

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

12-10057-04

Docket or Reference number

030-15269

Amendment No. 06

Veterans Administration Medical Center
North Chicago, IL 60064

In accordance with letter dated March 20, 1985, License Number 12-10057-04 is amended as follows:

Subitems 6.F., 7.F., 8.F. and 9.F. are amended to read:

6. Byproduct, source,
and/or special nuclear
material

F. Xenon-133

7. Chemical and/or
physical form

F. Gas or gas in solution
that is the subject
of an active (i.e., not
withdrawn or terminated)
"New Drug Application"
(NDA) approved by FDA or
an active (i.e., not
withdrawn, terminated
or on "clinical hold")
"Notice of Claimed
Investigational Exemption
for a New Drug" (IND)
that has been accepted
by FDA

8. Maximum amount that
licensee may possess
at any one time
under this license

F. 200 millicuries

9. Authorized Use

F. For blood flow and pulmonary function studies. For research on human volunteers in accordance with IND 24,978.

Conditions 12. and 22. are amended to read:

12. A. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

T. Balachandra, M.D.

Groups I, II, III, IV and V

In vitro studies

Xenon-133

Subitem O under IND 17,209

Subitem Q as approved by

FDA-approved Radioactive Drug
Research Committee

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12-10057-04 PDR

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Amendment No. 06

M. Breen, Ph.D.

Licensed material for laboratory
research including animal studies

Sant P. Singh, M.D.

Licensed material for laboratory
research including animal studies
In vitro studies

Thomas F. Sinclair, Ph.D.

Chromium-51 for in vitro use

Gregory A. Gergans, M.D.

Groups I, II, III, IV and V
Xenon-133
In vitro studies
Subitem F under IND 24,978

B. The Radiation Protection Officer for the activities authorized by this license
is Santa Loga, Ph.D.

22. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application received February 1, 1979; letter received May 22, 1979; application dated December 23, 1980; letters dated December 12, 1980, June 8, 1981, September 22, 1982 and March 20, 1985; letter and attachment dated April 13, 1983; and ALARA Program dated October 1, 1981. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

Condition 17. is hereby deleted.

For the U.S. Nuclear Regulatory Commission

Original Signed

By B.J. Holt

Materials Licensing Section, Region III

Date 5 23, 1985

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