NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 41

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

302462

Licensee	
1. Children's Hospital	In accordance with letter dated March 10, 1997 3. License Number 34-03111-02 is amended in its entirety to read as follows:
2. 700 Children's Drive Columbus, OH 43205	4. Expiration Date May 31, 2001
	5. Docket or Reference No. 030-02713

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Hydrogen-3	E. Any	E. 499 millicuries
F. Carbon-14	F. Any	F. 49 millicuries
G. Phosphorus-32	G. Any	G. 1 curie
H. Sulfur-35	H. Any	H. 1 curie
I. Scandium-46	I. Any	I. 10 millicuries
J. Ruthenium-103	J. Any	J. 10 millicuries
K. Tin-113	K. Any	K. 10 millicuries

120124

0/1

JAL 230 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-03111-02

Docket or Reference Number
030-02713

Amendment No. 41

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
L. Iodine-125	L. Any	L. 50 millicuries
M. Cesium-137	M. Sealed source (which have been evaluated by and registered with the NRC or an Agreement State)	M. 100 millicuries
N. Chromium-51	N. Any	N. 500 millicuries
O. Technetium-99m	O. Any	O. 1 curie
P. Niobium-95	P. Any	P. 20 millicuries
Q. Rubidium-86	Q. Any	Q. 50 millicuries
R. Phosphorus-33	R. Any	R. 50 millicuries
S. Cesium-137	S. Sealed source (Nordion International, Inc. C-1000 or C-1001) Isomedix Model ISO-1000)	S. 900 curies

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. In vitro studies.

E. through L. To be used for small case laboratory research including animal studies.

M. To be used for instrument calibration.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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N. through R. To be used for laboratory research including animal studies.

S. To be used in a Nordion International, Inc. Gammacell 1000 Elite irradiator for irradiation of transfusion specimens (excluding the irradiation of explosives and flammable materials).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 700 Children's Drive, Columbus, Ohio.

11. Licensed material shall be used by, or under the supervision of, individuals designated by Children's Hospital Radiation Safety Committee, Larry A. Binkovitz, M.D., Chairperson.

12. The Radiation Protection Officer for the activities authorized by this license is Nancy L. Joy.

13. A. (1) The source(s) specified in Item(s) 7.M. and 7.S. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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030-02713

Amendment No. 41

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

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

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-125 and/or iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

16. The Radiation Safety Officer shall conduct a semiannual program audit and confirmatory radiation survey of each location where radioactive material will be utilized.

17. The Licensee shall ensure that the quorum of the radiation safety committee include as a minimum, the radiation safety officer, the management representative and persons representing the activities that will use radioactive material.

18. The licensee shall establish a bioassay program for individuals handling millicurie amounts of tritium in accordance with frequencies and procedures contained in Regulatory Guide 8.32, "Criteria For Establishing A Tritium Bioassay Program."

19. The licensee shall follow procedures contained in Appendix M.3, "Measuring and Recording Molybdenum Concentration," of Regulatory Guide 10.8, Revision 2, August 1987.

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

MATERIALS LICENSE
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21. The licensee shall maintain records of information important to safe and effective decommissioning as listed in Condition 10. per the provisions of 10 CFR 30.35g until this license is terminated by the Commission.

22. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated June 26, 1992.

    B. Letters dated July 27, 1990 (excluding references to interim storage and isotopes with half-lives greater than 65 days); March 21, 1991 (excluding references to interim storage and isotopes with half-lives greater than 65 days), October 6, 1992, December 15, 1992, August 23, 1996, October 4, 1996, October 28, 1996, November 27, 1996, March 10, 1997, May 1, 1997, and May 19, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 02 1997

By Deborah A. Scott
Nuclear Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 3E
Exp. Date: 20010531
Fee Comments:
Decom Fin Assur Reqd: N

50

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: CHILDREN'S HOSPITAL
   Received Date: 970326
   Docket No: 3002713
   Control No.: 302462
   License No.: 34-03111-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 457816

3. COMMENTS

Signed D. Hersey
Date 3-28-97

1997 MAR 31 PM 4:25

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: 7C 3E #440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed JC
Date 4/1/97

APR 03 1997

Log Mar 13 III
Remitter
Check No. 457816
Amount $440
Fee Category 7C 3E
Type of Fee Amd
Date Check Rec'd 3/31/97
Date Completed 4/1/97
By: JC

Children's Hospital

709 Children's Drive
Columbus, Ohio 43205-2696

614/722-2000

March 10, 1997

U.S.N.R.C.
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: License #34-03111-02

To whom it may concern:

We request that our license be amended to affect the following changes.

