

Internal Correspondence

MARTIN MARIETTA ENERGY SYSTEMS, INC.

707597

HEALTH SCIENCES RESEARCH DIVISION
 Date: 1/14/94
 To: _____
 From: _____
 Subject: _____

Date: January 12, 1994
To: B. A. Berven
From: F. F. Knapp, Jr., 4501, MS 6229 (4-6225)
Subject: Human Subjects Research

In response to your questions concerning human subjects research, I am writing this memorandum to summarize the regulations regarding our distribution of radioactive materials and the collaborative studies of our ORNL Nuclear Medicine Program. The requirements for ordering a radioisotope from ORNL include completion, submission and approval of the attached DOE Form ER-391 and submission of a current license verifying that the institution can receive the radioactive material.

Since ORNL is not licensed to distribute radioactive materials for human use, radioisotopes are explicitly shipped from ORNL with the understanding that they are not approved for human use, as described on the attached label which indicates the material is "Pharmaceutically Unrefined." Approval and liability for human use are the sole responsibilities of the institution receiving the radioisotopes, since the material was purchased from ORNL as "Unrefined." The physician-sponsored protocols for human use at the collaborating institutions require institutional and regulatory approval. In terms of our interaction with our Medical Cooperative Programs where ORNL radioisotopes are used for human use, we are not considered as "Principal Investigators."

Please contact me if you require any further information or clarification of these points.

FFK:bm

REPOSITORY ORNL RIDGE/ENERGY SYSTEMS
ORNL (X-10)
 COLLECTION HEALTH SCIENCES RESEARCH DIV.
CORRESPONDENCE FILES OF
 BOX No. F.F. KNAPP JR., BLDG. 4501
 FOLDER _____

1024034

A-00003

ORDER NUMBER



**CAUTION:
RADIOACTIVE
MATERIAL**

Pharmaceutically unrefined - "If intended for drug purposes, CAUTION for manufacturing processing or repacking in the preparation of a new drug, limited by Federal law to investigational use, unless recipient holds an effective new drug application."

**OAK RIDGE NATIONAL LABORATORY
OPERATED BY
MARTIN MARIETTA ENERGY SYSTEMS, INC.
FOR THE U.S. DEPARTMENT OF ENERGY**

UCR 2629
13 4 641

DATE

ACTIVITY

1024035

DOE Form ER-391
(4-84)

U.S. Department of Energy

Form Approved
OMB No. 1901-0006

Previous Editions May
Not Be Used

ISOTOPE AND TECHNICAL SERVICE ORDER FORM

This form is to be used by all persons other than Federal Agencies or DOE cost-type contractors ordering byproduct material, technical services, stable isotopes, or cyclotron-produced radioisotopes, or related services from the U. S. Department of Energy. Submit in duplicate. (Use continuation sheet if required.)

1. TO: (Give name and address of facility from which materials or services will be obtained.) U. S. Department of Energy C/O Martin Marietta Energy Systems, Inc. Oak Ridge National Laboratory, Post Office Box 2009 Oak Ridge, Tennessee 37831-8044	2. BUYER'S ORDER NUMBER
	3. DATE

4. SHIP TO:	5. BILL TO:
6. VIA:	

7. MATERIAL OR SERVICE

CATALOG ITEM NO. (If any)	BYPRODUCT MATERIAL OR OTHER RADIOISOTOPE: State isotope, chemical form, desired total activity, specific activity. TECHNICAL SERVICE: State desired service. STABLE ISOTOPE: State isotope, chemical form, quantity, isotopic concentration (specifying desired enrichment, minimum enrichment).	PURCHASE PRICE	RENTAL FEE
<p>"THE NOTICE TO CUSTOMERS, EFFECTIVE JANUARY 1, 1993, WHICH IS ATTACHED HERETO IS MADE A PART OF THIS ORDERS'S TERMS."</p>			
<p>SHIPPING SCHEDULE</p>		<p>Technical Service Charge (if any)</p> <p>Handling Charge (if any)</p>	
		TOTAL	

THIS ORDER IS SUBJECT TO THE TERMS AND CONDITIONS ON REVERSE SIDE

8. The undersigned certifies that he (it) is authorized to receive the above described byproduct material by: (Check block and give license number and expiration date if applicable.)

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- (a) NRC or _____ License No. _____ which expires _____
or (Name of State)
- (b) Exemption or General License provided by U.S. Nuclear Regulatory Commission (NRC) regulations:
or
- (c) Exemption or General License provided by _____ regulations.
(Name of State)

Accepted for the U.S. Department of Energy	9. FROM: Name and address of buyer:
BY _____	BY _____
TITLE _____ DATE _____	DATE _____

Signature: _____

TERMS AND CONDITIONS

The order on the face hereof is placed in accordance with and subject to the following terms and conditions:

1. The term "buyer" as used herein means the person, corporation, partnership, association, firm, or other organization placing this order. The term "Department" means the U.S. Department of Energy. The phrase "persons acting on behalf of the Department" includes employees and contractors of the Department, and employees of such contractors, who fill or participate in the filling of this order pursuant to their employment or their contracts with the Department. The term "Byproduct Material" as used herein means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term "DOE Facility" means a laboratory, plant, or office operated by or on behalf of the Department.

