May 5, 1987

United States Nuclear Regulatory
Commission, Region III
799 Roosevelt Road
Glen Ellen, IL 60137

RE: Control Number 78802

ATTN: John R. Medera
Material Licensing Section

Dear Sirs:

1. Item 7.1 of our application states that the Radiological Control Officer, or his designee, is authorized to act for the Radiological Control Committee between meetings. The authority of the Radiological Control Office to act for the Committee is, however, very limited in the granting of temporary authorizations. He is allowed to give temporary authorizations only when the procedures to be used are procedures which have been previously authorized by the Radiological Control Committee, the quantities of radioactive materials are no greater than quantities previously approved by the Committee for such procedures and when the laboratory facility for the project when evaluated for safety for the proposed use of byproduct material are adequate and meet pre-established criteria (see question 7). Also, the user of the byproduct material must have met pre-established training and experience requirements. If all of these considerations are met, then temporary authorization is granted by the Radiological Control Officer for the Radiological Control Committee. If they are not met, then the project must go through the Radiological Control Committee and temporary approval is not granted. All projects go to the Radiological Control Committee for review and must be approved by the Radiological Control Committee for continuing approval. A step by step narrative of the temporary approval procedure follows:

<u>Procedures Used for Temporary Approval of Project Applications and amendments</u>

1) Appropriate forms are submitted by the project director (A-1, A1s, etc.)

2) Applications are reviewed by the Radiological Control Officer and/or a member of his staff.

(A) Procedure Review

(i) If the procedures to be used are: procedures previously authorized by the Radiological Control Committee (i.e. nick translation or Maxim and Gilbert for P32), similar to previously authorized procedures (i.e. cell culture with centrifuge separation and counting of phases), or employ the use of a RIA kit, the authorization proceeds to quantity review.

(ii) If the procedures are unusual, the project director is contacted and the project application is sent to the committee for review.

(B) Quantity Review

(i) If requested quantities are less than or the same as quantities previously approved by the Committee, the application precedes to laboratory review.

(ii) If requested quantities are larger than approved previously by the Committee, the project director is contacted.

a) New limits are established which are the same or lower than limits previously approved by the Committee. The application precedes to laboratory review.

b) If the project director feels the higher limits are necessary, the reasons are recorded and the project application goes to the Committee for review.

(C) Laboratory Review

(i) Laboratory applications are reviewed and classification established based upon radionuclides, use and quantity (procedures for classification of laboratories are listed in response to question 7).

(ii) The laboratory facility is evaluated to insure that it meets the criteria established for that laboratory classification.

a) If a laboratory meets the criteria established by the RCC application precedes to step iii.

b) If a laboratory does not meet the established criteria the project director is contacted and changes to the laboratory are made so it meets the criteria or a new laboratory is designated.

(iii) Restrictions are added to projects based on previous committee action (i.e. survey meter required for all radionuclides except H-3 and sealed sources, film badge and ring required for use with P32).

(iv) The project is typed up and temporary authorization granted until committee approval is obtained.

(v) The application is reviewed by the committee.

(vi) Committee approves project.

2a. The Radiological Control Committee uses the following Procedures for Approving Personnel Applications. The procedures are as follows:

1) The application is reviewed by the Radiological Control Officer or a member of his staff to assure that the following requirements are met.

A) attendance of safety training
B) submission of CBC blood test results
C) submission of completed form A-4.

2) The following experience and training criteria serves as general guidelines for the Radiological Control Committee.

The Radiological Control Committee considers a "worker" to be anyone who works with radioactive material and may include dishwashers, student employees, and laboratory technicians. Not all of these persons have a B.S. degree or 40 hours of formal radiation safety training. Purdue considers a "user" to be the project director and as such would normally have a BS Degree or 40 hours of training.