1. Please remove the requirement for performing tritium bioassays. We confirm that we will comply with 10 CFR 20.1502(b).

2. We will continue to perform bioassays for the use of sodium iodide I-125 and I-131. However, please amend our license to allow for such bioassays to be performed only after the use of greater than 10 mCi in laboratory areas (iodinations) and 30 mCi in the nuclear medicine department (therapeutic medical administrations).

3. We request the ability to name and remove areas of use internally through the Radiation Safety Committee. Areas will only be released for unrestricted use after a thorough close-out survey has been performed and approval has been specifically granted by the committee. Records of close-out surveys will be maintained for commission review for a period of five (5) years.

4. We request authorization to hold for decay-in-storage radioactive materials which are used for in-vitro applications with physical half-lives of ninety (90) days or less. We will comply with all requirements of 10 CFR 35.92, regarding decay-in-storage, for any material held in decay-in-storage prior to disposal.

5. We request that laboratories using only H-3, C-14, P-33, and/or S-35 not be required to perform surveys of the area using a radiation detection survey instrument. Such areas will be surveyed monthly for removable contamination by liquid scintillation.

302462 PM: ~~3-19-97~~ 3-21-97 ~~3-21-97~~

6. We wish to modify our dose calibrator testing procedures to allow for a ten (10) percent variance before being required to have the instrument repaired or replaced. We specifically request the dose calibrator testing protocols enclosed as item 9.3.

7. We wish to allow for a quarterly review of survey records by the RSO.

8. We request that the requirement for providing personal radiation dosimeters to laboratory personnel be removed. We confirm that we will comply with 10 CFR 20.1502(a).

9. Please modify our license to allow for training of blood bank personnel in the use of the blood irradiator to be performed by either the RSO or the physician in charge of the blood bank. Currently, our license lists specific individuals who will provide the training. We wish to specify individuals more generically in the case that one or both of the individuals should leave our institution.

Thank you for your attention in this matter.

Sincerely,

Jeff Ziegler
Assistant Executive Director
Children's Hospital
Columbus, OH 43205

JZ:lm
cc: file

NRC FORM 313
(3-92)
10 CFR 30, 32 33,
64, 65 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB NO 3150-0120
EXPIRES 6 30 93
ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3 25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATION WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATION AS FOLLOWS.

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

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

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

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

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 34-03111-02
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Children's Hospital
700 Children's Drive
Columbus, Ohio 43205-2696

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

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

LeRoy H. Steckar, III, Consultant, Associates in Medical Physics, LLC.

TELEPHONE NUMBER

412-225-3106

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

FEE CATEGORY 7C

AMOUNT ENCLOSED $ 440

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

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

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE: CERTIFYING OFFICIAL	TYPED/PRINTED NAME	TITLE	DATE
C. Jeff Ziegler	C. JEFF ZIEGLER	Assistant Executive Director	3/24/97

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER	

APPROVED BY	DATE

JUN 0 2 1997

Nancy L. Joy
Radiation Safety Officer
Children's Hospital
700 Children's Drive
Columbus, OH 43205

Dear Ms. Joy:

Enclosed is Amendment No. 41 to your NRC Material License No. 34-03111-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes. (No fee is required if the location of byproduct material remains the same.)

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

302462

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when

dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Deborah A. Piskura
Nuclear Materials Licensing Branch

License No.: 34-03111-02
Docket No.: 030-02713

Enclosure: Amendment No. 41

DOCUMENT NAME: M:\03002713.CL7
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII							
NAME	DAPiskura:brt							
DATE	05/30/97							

OFFICIAL RECORD COPY

Children's Hospital

700 Children's Drive
Columbus, Ohio 43205-2696

614/722-2000

Department of Radiology

William E. Shiels II, DO
Chairman

614/722-2363

Larry A. Binkovitz, MD
David A. Bloom, MD
Brian D. Coley, MD
Jerry R. Dwek, MD
Mark J. Hogan, MD
Frederick R. Long, MD
Lisa C. Martin, MD
Jerome A. Rusin, MD

614/722-2359

614/722-2332 (Fax)

Children's HOSPITAL

May 19, 1997

Debbie Piskura
U.S.N.R.C.
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Re: License #34-03111-02

Dear Ms. Piskura,

This letter is in response to your request for additional information in a telephone conversation between you and our consultant, Chip Stecker, on May 19, 1997.

