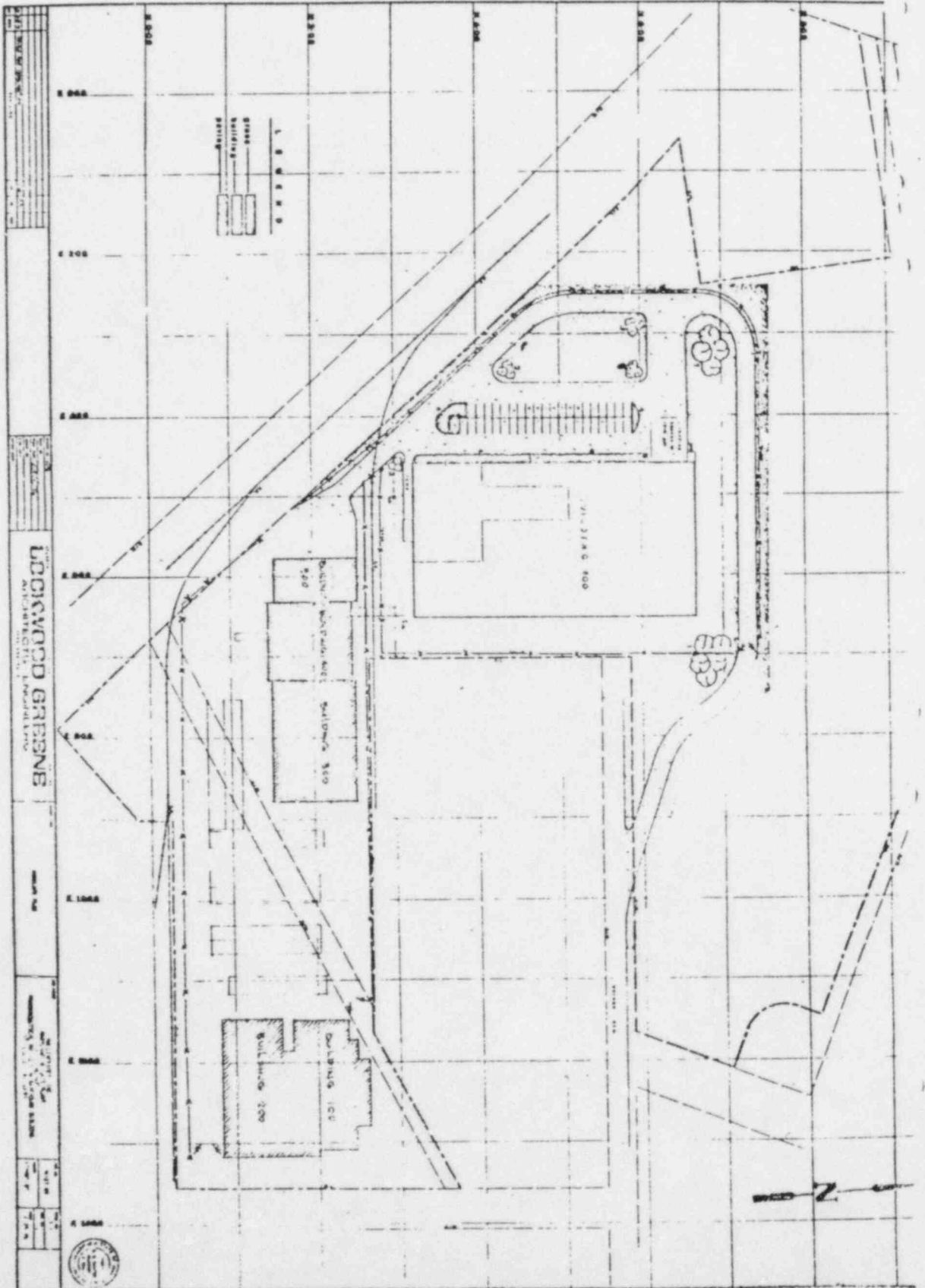
The Research and Development operations previously performed in Building 200 have been transferred to our new Research and Development laboratories in Hazelwood, Mo. under U.S. NRC License No. 24-17450-01 effective March 22, 1977. This transfer of operations has permitted partial expansion of our Quality Control Department to some areas previously occupied by R & D. The East end of Building 200 on the upper level is under final stages of renovation as office areas.