1) Regular (non-restricted) authorization is granted to an applicant if:

a) the applicant has had sufficient training and/or experience with radioisotopes so as to carry out the proposed work in a safe manner (project directors or major investigators will generally be required to meet a minimum of the following re-

quirements: A college degree at the bachelor level in the physical or biological sciences or engineering, and at least 40 hours of training and/or experience in the safe handling of radioactive materials, the characteristics of ionizing radiation, quantities, and units of radiation dose, and biological hazards of radiation exposure), and

b) the work to be performed as set forth in the project summary is commensurate with the applicant's knowledge and ability relative to the hazards involved, and

c) the applicant agrees in writing to follow all University, State, and Federal regulations governing the use of radioactive materials and agrees to assume all responsibility for personal injury resulting from the failure to comply with such regulations, and

d) the applicant submits a record of a recent complete blood count, a history of past occupational exposures, and meets any other special medical requirements that the Radiological Control Committee may stipulate from time to time.

2) Temporary restricted authorization is granted to an applicant if in the opinion of the Committee, the applicant has not had adequate training or experience. Restricted authorization is granted provided:

a) Supervised on-the-job training is available such that the individual works under the direct personal supervision of an individual who has received regular authorization; and

b) The work involves low levels of activity as specified by the Radiological Control Committee.

c) After six months of supervised on-the-job training, the applicant will normally be considered qualified for regular authorization provided the requirements of paragraphs 1 (c) and (d) above are met.

3) General Authorization for Use of Sealed Sources

Individuals requesting authorization to use sealed sources in gauging devices (such as moisture or density gauges) or other devices, may be authorized to use such devices, without prior special training or experience with radioactive materials provided:

a) The applicant demonstrates that he is competent in the use of the device, and

b) The applicant meets the requirements of paragraph 1 (c) and (d), and

c) The applicant meets any special operating conditions (such as working under qualified supervision) that may be imposed by the Radiological Control Committee.

4) General Authorization for Certain Kits or Devices

A general authorization is issued to laboratory personnel trained in the safe and proper use of the following kits or devices provided the principal investigator in charge of the kit or device has received project approval.

a) Radioimmunoassay kits for use as <u>in vitro</u> laboratory tests not involving internal or external administration of radioactive material to animals or humans and containing not more than the activity listed below (total possession limit 200 uCi):

H-3	50 uCi
C-14	10 uCi
Fe-59	10 uCi
Se-75	10 uCi
I-125	10 uCi
I-131	10 uCi

b) Static elimination devices containing not more than 0.5 mCi Po-210 per device (total possession limit 5 mCi).

c) Electron capture detectors containing not more than 20 mCi Ni-63 or 300 mCi H-3. Foils shall be changed by Radiological Control personnel only. The gas chromatograph shall be operated in a hood, or the detector shall be vented into a hood. Detector cells containing H-3 foils shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Celcius.

5) Classroom authorization for students in radioisotope courses.

Students formally enrolled in laboratory courses in which radioactive materials are used are authorized to work with radioactive materials in such courses provided:

a) The course instructor has met the requirements for Regular Authorization and has obtained Project Approval, and

b) Any special requirements which may be imposed by the Radiological Control Committee are met.

Use of Byproduct Material for Veterinary Nuclear Medicine

The project director(s) for project(s) performed in Veterinary Nuclear Medicine are licensed veterinarians.

2b. Annual audits of the Radiation Safety Program will be conducted. The audits will be performed by a member of the (1) Radiological Control Committee, (2) a University employee, appointed by the committee, who has at least 40 hours of training or experience in the use of radioactive materials or (3) a person outside the university, appointed by the committee, who has at least 40 hours of training or experience in radiation operations. The audit will cover the activities of the Radiological Control Officer, and records that must be maintained to ensure compliance with conditions of the license and applicable parts of NRC Regulations. Audits will be revieved by the Radiological Control Committee.

2c. The Radiological Control Committee or a subcommittee of the Radiological Control Committee will meet for a total of 4 times per year (quarterly).

