



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 22, 1996

Ohio University
ATTN: Jimmy D. Matthews, Director
Environmental Health and Safety
Hudson Health Center
One President Street
Athens, OH 45702

Dear Mr. Matthews:

This is in regard to the submittal of Certifications of Small Entity Status (NRC Form 526) by Diagnostic Hybrids, Inc. for the annual fees assessed for Materials License 34-01260-11, which is issued to the Ohio University, Hudson Health Center.

A review of our files indicates that License 34-01260-11 authorizes the use of licensed material on the Ohio University campus by Diagnostic Hybrids, Inc., which operates as part of the Ohio University Innovation Center. It is our understanding that the Ohio University Innovation Center was developed to assist the start up of small privately owned industrial type laboratories, such as Diagnostic Hybrids, Inc., to operate under the University's control until the demand for their products could be determined. The laboratories would then relocate off of the University's campus and apply for a new license in their name. We have no record of receiving an application for a new license from Diagnostic Hybrids, Inc. We recognize that Diagnostic Hybrids, Inc. is a small manufacturing concern; however, as long as Ohio University is the licensee, small entity status cannot be granted based on small entity certifications filed by Diagnostic Hybrids, Inc. Accordingly, the fees assessed Ohio University cannot be reduced based on the small entity certifications. Please note that 10 CFR 171.16(c) provides that "a licensee (emphasis added) who is required to pay an annual fee under this section may qualify as a small entity."

The exemption from fees for nonprofit educational institutions in 10 CFR 170.11(a) and 10 CFR 171.11(a), do not apply to those byproduct, source, or special nuclear material licenses which authorize manufacturing and distribution of licensed material. Thus, the Ohio University is subject to 10 CFR Part 170 fees and 10 CFR Part 171 annual fees for fee Category 3B for License 34-01260-11, which authorizes the manufacture and distribution of in vitro diagnostic kits and radioiodinated products. Accordingly, Ohio University was appropriately assessed annual fees for License 34-01260-11 for Fiscal Years 1991 \$4,500 (AM05184-91), 1992 \$6,350 (AM4328-92), 1993 \$6,320 (AM04613-93), 1994 \$7,570 (AM3937-94), 1995 (AM3803-95) and 1996 \$5,200 (AM1679-96). The five invoices, the amounts paid and the outstanding balances due are listed in the enclosed chart. The outstanding amounts are due and payable. However, because of the amount of time it has taken to notify you of the denial of small entity status, interest and late charges will be waived if payment of \$24,564.84, is received within 90 days from the date of this letter. If payment is not received in 90 days, all late charges will be assessed.

J. Matthews

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November 22, 1996

We apologize for the inconvenience this may have caused the University. If you have any questions concerning this matter, please contact Cheryl A. Phillips of my staff at 301-415-6089.

Sincerely,

Original signed by
Ronald M. Scroggins

Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

Enclosure: Chart

cc: Diagnostic Hybrids, Inc.
One President Street
Athens, OH 45701

Distribution:

L. Tremper, OC/DAF/LFARB/ARS
S. Kimberley, OC/DAF/LFARB/LFS
License File 34-01260-11 w/cy inc & encl
Invoice File AM05184-91, AM4328-92, AM4613-93, AM3937-94,
AM3803-95, AM1679-96 w/cy inc & encl
NUDOCS (ML-61) w/cy inc & encl
PDR (w/cy inc and encl
OC/DAF/LFARB RF
OC/DAF RF (DAF-6-000)
OC/DAF SF (LF-3.2.2) w/orig inc & encl

OC R/F

DOCUMENT NAME: G:\OHIO

(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	OC/DAF/LFARB/LFS	DNMS/MLB (RGN-III)	OC/DAF/LFARB	OC/DAF	OC
NAME	CAPhillips	BJHolt	DBDandois	JTurdick	RMS Scroggins
DATE	11/21/96	11/18/96	11/21/96	11/22/96	11/22/96

