

MATERIALS LICENSE

Amendment No. 22

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.

OFFICIAL RECORD COPY

Licensee Department of Health and Human Services 1. Public Health Service Food and Drug Administration 2. Winchester Engineering and Analytical Center 109 Holton Street Winchester, Massachusetts 01890		In accordance with the application dated January 15, 1997, 3. License Number 20-08361-01 is amended in its entirety to read as follows: 4. Expiration Date February 28, 2006 5. Docket or Reference No. 030-04675	
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 with Atomic Numbers 3 through 83	A. Any	A. Not to exceed 50 millicuries per radionuclide and 10 curies total	
B. Fluorine 18	B. Any	B. 300 millicuries	
C. Phosphorus 32	C. Any	C. 300 millicuries	
D. Chromium 51	D. Any	D. 300 millicuries	
E. Cobalt 60	E. Any	E. 1 curie	
F. Selenium 75	F. Any	F. 300 millicuries	
G. Strontium 89	G. Any	G. 1 curie	
H. Yttrium 90	H. Any	H. 1 curie	
I. Molybdenum 99/ Technetium 99m	I. Generators	I. 50 curies	
J. Technetium 99m	J. Any	J. 500 millicuries	
K. Indium 111/114	K. Any	K. 300 millicuries	
L. Iodine 131	L. Any	L. 500 millicuries	
M. Xenon 133	M. Any	M. 1,500 millicuries	
N. Samarium 153	N. Any	N. 2 curies	
O. Cesium 137	O. Sealed sources	O. 1 curie	
P. Uranium 232	P. Any	P. 5 micrograms	
Q. Uranium 233	Q. Any	Q. 250 micrograms	
R. Uranium 235	R. Any	R. 10 grams	
S. Uranium 236	S. Any	S. 400 milligrams	
T. Uranium 237	T. Any	T. 0.03 nanograms	
U. Natural Uranium	U. Any	U. 20,000 grams	
V. Natural Thorium	V. Any	V. 20,000 grams	
W. Neptunium 237	W. Any	W. 10 microcuries	
X. Neptunium 239	X. Any	X. 100 microcuries	
Y. Americium (Any isotope)	Y. Any	Y. 200 microcuries	
Z. Polonium (Any isotope)	Z. Any	Z. Not to exceed 200 microcuries per isotope and 800 microcuries total	

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PDR ADDCK 03004675
C PDR

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SUPPLEMENTARY SHEET

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AA. Actinium (Any isotope)	AA. Any	AA. 200 microcuries
BB. Curium (Any isotope)	BB. Any	BB. Not to exceed 200 microcuries per isotope and 800 microcuries total
CC. Plutonium (Any isotope)	CC. Solution or alpha standard	CC. 3 milligrams except that no more than 1 microgram of Plutonium 238 may be possessed at any one time
DD. Hydrogen 3	DD. Foils	DD. Not to exceed 1000 millicuries each and 80 curies total
EE. Nickel 63	EE. Foils	EE. Not to exceed 25 millicuries each and 2.5 curies total
FF. Americium 241	FF. Sealed sources	FF. Not to exceed 10 millicuries per source and 20 millicuries total

9. Authorized use

A. through Z.	Research and development as defined in 10 CFR 30.4; animal studies.
AA., BB., and CC.	Research and development as defined in 10 CFR 30.4; animal studies.
E., O., and FF.	Instrument calibration.
U., V., and FF.	For storage as waste.
DD. and EE.	For use in electron capture detectors or for storage as waste.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at Winchester Engineering and Analytical Center, Winchester, Massachusetts and licensed material in the form of sealed sources may be used at temporary job sites of the licensee anywhere in the United States.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, James W. Fitzgerald, Chairperson.
B. The Radiation Safety Officer for this license is Edmond J. Baratta.
12. Licensed material shall not be used in or on human beings.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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15. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. 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, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19.
 - A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
 - B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
21. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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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. 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 May 19, 1995
- B. Letter dated November 8, 1995
- C. Letter dated January 12, 1996

For the U.S. Nuclear Regulatory Commission

Date FEB - 7 1997

Original Signed By:
By John D. Kinneman
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

FEB - 7 1997

James W. Fitzgerald
Center Director, WEAC
Department of Health & Human Services
Food & Drug Administration
109 Holton Street
Winchester, MA 01890

Dear Mr. Fitzgerald:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

In accordance with the current NRC policy, Condition 20 is added to your NRC license. Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

License No. 20-08361-01
Docket No. 030-04675
Control No. 124135

Enclosure:
Amendment No. 22

OFFICIAL RECORD COPY **ML 10**

J. Fitzgerald, WEAC Director
Food & Drug Administration

-2-

DOCUMENT NAME: R:\WPS\MLTR\L2008361.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/> C	<input type="checkbox"/> E	<input type="checkbox"/> N
NAME	SLodhi	<input checked="" type="checkbox"/>	Jenneman	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DATE	01/29/97	<input checked="" type="checkbox"/>	01/30/97	<input type="checkbox"/>	01/ /97	01/ /97