2d. The gauges listed in the license require no installation and are portable gauges used for moisture and density measurements and research. The criteria for approving users is essentially the same as for all other users of radioactive materials. The only difference is that to be granted authorization without supervision the applicant must have experience using a similar gauge or education on the use of the gauge through an established course.

Calibration and maintenance of the gauges are performed by the manufacturer. The RCC does not authorize users to perform onsite service.

Leak tests on licensed gauges are performed by a member of the Radiological Services Staff or under the supervision of the Radiological Services Staff. The procedures for leak testing require a smear wipe to be taken at the nearest accessible point to the sealed source. The smear wipe is then counted with an instrument capable of detecting .005 uCi of the type of radiation emitted by the gauge's radioactive component.

3. Minimum bioassay action levels and follow-up procedures in the event of material uptake by authorized personnel using iodine-131 and hydrogen-3 currently in effect are as follows:

H-3:

.001 uCi/ml - procedures revieved

.005 uCi/ml - biweekly bioassay

.05 uCi/ml - no H-3 work until < .025 uCi

I-131:

.12 uCi - procedures revieved

.5 uCi - biweekly bioassay and medical consultation

1.0 uCi - no I-131 work until <.5 uCi

4a. Any radionuclides authorized under the license could be incinerated (Z=1-83). The most restrictive MPCa will be used to calculate stack release limits. The percent of the incinerated activity which is released will be based upon Bush and Hundal's, "The Fate of Radioactive Materials Burnt in an Institutional Incinerator", (Health Physics 24, 564-568(1973)), or other appropriate research, or will be assumed to be 100% for volatile elements and 50% for non-volatile elements.

4b. Currently all ash from the incineration of radioactive materials is collected and disposed of at an approved low level radioactive waste disposal site. When disposed of by shipment to an approved disposal site as radioactive waste, we feel calculating ash activity by subtracting the amount released from the amount burned is a practical quantification method.

If the ash is to be disposed of as non-radioactive waste, a representative sample of the ash will be collected for analysis. Ash from waste that contains beta emitters will be analyzed by using a liquid scintillation counter or proportional counter. Ash from waste that contains gamma emitters will be analyzed with a NaI(Tl) counting system or other suitable gamma counting system. Any ash that shows radioactive concentrations that do not exceed concentrations (in uCi/g) specified for water in Appendix B, Table II of 10CFR20, would be disposed of a non-radioactive waste.

5a. Procedures for Ordering/Receipt of Radioactive Material are as follows:

1) All requests for radioactive material are normally submitted on a form R-1 to the office of Radiological Services.

2) Upon receipt of a form R-1, the order is reviewed to determine if:

   (a) The radionuclide is authorized under the project.

   (b) The radionuclide can be ordered under the project at the quantity requested.

   (c) The total quantity possessed by the project will be less than the project limit.

   (d) The requested user is authorized on the project.

3) If the answer to all questions in (2) are positive, the order is placed.

4) All orders/packages of radioactive material are delivered to the Radiological Services Office, unless prior approval is granted.

5) After processing of the package, the user is notified.

6) The person picking up the material signs and dates the R-1 form and radioactive material is transferred to user.

5b. Procedures for Examining Incoming Packages are as follows:

Packages of radioactive material received at Radiological Services will be processed following section 20.205 of 10CFR Part 20.

Receipt of Radioactive Materials During Off Hours are as follows:

Generally shipments of radioactive material are not received during off duty hours. Prearrangement for receipt of packages after regular work hours can be authorized on a case by case basis. The only shipments currently authorized for off hour delivery are radiopharmaceuticals at less than type A quantities. The radiopharmaceuticals are received at the police station. The police have a radiopharmeceutical pickup list of approved people who may pickup these packages, and an emergency call list for accidents involving radioactive materials.

5c. Procedures for Maintaining Byproduct Material Inventory are as follows:

1) A form R-1 is completed for all radionuclides received. One copy of the multicopy form R-1 is used for inventory control.