Final plans for renovation and expansion of the Health Physics Department on the East end of the lower level of Building 100 have been completed. This renovation should begin late in 1977.

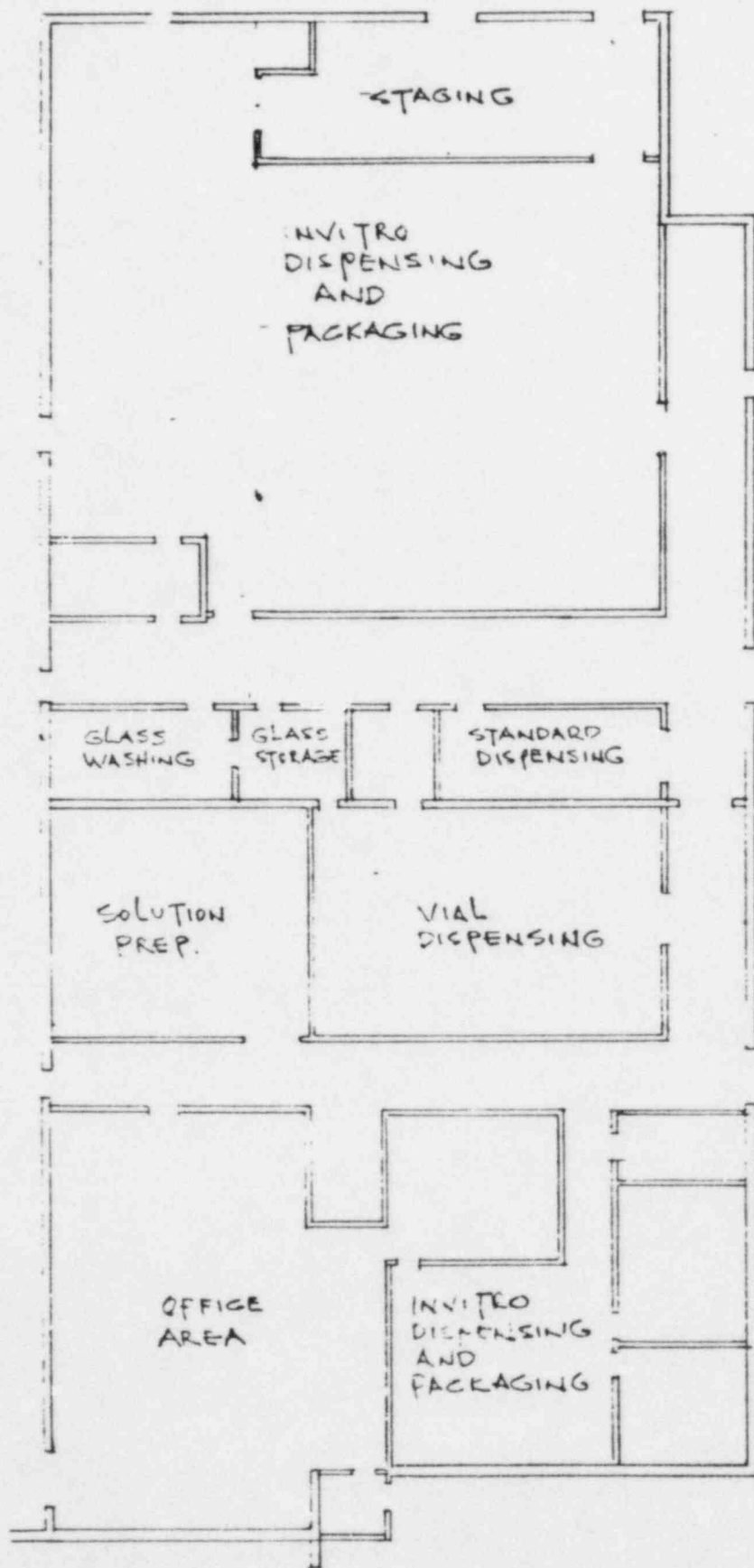
Drawings for renovation of the West end of the upper level of Building 100 have been partially completed. This area was previously used for in vivo product production and will be converted for dispensing and packaging of in vitro products. Construction should also begin late in 1977.