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
Winchester Engineering and Analytical Center
109 Holton Street, Winchester, MA 01890
Telephone: 617-729-5700

January 15, 1997

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

030-04675

License: 20-08361-01
Exp. Date: February 28, 2006
Docket No.: 03004675
Control No.: 121843

Gentlemen:

Attached is a request for an amendment to our license. This amendment will enable us to handle future radiopharmaceutical products that have been or are being introduced into the health care system for therapeutic purposes. These are:

<u>Radionuclide</u>	<u>Present Limit</u>	<u>Requested increase</u>
Strontium-89	50 mCi	1.0 curie
Yttrium-90	50 mCi	1.0 curie
Samarium-153	50 mCi	2.0 curie

We are also requesting an amendment to our license to allow for waste storage of our 10 mCi Americium-241 x-ray source that is no longer useful. We would however, want to retain the 10 mCi for a new Americium-241 source when one becomes available.

James W. Fitzgerald
James W. Fitzgerald
Center Director, WEAC

Attachments

cc: E.J. Baratta, HFR-NE400

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JAN 21 1997

OFFICIAL RECORD COPY

ML 10

(20-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

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 APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS 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 LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

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 RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

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

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

B. AMENDMENT TO LICENSE NUMBER 20-08361-01

C. RENEWAL OF LICENSE NUMBER _____

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

DHHS/PHS/Food and Drug Administration
Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MA 01890

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

DHHS/PHS/Food and Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Edmond J. Baratta

TELEPHONE NUMBER

(617) 729-5700 x728

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

5. RADIOACTIVE MATERIAL

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT Decay in storage (10 half-lives)

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

FEE CATEGORY N/A AMOUNT
ENCLOSED \$ -----

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, 36, 39 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 82 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Edmond J. Baratta, Radiation Safety Officer

SIGNATURE

Edmond J. Baratta

DATE

1/15/97

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		

APPROVED BY

DATE

1 2 4 1 3 5
JAN 21 1997

License No.: 20-08361-0
Docket No.: 030-04675
Control No.: 121843

5.) Radioactive Material

a.	Element/Mass No.	b.	Chemical Form	c.	Maximum Amt.
1.)	Yttrium-90		any		1.0 Curie
2.)	Strontium-89		any		1.0 Curie
3.)	Samarium-153		any		2.0 Curies
4.)	Americum-241		Sealed Source (Amersham/Searle Model AMC 2084)		20 Millicuries

6.) Purpose:

Items 1-3	Research and development as defined in 10CFR 30.4; animal studies
Item 4	Instrument calibration and/or waste storage

- 7.) a.) Licensed material shall be used by or under the supervision of individuals designated in writing by the Radiation Safety Committee, James W. Fitzgerald, Chairperson.
- b.) The Radiation Safety Officer for this license is Edmond J. Baratta.

8.) See license request re: amendment 21.

9.) See license request re: amendment 21. These radionuclides are dispensed in vials containing ~50 mCi/mL. Normally, they contain 2-3 mls. The FDA requires that three (3) vials be obtained per sample. The first vial is for the analysis. The second vial is for the "check" analysis that is required to confirm the original analysis. The third vial is to be held unopened, should a third independent analysis be required. Only one vial is analyzed at a time and each analysis requires a different analyst. These are handled behind the lead and/or plastic shielding.

We have available the following shields for protection for the analysts:

<u>No.</u>	<u>Type</u>	<u>Thickness</u>	<u>Size</u>
3	Leaded Acrylic	1 1/4"	18"h x 12"w
2	Leaded Acrylic	1 1/4"	24"h x 12"w
1	Lead	2"	20"h x 12"w x 15"d

1	Lead	1"	20"h x 16"w x 12"d
8	Steel	1/2"	14"h x 14"w
1	Steel	1/2"	12"h x 12"w x 24"d
3	Lead	1/2"	16"h x 16"w x 14"d

10.) See license request re: Amendment 21

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

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:      (FOR LFMS USE)
:      INFORMATION FROM LTS
:      -----
:
:  PROGRAM CODE: 03610
:  STATUS CODE: 0
:  FEE CATEGORY: EX 3L 2C 1D
:  EXP. DATE: 20060228
:  FEE COMMENTS: 2C IS THORIUM
:  DECOM FIN ASSUR REQD: Y
:  . . . . .

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A. REGION

I

APPLICANT/LICENSEE: HEALTH & HUMAN SERVICES, DEPT. OF
RECEIVED DATE: 970121
DOCKET NO: 3004675
CONTROL NO.: 124135
LICENSE NO.: 20-08361-01
ACTION TYPE: AMENDMENT

AMOUNT: _____
CHECK NO.: _____

SIGNED *M. Asperheim*
DATE *1/22/92*

1. FEE CATEGORY AND AMOUNT: _____

AMENDMENT	----
RENEWAL	-----
LICENSE	-----

SIGNED _____
DATE _____