We confirm that individuals handling greater than one millicurie of P-32 will be required to wear a ring type extremity dosimeter.

Thank you for your attention in this matter.

Sincerely,

Jeff Ziegler

C. Jeff Ziegler
Assistant Executive Director,
Department of Radiology

CJZ/lec

Children's Hospital

700 Children's Drive
Columbus, Ohio 43205-2696

614/722-2000

May 1, 1997

Debbie Piskura
U.S.N.R.C.
Region III
801 Warrenville, Road
Lisle, Illinois 60532-4351

RE: License # 34-03111-02

Dear Ms. Piskura:

This letter is in response to your request for additional information in a telephone conversation between you and our consultant, Chip Stecker, on April 6, 1997.

In addition, we request an addendum to the amendment to allow for the use of Iodine-131, in any chemical or physical form, for small case laboratory research including animal studies. The possession limit we request is 100 mCi. Users will be authorized by the Radiation Safety Committee.

Regarding your questions about the amendment applications:

1. Regarding H-3 bioassays. Currently our license states that "all individuals using H3, C14, and S35 are encouraged to have urine bioassays every 6 months. We request that this wording be removed from the license. We will continue to abide by the remainder of the paragraph. further, we confirm that we will comply with 10 CFR 20.1502(b).

2. Regarding bioassays for the use of I-125 and I-131. Please amend our license such that bioassays will be required to be performed on any individual involved in an iodination procedure using greater than one millicurie. Bioassays for individuals involved in therapeutic medical administrations will be required for administrations of 30 millicuries or more.

3. Regarding the ability for the Radiation Safety Committee to name areas of use. Please see attachment #1.

4. Regarding the ability for the Radiation Safety Committee to remove areas of use. We confirm that we will follow the procedures contained in the August, 1987 NRC publication "Guidelines For Decontamination Of Facilities And Equipment Prior To Release For Unrestricted Use Or Termination Of Prior To Release For Unrestricted Use Or Termination Of Licenses For Byproduct, Source, Or Special Nuclear Material" before allowing an area to be released for unrestricted use.

5. Regarding decay-in-storage of radioactive materials with half-lives of 90 days or less. Please see attachment #2.

6. Regarding the request to remove the requirement for providing laboratory personnel with personal radiation dosimeters. We confirm that individuals who use greater than one millicurie of P-32 at any one time will be issued a whole body dosimeter. Additionally, any individual using greater than ten millicuries of P-32 at any one time will be required to wear eye protection. Further, we confirm that we will comply with 10 CFR 20.1502(a).

Thank You for your attention in this matter.

Sincerely,

C. Jeff Ziegler

C. Jeff Ziegler
Assistant Executive Director
Children's Hospital - Columbus

ATTACHMENT #1
Criteria for Approval of Areas of Use.

Based on the materials currently used, and any anticipated to be used by the laboratory facilities, all laboratories use materials classified by the IAEA to be of moderate to high toxicity. The majority of materials used are considered to be of moderate toxicity. In addition, based on the amount of materials used by the labs, all of the labs would be considered to be type B laboratories as classified by the IAEA. Currently, the amount of material in any given lab may be as low as 200 uCi and as high as 5 mCi.

The following criteria will apply to all laboratories:

1. All radioactive materials will be received through the radiation safety office. This will assure that only radioactive materials and quantities approved by the license will be received.

   All package receipt procedures, therefore, will be performed by the RSO or an individual specifically trained by the RSO.

2. All laboratories will have available a G-M meter equipped with a thin-end window or pancake probe. The meters will be calibrated at least annually and upon repair according to the model procedure for calibrating survey instruments as published in Appendix B to Regulatory Guide 1018, Revision 2. The instruments will be calibrated in-house by a qualified individual, by the manufacturer, or by a facility specifically licensed by the NRC or an Agreement State. Records of calibration will be kept a minimum of three years.