2) After receipt and transfer of radionuclide to the user, the inventory control copy of the form R-1 is placed in a box for computer entry.

3) Periodically, the inventory control copy(s) of the form R-1 are collected and the information is entered into the computer.

4) Each quarter (generally early January, April, July, and October) a hard copy of the inventory is prepared. For the hard copy the computer calculates the decayed activities of the radionuclides to a specified date and calculates a total for each radionuclide. The totals are compared to license limits.

5) Annually, a copy of the project's inventory (last inventory and new radionuclide orders) are sent to the project director(s). The project director(s) returns a corrected inventory (what is currently in their possession). Changes are entered into the computer and an updated hard copy inventory processed.

6. The 1000 mCi possession limit for P32 is distributed among many investigators and projects. No single authorization is allowed 1000 mCi. Purdue's training slide presentation covers the use of low density shielding for P32 use and all P32 users are issued both a ring badge and whole body badge. Dry runs will be required for all unfamiliar uses of P-32 and all users will be required to follow standard laboratory techniques and perform radiation surveys and wipe tests after each use. Eye protection will be required for all procedures that involve 10 millicuries or more of P-32.

7a. When using radioactive materials, users are instructed to use a survey meter or other appropriate survey technique, frequently during and following work with unsealed radioactive materials. The Radiological Services Office regularly performs formal surveys, which involve both a survey meter evaluation and a smear wipe survey, depending upon laboratory classification.

Class A laboratory	-	weekly
Class B laboratory	-	monthly
Class C laboratory	-	quarterly
Class D laboratory	-	annually

Laboratory classification is determined by radionuclide(s) to be used, radionuclide toxicity, maximum quantity/experiment, experimental procedures and storage limits as stated in the original application (See page 22 of April 23, 1985, application).

Before release of a laboratory or a piece of equipment for unrestricted use, a survey is performed by a Radiological Services staff member. The survey involves a survey meter evaluation, a smear wipe survey and a general area survey. For the laboratory or piece of equipment to be released as "non-radioactive" the survey must show:

a) survey meter evaluation results $\leq$ BKG.

b) smear wipe survey shows all results $\leq$ 100 dpm.

c) no radiation signs present or attached.

d) no radioactive material being stored in the room or equipment.

8. As requested, the manufacturers and model number of instrumentation currently used by Radiological Services Office follows. In the event replacement is necessary, we reserve the right to replace any instrument with an equivalent, but not necessarily the same, make and model. Also, we feel that the instrumentation currently available is in excess of actual needs for an effective Health Physics program. Therefore, we reserve the right to not replace equipment which is not needed for an effective program. Minimum number of instruments will consist of that previously stated in the license application.

Manufacturer	Model
Baird Atomic	441A
Bicron	Surveyor 2000
Bicron	EWGM
Bicron	TPGM
Bicron	GILE
Bicron	G1
Bicron	A50
Bicron	RS050
Bicron	3M3
Canberra	2802
Capintec	192
Dosimeter Corporation	3034-2
Eberline	PAC-3G
Eberline	E-120
Eberline	RO-2
Eberline	RO-4E
Harshaw	CT-285
W.B. Johnson	15
W.B. Johnson	GP-200
W.B. Johnson	GSP-2A
W.B. Johnson	HP-265
W.B. Johnson	DGSP-2A
W.B. Johnson	ASP-2A
W.B. Johnson	FNSP-2A
W.B. Johnson	GSM-5

W.B. Johnson	J200
Johnston Laboratories	1055B
Ludlum	22A
Ludlum	44-3
Ludlum	3
Ludlum	44-7
Ludlum	14A
Ludlum	15
MDH	1015
Nuclear Chicago	1043
Nuclear Measurements Corp.	PC-5
Packard Tri-Carb	4640
Technical Associates	TBM-35
Tracerlab	NP-1
Victoreen	570

9a. A diagram of animal housing at the Veterinary School, in Life Science animal house and in Pharmacy animal facilities are enclosed (fig. 1-3). Other animal housing may be approved by the Radiological Control Committee. The veterinary school's policy is that only authorized personnel (i.e. no owners) are allowed in animal housing/wards or areas of the veterinary school other than examination rooms. Unauthorized personnel are not allowed entry into animal quarters by the University. Researchers are assigned animal rooms for their work. Security to prevent unauthorized entry is maintained by the investigator.