2. The buyer understands and agrees that the Department may fulfill its obligations under this order through the operator of any of its facilities.

3. Materials and services are furnished at prices and service fees as fixed by the Department and in effect on the date of shipment of material or performance of the services. Prices in catalogs issued by the Department or the operator of any facility are subject to change without notice. Payment for materials and for services rendered shall be made promptly upon receipt of billing in accordance with instructions furnished therewith. Payments received after 30 days from date of invoice may result in the billing, at the Department's option, of interest charges at the per-annum rate (365-day basis) established from time to time by the Department for general application to monies due the Department, and so published in the *Federal Register* for past due accounts.

4. When shipment of material pursuant to this order requires the use of returnable Government-owned containers, title to such containers shall remain in the Government. The buyer will keep the containers in good condition, will not use them for any materials other than the materials shipped therein, and will deliver them to a carrier for return to the point of shipment, transportation prepaid, within 30 days from the date of receipt by the buyer of the shipment. The buyer agrees to pay to the Department a demurrage charge on each returnable Government-owned container for that period of retention which is in excess of the said 30-day period.

5. Except as provided in paragraph 7 as to material loaned or rented under this order, material covered by this order will be shipped f.o.b. the DOE facility from which the order is filled, provided, that in case of shipment by rail, f.o.b. shall mean delivery to the nearest railhead of the transporting carrier.

6. Title to material sold under this order shall pass to the buyer when such material is delivered to the carrier.

7. As to any material loaned or rented under this order:

- (a) Title to any material procured on a rental or loan basis under this order shall remain in the Department.
- (b) Upon expiration or earlier termination of the loan or rental period, as provided on the face of this order, the buyer shall return such material to the Department or designated DOE facility, together with a statement describing use made of the material.
- (c) Unless otherwise expressly provided for, on the face of this order, the buyer shall not expend, alter, destroy, contaminate, or dilute such material. The buyer shall be responsible and shall reimburse the Department for any loss, contamination, dilution, consumption of, or damage to, the material loaned or rented hereunder from the time of delivery of such material to the buyer until the material has been returned to the Department or designated DOE facility, or to a carrier for such return.

8. Neither the Government, the Department, nor persons acting on behalf of the Department makes any warranty or other representation, express or implied, that (a) materials accepted for a technical service will not be destroyed, damaged, lost, or otherwise altered in physical or chemical properties in the process of performing the requested technical service, or that (b) materials furnished under this order (1) will not result in injury or damage when used for purposes authorized by the Department or for any other purpose or use, or (2) will accomplish the results for which they are requested or intended.

9. If the quantity, quality, or physical or chemical properties, or form of material delivered under this order do not conform to the specifications set forth in item 7 on the face of this order the responsibility and liability of the Government, the Department, and of persons acting on behalf of the Department shall be limited solely to making reasonable efforts to correct such discrepancies by delivery of material which does conform to said specifications. The buyer agrees to report promptly any discrepancies between the materials supplied and that ordered so that replacement or other appropriate adjustment may be made. The Department will reimburse the buyer for reasonable costs of packaging and transportation incurred by the buyer in returning to the Department any material which does not conform to such specifications.

10. The Department will make reasonable efforts to perform services, or deliver material, at the time or times provided on the face of this order, but neither the Government, the Department, nor persons acting on behalf of the Department shall be subject to any liability for failure to do so.

11. Prior to delivery of material covered by this order, and upon timely request by the buyer, the Department will permit the buyer to cause said material to be tested or measured for conformity to specifications.

12. Unless otherwise expressly provided for in this order, materials supplied by the buyer for technical service, and analysis by the Department may be disposed of in accordance with the usual Department or DOE facility disposal procedures for radioactive materials and the buyer shall have no claim for the value or replacement of materials thus disposed of, provided, when the materials supplied by the buyer are held or stored by the Department in accordance with instructions of the buyer, or in order to protect health or to minimize other hazards to life or property, the buyer will pay all storage charges connected therewith. The buyer shall arrange for and bear the expenses of all other storage of such materials and the transportation of materials which are not to be disposed of by the Department.

13. The Department reserves the right to cancel this order (a) in the event the buyer's license (where applicable) is suspended, canceled, or revoked, or (b) when cancellation of this order is determined to be necessary to the national defense and security of the United States.