   The survey meters used for area surveys will be capable of reading in mR/hr. Each meter used for surveying will have a dedicated check source. A measurement of the source will be made upon return from calibration and each day of use. Meters will be removed from service if the reading differs significantly from the reading taken at the calibration facility.

3. All laboratories using pure beta emitting radioactive materials will have access to a liquid scintillation counter.

4. Laboratories will be required to perform surveys for ambient radiation exposure and removable contamination according to the following schedule:
   a) Laboratories possessing less than 200 uCi of pure beta emitting radionuclides only (except P-32): Monthly area wipe tests only.

b) Laboratories possessing greater than 200 uCi of pure beta emitting radionuclides only (except P-32): Weekly area wipe tests only.

c) Laboratories possessing less than 200 uCi of photon emitting radionuclides and/or P-32: Monthly area surveys and wipe tests.

d) Laboratories possessing greater than 200 uCi of photon emitting radionuclides and/or P-32: Daily area surveys and weekly area wipe tests.

Surveys and wipe tests need only be performed if radioactive materials were used during the period in question.

The RSO will be notified in instances when greater than 200 dpm or 2 mR/hr are noted. The RSO will give instruction on the appropriate action to be taken.

Each laboratory will maintain a record of surveys to include the date, the meter used, the check source reading, the background dose rate, the dose rate in each area surveyed, and the initials of the individual who completed the survey. All exposure rates will be noted in mR/hr. Survey records will be kept a minimum of three years.

5. Personal monitoring devices will be provided to personnel in accordance with 10 CFR 1502(a). In addition, individuals who use greater than one millicurie of I-125, I-131, or P-32 will be issued whole body and extremity dosimeters.

6. All disposals of radioactive material will be performed or supervised by the RSO, the Facility Manager for the Wexner Research Facility, or by individuals specifically trained by the RSO. A record will be maintained for each disposal to include:

a) For disposals into the sanitary sewer: the date of the disposal, the material(s) disposed, the activity disposed of each material, and initials of the person who performed the disposal.

Calculations will be maintained on file to demonstrate the monthly effluent concentration of all materials disposed by this method.

b) For disposals by decay-in-storage: we will follow the procedure as defined by 10CFR 35.92 for all materials disposed by this method.

c) For materials transferred to a broker for disposal: the date of transfer, the materials transferred, the approximate activity of each material transferred, the volume of waste transferred, the signature of the RSO.

All records of waste disposal will be held a minimum of three years.

7. All laboratories will be properly posted according to 10 CFR 20.1902

8. Laboratories will have shielding as deemed necessary by the RSO. At a minimum, individuals using greater than 10 mCi of P-32 will be required to wear eye protection.

In addition, all laboratories using radioactive materials will have available absorbent pads for use in work areas and waterproof gloves to be worn by workers at all times when handling radioactive materials. Workers will be required to wear lab coats or other protective clothing while in laboratories using radioactive materials. No eating, drinking, or application of cosmetics will be allowed in laboratory areas where radioactive materials are used.

Each laboratory will have materials on hand to allow for the containment and/or decontamination of radioactive spills.

For laboratories performing iodination procedures, all requirements and commitments in our license will be followed as previously approved by the NRC.

Bioassay procedures will be performed according to our license commitments which have been previously approved by the NRC.

ATTACHMENT #2

Additional Information Regarding D-I-S of Radioactive Materials With Half-Lives of Greater Than 65 Days.

Currently the only material with a half-life of greater than 65 days that we request authorization to hold for decay-in-storage prior to disposal is sulfur-35. Other than S-35, only materials with half-lives of 65 days less will be held for decay-in-storage prior to disposal.

Sulfur-35 has a half-life of approximately 90 days. Only solid waste materials contaminated with S-35 would be held for decay-in-storage. In 1996, a total of 37.5 cubic feet of material contaminated with a total of 6.5 mCi of S-35 was shipped for disposal. There is no indication that this volume will increase. Therefore, no increase in the possession limit is necessary.

No materials currently used in the laboratory are held for decay-in-storage. All materials are shipped through a broker for disposal. All materials are segregated into solid contaminated waste and liquid waste.

A diagram of the rooms to be used for decay-in-storage is attached. The rooms are interior rooms in the Wexner Research Building and are constructed of concrete block. Only the RSO, the Facility Manager of the building, and Security personnel will have access to the area.