9b. Purdue University has no "permanent" places of radionuclide use. Currently, research and development using radionuclides has been authorized by the Radiological Control Committee for users at Purdue's main campus in West Lafayette and Purdue's Fort Wayne Campus. Any of Purdue's regional campuses or farms may, from time to time, be potential locations for use of radioactive materials.

A list of authorized places of radionuclide use not on the main campus of Purdue University and a description of the type of use at each facility is as follows:

LOCATIONS:	TYPE OF USE:
Purdue University Fort Wayne Campus 2101 East Coliseum Boulevard Fort Wayne, IN 46805	Research & Development Animal Research
Crooked Lake Biological Station State Road 109 Columbia City, IN 46725	Research & Development
Purdue University Calumet Campus 2233 171 Street Hammond, IN 46323	No authorized projects
Purdue University North Central Campus U.S. 421 and Indiana Toll Road Westville, IN 46391	No authorized projects
Purdue Farms:	
Tippecanoe County -	
University Farm Center Rodent (Thomas)	Radiological Waste processing.
Anywhere in the State of Indiana	Moisture and Density Gauges.

Purdue University has in the past informed the NRC of the proposed use or storage of waste at locations other than the main campus. Amendment to our license will be requested prior to initiation of isotope usage at other locations. Licensed activities will only be conducted at those permanent facilities specified in our license.

9c. A list of the current equipment used for Veterinary Nuclear Medicine follows. In the event replacement is necessary, we reserve the right to replace any instrument with an equivalent, but not necessarily the same, make and model.

Gamma Camera:

Medex
Model 6413
Series 75000
PHOV/Gamma LFOV

Dose Calibration:
Victoreen
Model 34061

Survey Meter:
Ludlum
Model 14C

Ion Chamber:
Victoreen
Model 470A

10. Upon receipt of tritium target(s), the exterior of the package is surveyed. The tritium target(s) is then placed for storage in a hood or glove box until use.

Tritium Target Change Procedures (Current Procedures) is as as follows:

1) Allow at least one hour after beam shutdown prior to changing target.

2) Turn on tritium monitor at least one hour prior to changing target.

3) Survey target assembly for activation product activity.

4) With forepump on close diffusion pump gate valve and target gate valve to isolate target assembly.

5) Disconnect cooling water lines to target.

6) Tape two plastic bags from glove box to drift tube. Leave a small air intake space in the connection on the drift tube.

7) Make sure that the following items are in the glove box:

   Allen wrench
   Screwdriver
   Hammer
   Forceps
   Greased 2 1/2" o-ring
   Kim Wipes
   Waste Containers
   Yellow tape
   Scissors
   New Target Assembly Metal Can
   Plastic bags
   Gloves

8) Activate room exhaust vent

9) Activate glove box vacuum pump

10) Activate tritium monitor sniffer near breathing zone.

11) Slowly bleed in N_2 gas to target chamber.

12) Turn off N_2 bleed in valve when target chamber reaches atmospheric pressure.

13) Remove target assembly by unscreving four Allen bolts.

14) Install new target assembly

15) Seal old target assembly in a plastic bag and place in metal can. Seal metal can in plastic bag.

16) Open target bypass valve.

17) When target chamber reaches 50 microns open high vacuum gate valve and target chamber gate valve.

18) Close target bypass valve.

19) Switch tritium monitor intake to glove box.

20) When tritium can not be measured in glove box, then disconnect tritium monitor from glove box and seal hose.

21) Sniff breathing zone with tritium monitor.