A plot plan showing the location of these buildings and the renovations in Buildings 100, 200, 300 and 400 are attached for your information and review.

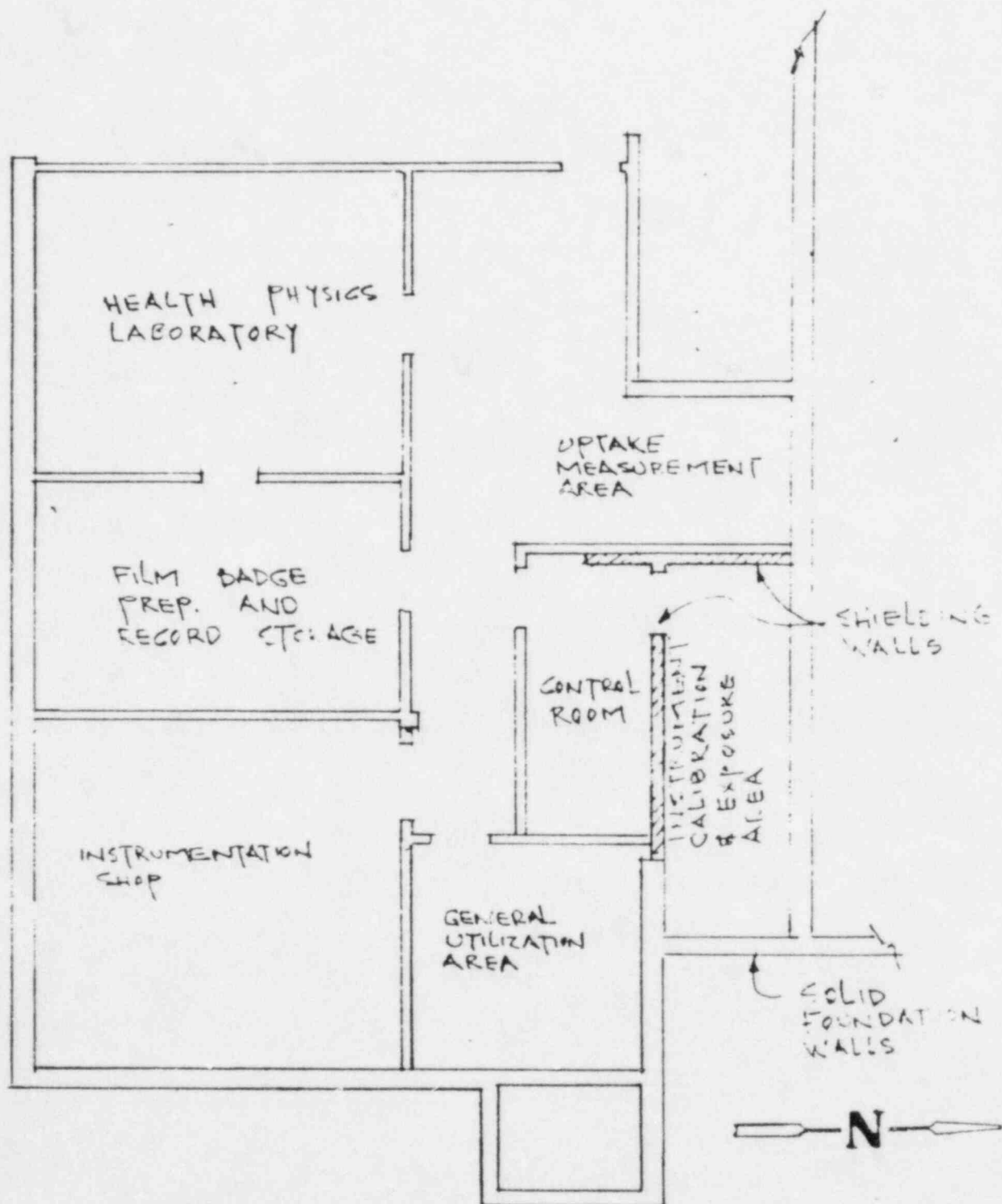
PLOT PLAN - FIGURE 1



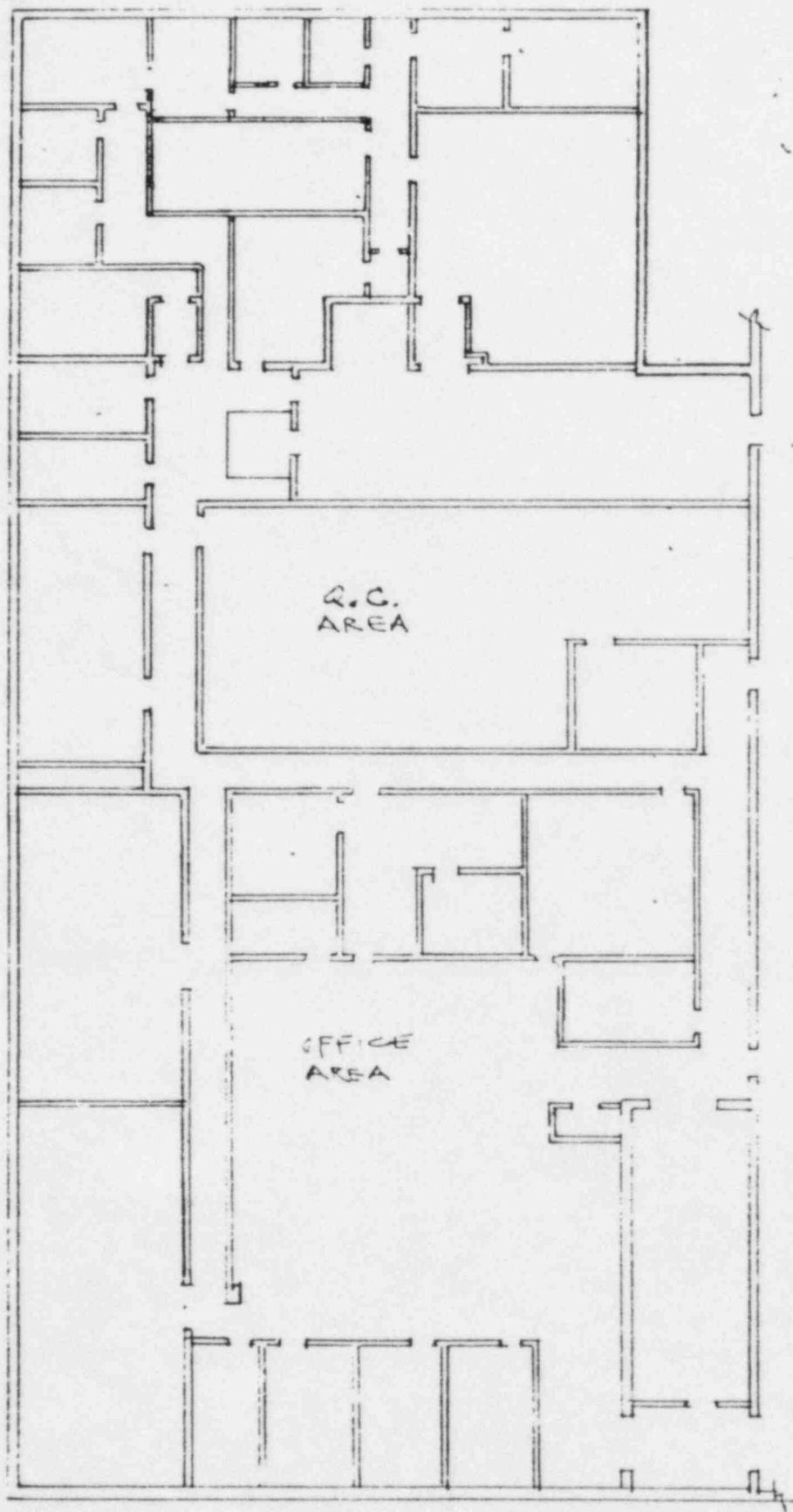




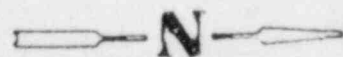
BLDG. 100  
FIRST FLOOR PLAN  
1" = 20'