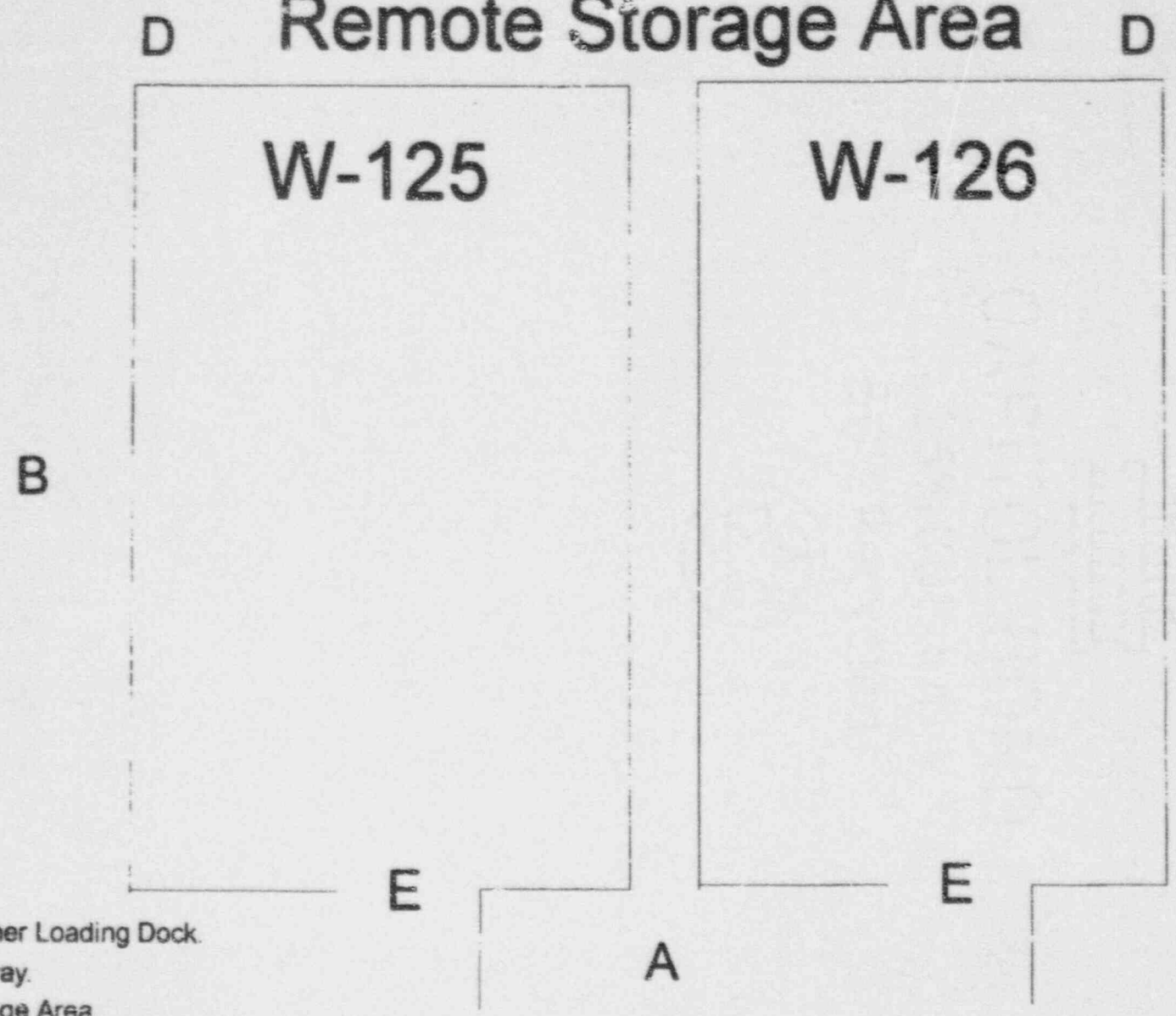
The sulfur-35 is packaged in individual plastic bags in the individual laboratories. The waste will be consolidated into 55 gallon steel drum(s) lined with a heavy plastic liner(s). At a minimum, the material will be checked monthly.

Surveys of the areas for ambient radiation exposure will be performed monthly. Surveys for removable contamination will only be performed if the possibility of contamination is expected. The areas will be posted in accordance with 10 CFR 20.1902.