22) Remove tape on plastic bags on drift tube and slowly slide bag off drift tube and seal bag with tape.

23) Connect water lines to target assembly.

24) Disconnect vacuum pump from glove box and seal hose.

25) Remove glove box to Hot Lab for storage.

26) Log target change in generator log.

27) Take 24 hour urine sample and analyze.

Methods of Removal & Disposal

We have never changed the pump oil or gaskets and probably never will. As there are no current plans for accelerator use, there are no "cleaning materials" and our current accelerator does not have a vacuum ion pump nor uses coolant fluid. Depleted targets have been used in research conducted by Dr. Robert Landolt, a Purdue faculty member, whereby they have been encapsulated and treated for tritium leaching. The targets will continue to be kept on hand for long-term testing.

11a. Currently, Veterinary Nuclear Medicine is authorized by the Radiological Control Committee to perform diagnostic tests and research using Tc99m. Animals are not released to their owners until a survey of the animal with an ion chamber indicates no detectable exposure.

Since holding animals, until no radiation is detectable could cause unnecessary stress for the animal, it is requested that animals be released to their owner when the following criteria have been met:

1) The maximum exposure rate when measured at 1 foot from the animal's body shall not exceed 0.5 mR/hr.

2) The calculated urinary excretion rate of iodine-131 will not exceed 9 uCi/day by the time of release and the owners certify in writing both before treatment begins and immediately prior to the patient's release that they have read, understand and will comply with the release criteria specified below:

   A) The warning collar will not be removed (warning collar is a collar with Caution Radioactive Material label attached).

   B) Persons over 45 years of age should stay three feet or further away from the pet, except for brief periods for necessary care.

   C) Persons under 45 years of age should stay six feet or further from the pet, except for brief periods for necessary care.

D) Children under 18 and pregnant women should not have any contact with the pet.

E) The pet must be kept strictly confined to the owner's premises for at least two weeks from the date of release. If the area is unfenced, the pet will be leashed at all times.

F) The owners will be advised that:

1) They should minimize close contact with the pet, including arranging to have the pet sleep in a separate room,

2) The pet is still excreting low levels of radioactive material. If the pet is a cat, they must make sure that it urinates and defecates in its litter pan. If it is a dog, it must not leave the owner's property during the restricted period. Plastic disposable litter pan liners should be used to minimize handling of litter,

3) They should wash their hands carefully after handling the pet, its food dishes, or litter pan.

We feel the above criteria will maintain potential exposure to the public ALARA and should ensure that no individual member of the public will receive a committed effective dose equivalent in excess of 100 mRem.

If you have any questions or require further clarification, you may contact me at 317-494-6232.

Sincerely,

Gordon S. Born,
Radiological Control Officer

Attachment: Housing diagram
1. Veterinary School (Animal Housing)
2. Life Science Animal Bldg.
3. Pharmacy Bldg. (Animal Housing)

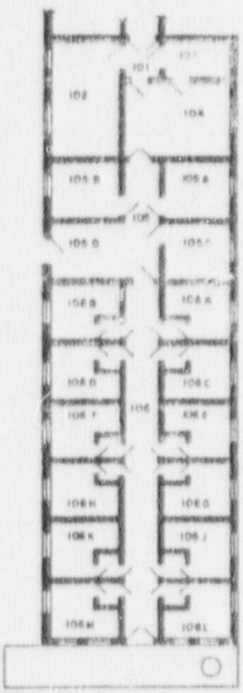
Figure 1

Veterinary School

(Animal Housing)

ANIMAL ISOLATION BLDG. 1

SCALE: 1/16" = 1'-0"
SHEET 6 OF 10
CODE 259



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ANIMAL ISOLATION BLDG. 2

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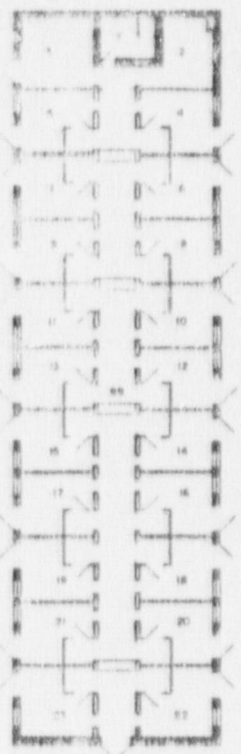