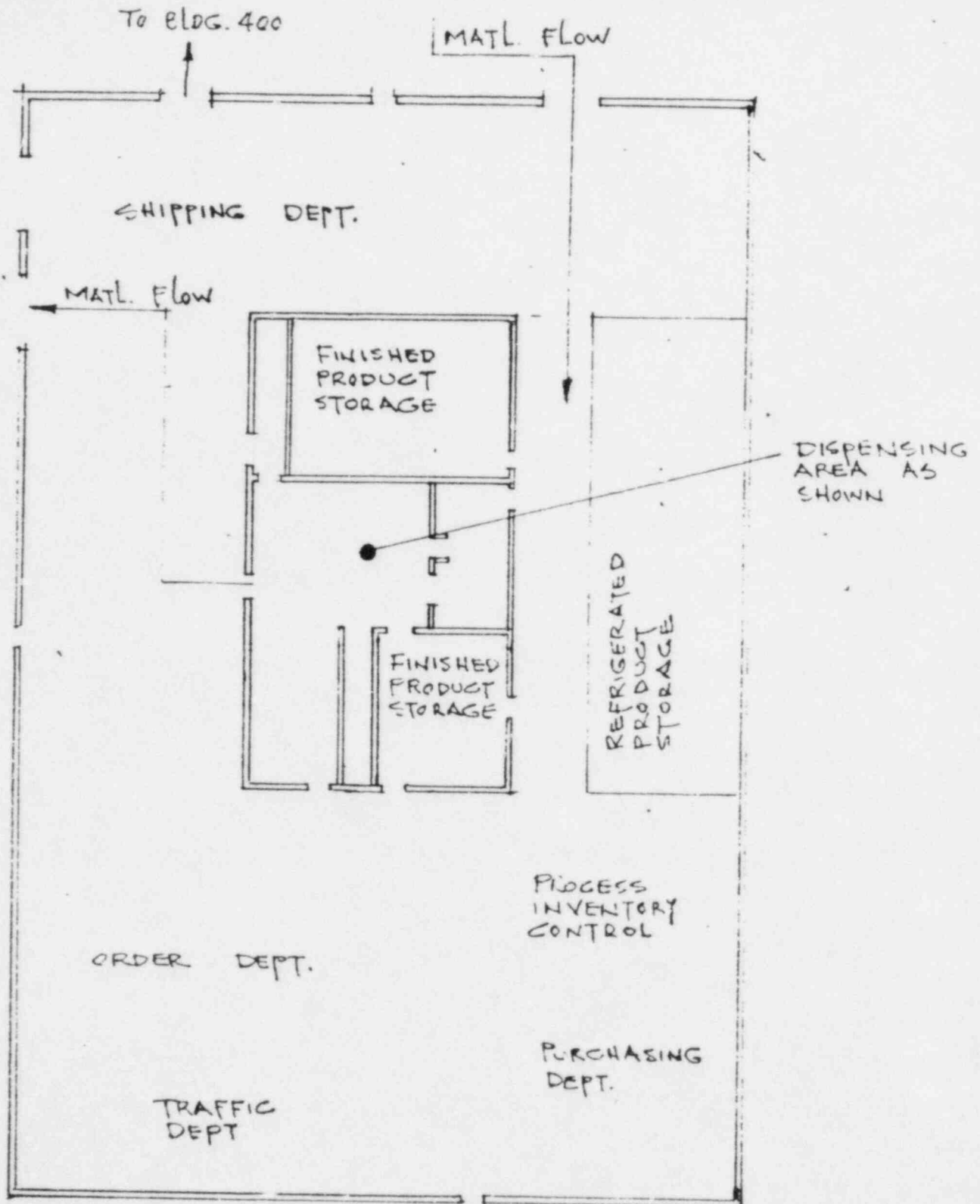


BLDG. 100  
GROUND FLOOR PLAN  
HEALTH PHYSICS AREA  
 SCALE:  $\frac{1}{8}" = 1'-0"$

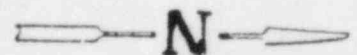