OFFICIAL RECORD COPY

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11/22/96 RMB

INVOICE	BILLED AMOUNT	INTEREST AMOUNT	ADMINISTRATIVE CHARGES	PENALTY AMOUNT	TOTAL AMOUNT DUE	COLLECTED AMOUNT	OUTSTANDING {1} AMOUNT DUE	TOTAL AMOUNT DUE {2} LESS ADMIN CHARGES
AM01679-96	\$ 5200	\$ 66.31	\$ 40.00	\$ 85.57	\$ 5391.88	\$ 1832.39	\$ 3559.49	\$ 3367.61
AM03803-95	5500	236.19	150.00	274.90	6161.09	1842.77	4318.32	3657.23
AM03937-94	7570	386.70	260.00	766.21	8982.91	1800.00	7182.91	5770.00
AM04613-93	6320	602.39	390.00	867.24	8179.63	1800.00	6379.63	4520.00
AM04328-92	6350	1154.70	500.00	1142.53	9147.23	1800.00	7347.23	4550.00
AM05184-91	4500	1132.07	620.00	849.96	7102.03	1800.00	5302.03	2780.00
							\$34089.61 {1}	\$24564.84 {2}

{1} Total amount due including interest and late charges

{2} Total amount due if paid within 90-days from the date of this letter

NRC FORM 526
(4-96)
10 CFR 171

U.S. NUCLEAR REGULATORY COMMISSION

INVOICE NUMBER

AM1679-96

LICENSE NUMBER

34-01260-11

**CERTIFICATION OF SMALL ENTITY STATUS
FOR THE PURPOSES OF ANNUAL FEES
IMPOSED UNDER 10 CFR PART 171
FY 96**

To be completed ONLY by those licensees who meet the size standards below. See instructions on reverse side.

NAME AND ADDRESS OF LICENSEE (as it appears on the invoice):

OHIO UNIVERSITY
ONE PRESIDENT ST.
HUDSON Health Center
ATHENS, OH 45701
Attention: Radiation Safety Officer

If a licensee qualifies as a small entity under the size standards below and completes this form (NRC Form 526), the licensee may pay the reduced annual fee for each category applicable to the license. A separate form must be submitted for each invoice. Submit the required reduced annual fee with the "Payment Copy" of the invoice and the NRC Form 526 to:

License Fee and Accounts Receivable
U.S. Nuclear Regulatory Commission
P.O. Box 954514
St. Louis, MO 63195-4514

SIZE STANDARDS (Check one box only)

**MAXIMUM ANNUAL FEE
PER LICENSED CATEGORY
(See item 3 on back)**

1. SMALL BUSINESS

A for-profit concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$5 million or less over its last 3 completed fiscal years.

- ☒ A. \$350,000 TO \$5,000,000
☐ B. LESS THAN \$350,000

\$1,800
\$ 400

2. MANUFACTURING INDUSTRY

A manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

- ☐ A. 35 TO 500 EMPLOYEES
☐ B. LESS THAN 35 EMPLOYEES

\$1,800
\$ 400

3. SMALL ORGANIZATION

A not-for-profit organization which is independently owned and operated and has annual gross receipts of \$5 million or less.

- ☐ A. \$350,000 TO \$5,000,000
☐ B. LESS THAN \$350,000

\$1,800
\$ 400

4. SMALL GOVERNMENTAL JURISDICTION (INCLUDING PUBLICLY SUPPORTED EDUCATIONAL INSTITUTIONS ¹)

A government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

- ☐ A. 20,000 TO 50,000 POPULATION
☐ B. LESS THAN 20,000 POPULATION

\$1,800
\$ 400

5. SMALL EDUCATIONAL INSTITUTION THAT IS NOT STATE OR PUBLICLY SUPPORTED AND HAS 500 OR FEWER EMPLOYEES ¹

- ☐ A. 35 TO 500 EMPLOYEES
☐ B. LESS THAN 35 EMPLOYEES

\$1,800
\$ 400

¹An educational institution referred to in the size standards is an entity whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public.

CERTIFICATION

This certification MUST be signed by the owner of the entity named above or an official empowered to act on behalf of the entity.

I certify that the above named NRC licensee qualifies as a small entity under the size standards established by the NRC for its licensees in 10 CFR 2.810 (60 FR 18344). The licensee qualifies as a small entity under the specific size standard indicated above.

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. The submittal of willful false statements is punishable by fine or imprisonment, or both, and for purposes of this certification, may result in revocation or suspension of the license.

I CERTIFY UNDER PENALTY OF
PERJURY THAT THE FOREGOING
IS TRUE AND CORRECT.

TYPED OR PRINTED NAME AND TITLE

J.L. BROWN
V.P. Product Development

SIGNATURE

J.L. Brown

DATE

8-2-96