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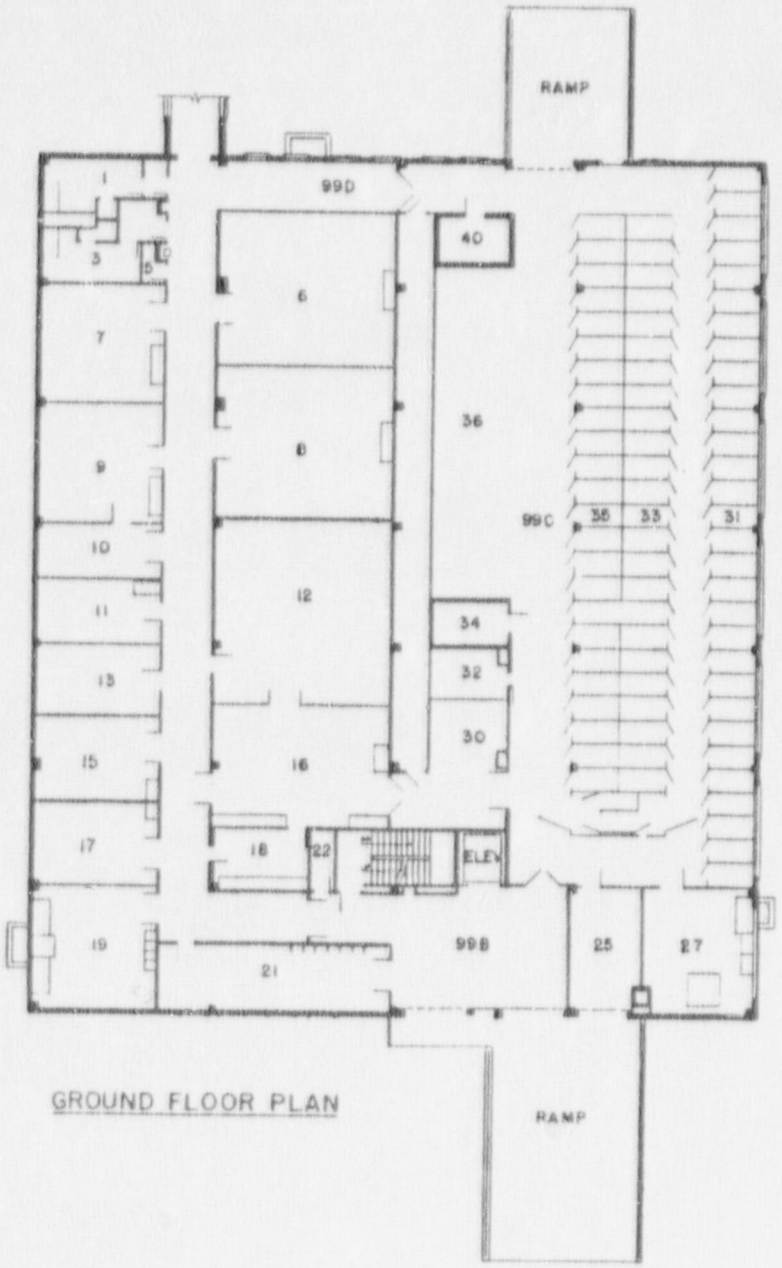
Figure 2

Life Science Animal Bldg.