We will comply with all requirements of 10 CFR 35.92, regarding decay-in-storage, for all materials held in decay-in-storage prior to disposal. A pancake G-M or thin end window G-M probe will be used to monitor the waste to determine if it is indistinguishable from background.

Only the RSO or individuals specifically trained by the RSO will be responsible for maintenance and disposal of materials held in decay-in-storage.
No financial assurance or emergency preparedness plans are necessary due to the small quantity of material proposed for decay-in-storage.

Children's Hospital
Remote Storage Area



A - Wexner Loading Dock.
B - Hallway.
C - Storage Area.
D - Electrical Access Room.
E - Lockable Door.

Each room measures 8 x 12.75 feet.

not to scale - 4/97

Children's Hospital
700 Children's Drive
Columbus, Ohio 43205-2696
614/722-2000

Children's HOSPITAL

CONVERSATION RECORD

TIME 10:00 DATE 4/29/97

O VISIT X CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Chip
ORGANIZATION (OFFICE, DEPT.ETC.): Consultant for Children's Hosp.
TELEPHONE NO.: 412.225.3106

SUBJECT
Lic. No. 34-03111-02
CN 302462

SUMMARY
I spoke with Chip on the information requested during the 4/15/97 telecon. He requested a re-iteration on the matter regarding in-house approval of labs.

Please expand upon minimum facilities and equipment required for various types of operations. The application should include a laboratory or facility classification scheme that relates the toxicity and quantity of radioactive materials to minimum facility and equipment requirements. The International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (e.g., for equipment and facilities, user training, personnel monitoring, or surveys) in relation to the hazard and quantity of byproduct materials to be used. The NRC staff recommends that applicants consider developing such a classification scheme, since all aspects of the radiation safety program can be correlated to it. The IAEA document is not meant to be a model, but simply a reference. Each applicant's scheme should be based upon the types and quantities of byproduct materials that are anticipated to be needed. The criteria used to develop the classification scheme should be made into a manual and provided to each RCC member for use when evaluating requests to use licensed materials. Appendix J to Regulatory Guide 10.5 has been excerpted from the IAEA Standard which provides information on radionuclide toxicity and laboratory classification. A license application should describe the minimum facilities and equipment required for each laboratory classification

ACTION REQUIRED
Reply within 30 days of 4/15/97 telecon.

NAME OF PERSON DOCUMENTING CONVERSATION: D.A. Piskura
SIGNATURE: D.A. Piskura
DATE: 4/29/97

CONVERSATION RECORD

TIME 2:30 pm DATE 4/15/97

O VISIT X CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Nancy Joy, RSO	Children's Hospital	614.722.2000

SUBJECT
License amendment request to No. 34-03111-02
CN 302462

SUMMARY

I spoke with Nancy about the review of this amendment request and noted that we found numerous deficiencies with the letter. These items are outlined below. Upon receipt of this information, I will complete my review and issue the amendment.

1. Respond to the information sheet for DIS of wastes with half-lives greater than 65 days. Note that the licensee has applied for this waste management modality twice before and NRC requested this information from the licensee on both occasions without a reply.

2. Justify bioassay program changes. Also provide your revised criteria for not issuing dosimetry to radiation workers.

3. Please describe the surveys you will require and the criteria you will use for release of facilities and equipment for unrestricted use. Confirm the facilities and equipment will not be released until the results of surveys are reviewed and approved by the RSO. Refer to the information contained in "Guidelines for Decontamination of Facilities....."

4. Please discuss the minimum facilities and equipment required for various types of operations. You should include a laboratory or facility classification scheme that relates the radiotoxicity and activity to specific lab types. Your classification scheme should be based upon the types and quantities of byproduct materials routinely used by hospital. The criteria used to develop the classification scheme should be made into a manual and provided to each RSC member for use when evaluating requests to use RAM. Appendix J to Reg. Guide 10.5 contains an excerpt from the IAEA Standard. This excerpt can provide you information on radionuclide toxicity and laboratory classification.

ACTION REQUIRED
Respond within 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
D.A. Piskura	D.A. Piskura	4/15/97

ACTION TAKEN
/

SIGNATURE	TITLE	DATE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 28, 1997

Nancy L. Joy
Radiation Safety Officer
Children's Hospital
700 Children's Drive
Columbus, OH 43205

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter & Application Dated 03/10/97 & 03/20/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License _X_ Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302462
License No. 34-03111-02