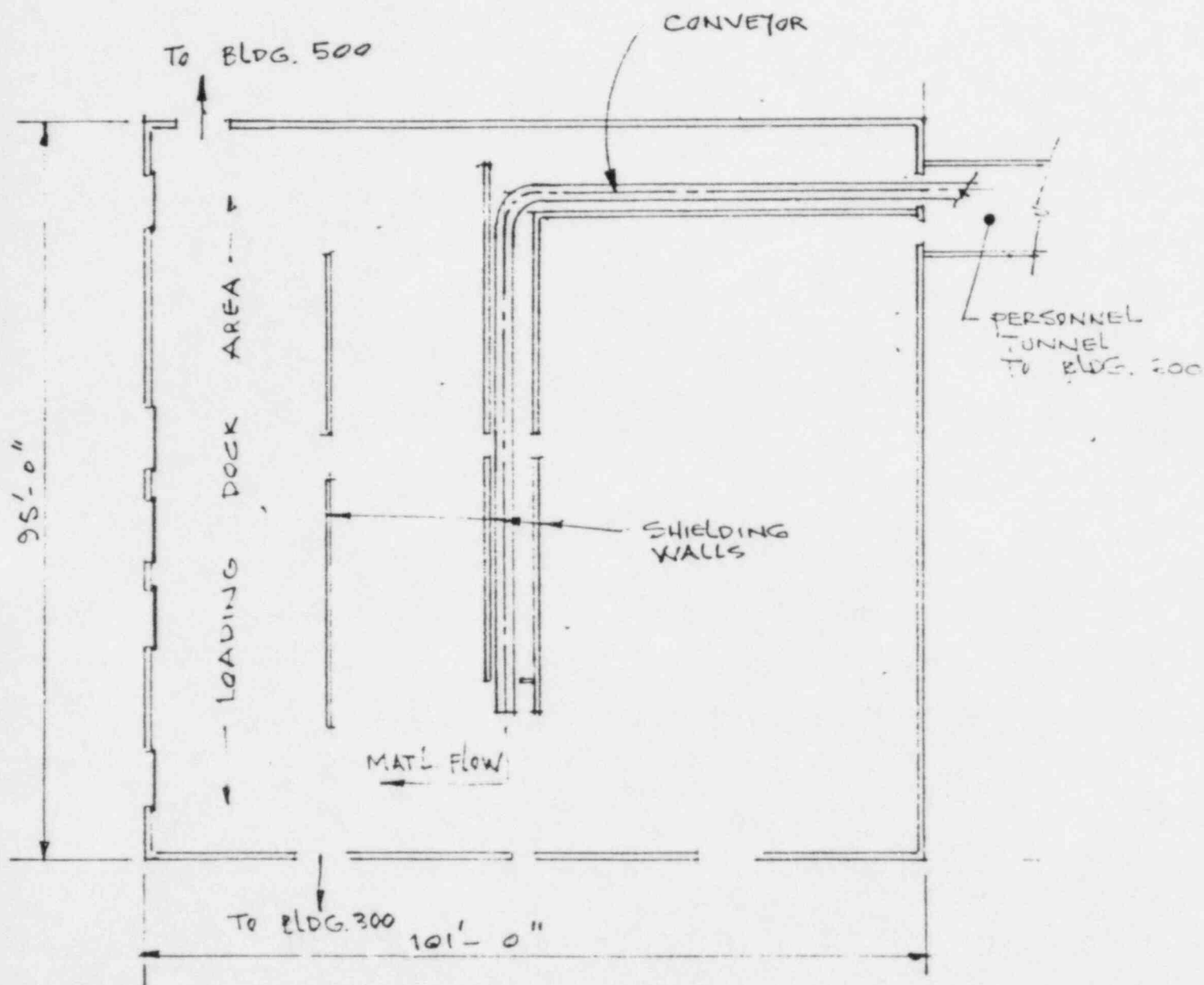
BLDG. 200  
FIRST FLOOR PLAN  
1" = 20'





BLDG. 300  
1" = 20'





BLDG. 400

1" = 20'



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