GROUND FLOOR PLAN

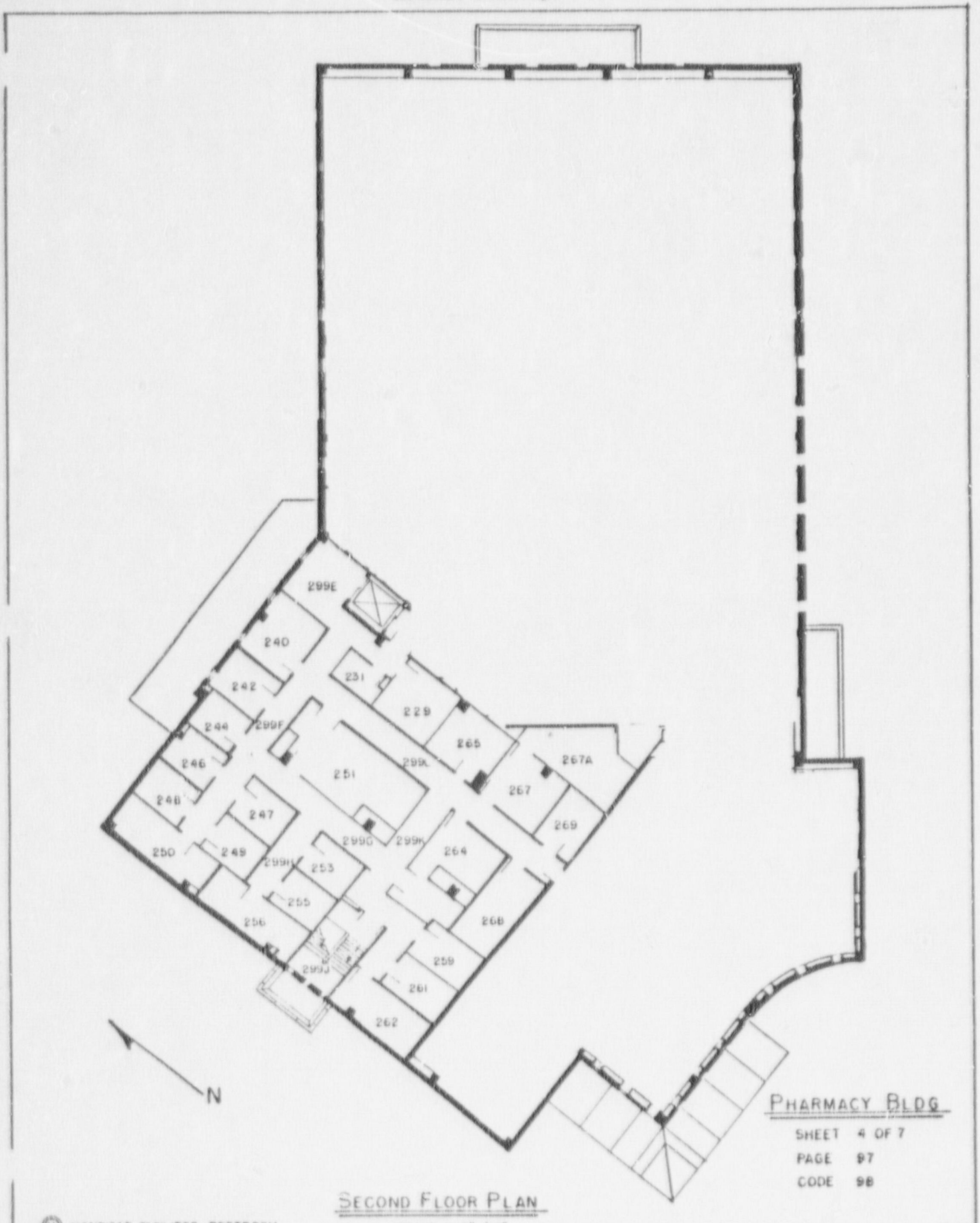
SMALL ANIMAL BLDG.
SCALE 1/16" = 1'-0"
SHEET 2 OF 4
PAGE 77B
CODE 92

2-82

Figure 3

Pharmacy Bldg.

(Animal Housing)



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