14. The Department shall have the right to publish and use any information or data developed or produced by the Department or persons acting on behalf of the Department in the course of or in connection with the technical service, testing, or analysis of materials or other services performed hereunder for the buyer, whether such materials are furnished by the buyer or the Department.

15. The buyer agrees to indemnify the Government, the Department, and persons acting on behalf of the Department against liability, including costs and expenses incurred, for infringement of any Letters Patent occurring in the course of the performance of any service, analysis, or test performed for the buyer as a result of following specific instructions of the buyer in connection therewith, or occurring in the utilization by the buyer of any material procured hereunder, provided, that insofar as such materials are prepared or used or services utilized in the performance of a Government contract, this indemnity agreement shall not apply unless such Government contract contains provisions indemnifying the Government against patent infringement.

16. Data supplied on this form will be held confidential only to the extent that is determined to be within the exemption for trade secrets and confidential commercial information as specified in the Freedom of Information Act 15 U S C Section 552(b)(4).

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Signature: _____

MARTIN MARIETTA ENERGY SYSTEMS, INC.
(ACTING UNDER U.S. GOVERNMENT CONTRACT DE-AC05-840R21400
WITH THE U.S. DEPARTMENT OF ENERGY)
* * * * NOTICE TO CUSTOMERS * * * *
EFFECTIVE JANUARY 1, 1993

INTEREST, ADMINISTRATIVE CHARGES, AND PENALTIES ON PAST DUE INVOICES

Martin Marietta Energy Systems, Inc., (Energy Systems) is a U. S. Department of Energy (DOE) Management and Operating Contractor, as defined in the Federal Acquisitions Regulations, Subpart 17.6 - Management and Operating Contracts. As such, Energy Systems is a dedicated business unit established exclusively for the purpose of managing and operating certain production, fabrication and research facilities for the DOE. In this capacity, Energy Systems is required to invoice and collect for any services, fabrication or research performed at the Government-owned, contractor-operated facilities, including work for other Federal agencies. All collections are deposited directly to the U. S. Treasury. Any indebtedness is money due the United States Government. The collection of debt, including the assessment of interest, penalties and administrative charges, is governed by the provisions of the Federal Claims Collection Act of 1966 (31 U.S.C. 3701-3719), the Debt Collection Act of 1982 (Public Law 97-365), as amended, the revised Federal Claims Collection Standards (4 CFR 101-105), and OMB Circular A-129. Energy Systems is the DOE's agent in collecting amounts due the DOE for the following DOE facilities: Oak Ridge National Laboratory, Y-12 Plant, Oak Ridge Gaseous Diffusion Plant and Paducah Gaseous Diffusion Plant.

Pursuant to the above laws and standards, payments not received within 30 days of the invoice date will be assessed interest on the amount due from the invoice date through the date of payment. A late payment handling charge shall be imposed on delinquent invoices for each 30-day period of delinquency or portion thereof. A penalty on any principal amount not paid within 90 days of the due date will be assessed from the date the debt becomes delinquent through the date of payment. Credit will be suspended and shipments will be stopped or services interrupted when an invoice is over 30 days past due. Interest and other late payment charges duly assessed are not waived by payment of principal. The collection actions, including the use of credit bureaus, administrative offset, holdup lists, suspension of eligibility, liquidation of collateral, collection agencies, or litigation, made available under the laws and standards cited above will be used as necessary to ensure the collection of the amount due. Interest rates, administrative charges and penalties are subject to change. The current rates are:

- Interest Rate: 4% per annum
- Administrative Charge per Delinquent Invoice per 30-day Period: \$13.75*
- Penalty Rate: 6% per annum

Interest and late charges do not apply to other Federal agencies and other management and operating contractors of the DOE, nor to State and local governments and their agencies.

Amounts received as partial payments will be applied first to accrued penalties, then to accrued administrative charges, then to accrued interest, and finally to the principal, pursuant to 4 CFR 102.13(f).

Address for Correspondence Regarding Invoices:

Martin Marietta Energy Systems, Inc.
Attention: Central Accounting
Post Office Box 2003
Oak Ridge, Tennessee 37831-7057

Remittance Addresses:

By wire:

FIRST TN MEM
ABA #084000026
FOR CREDIT FTB-KNOX
FOR FURTHER CREDIT MARTIN MARIETTA ENERGY SYSTEMS, INC.

By mail:

MARTIN MARIETTA ENERGY SYSTEMS, INC.
P. O. Box 100259
Atlanta, Georgia 30384-0259

For amounts over \$10,000, please use wire payments to assure timely receipt.

*Minimum charge. This amount does not include such charges as credit reports, court costs, attorney's fees and fees for outside collection agencies. These additional administrative costs will be assessed as incurred.

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