

which subpopulations are exposed to a product. The draft guidance also does not discuss increasing the total number of participants or members of a subpopulation in clinical trials.

This draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in sections III and IV of this draft guidance are approved under OMB control number 0910–0014.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to collect race and ethnicity data in certain clinical trials for FDA regulated products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 24, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–2162 Filed 1–29–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[NM–090–03–9971–EK]

### Conservation Helium Sales

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice implementing first Conservation Helium sale.

**SUMMARY:** The purpose of this action is to implement the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale*, beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, Texas. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region, and that given the current market, Conservation Helium sold in this sale will likely minimize market disruption. The Bureau just concluded a 30-day comment period in which eight comments were received. The comments were generally supportive with mainly long-term concerns expressed. The Bureau made some minor modifications to address concerns expressed by those comments.

**DATES:** Submit bids and other documentation as required in notice on or before March 3, 2003.

**ADDRESSES:** You may submit your bids and other documentation as required in this notice to the Bureau of Land Management, Amarillo Field Office, 810 S. Fillmore, Suite 500, Amarillo, TX 79101, Attention: Crude Helium Sale.

**FOR FURTHER INFORMATION CONTACT:** Timothy R. Spisak, (806) 356–1002. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., eastern time, Monday through Friday.

#### SUPPLEMENTARY INFORMATION:

### 1.01 What Is the Purpose of the Sale?

The purpose of this sale is to begin implementation of the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale*, beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, TX. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a

supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region. This is the first of 12 annual sales that the Department will conduct to dispose of the Conservation Helium stored underground at the Cliffside Field. The annual sales are being conducted in a manner intended to prevent pure helium market disruptions from occurring to end users; shortages of crude helium to pure helium refiners; and an oversupply of crude helium on the market for crude helium extractors. This first sale will be used to test the disposal process with subsequent sales adjusted as needed.

### 1.02 What Terms Do I Need To Know To Understand This Sale?

**Allocated Sale**—That portion of the annual sale volume of Conservation Helium that will be set aside for purchase by the crude helium refiners.

**Annual Conservation Helium Sale**—The sale of a certain volume of Conservation Helium to private entities conducted annually beginning no later than 2005.

**Bidder**—Any entity or person who submits a request for purchase of a volume of the annual Conservation Helium sale and has met the qualifications contained in part 1.05 in this notice.

**BLM**—The Bureau of Land Management.

**Conservation Helium**—The crude helium purchased by the U.S. Government under the authority of the Helium Act of 1960 and stored underground in the Cliffside Field.

**Crude Helium**—A partially refined gas containing about 70 percent helium and 30 percent nitrogen. However, the helium concentration may typically vary from 50 to 95 percent.

**Crude Helium Refiners**—Those entities with a capability of refining crude helium and having a connection point on the crude helium pipeline and a valid helium storage contract as of the date of a Conservation Helium sale.

**Excess Volumes**—Allocated sale volumes not requested by the crude helium refiners.

**Helium Storage Contract**—A contract between the BLM and a private entity allowing the private entity to store crude helium in underground storage at the Cliffside Field.

**HPA**—The Helium Privatization Act of 1996.

**In-Kind Crude Helium**—Conservation Helium purchased by private refiners in exchange for like amounts of pure helium sold to Federal agencies and

their contractors in accordance with the HPA.

*MMcf*—One million cubic feet of gas measured at standard conditions of 14.65 pounds per square inch (psi) and 60° F.

*Mcf*—One thousand cubic feet of gas measured at standard conditions of 14.65 psi and 60° F.

*Non-allocated Sale*—That portion of the annual sale volume of Conservation Helium that will be offered to all qualified bidders.

### **1.03 What Volume of Conservation Helium Will Be Offered in the Year 2003 Annual Conservation Helium Sale?**

The volume of helium available for this sale is 2,100 MMcf. In accordance with the HPA, this volume was determined by dividing the total volume of stored Conservation Helium less the statutory required reservation of 600 MMcf for government purposes less estimated in-kind crude helium transfers for 12 years divided by 12.

### **1.04 At What Price Will the Conservation Helium Be Sold?**

The Conservation Helium will be sold at the same price as in-kind crude helium. In accordance with the HPA, this price covers helium debt repayment and includes administrative and storage costs associated with the Conservation Helium. For Fiscal Year 2003, that price is \$52.50 per Mcf.

### **1.05 Am I Qualified To Purchase Conservation Helium at This Sale?**

Any person, firm, partnership, joint stock association, corporation, or other domestic or foreign organization operating partially or wholly within the United States who meets one or more of the following requirements is qualified to submit a purchase request:

- Operates a helium purification plant within the U.S., or
- Operates a crude helium extraction plant within the U.S., or
- Is a wholesaler of pure helium or purchases helium for resale within the U.S., or
- Is a consumer of pure helium within the U.S., or
- Has an agreement with a helium refiner to provide its helium processing needs, commonly referred to as a "tolling agreement."

All entities requesting participation in the Non-allocated Sale must submit proof of being qualified to purchase Conservation Helium and must either have a Helium Storage Contract with the BLM or have a third-party agreement in place with a valid storage contract holder so that all Conservation Helium

sold to the Bidder will be properly covered by a Helium Storage Contract (including associated storage charges).

### **1.06 When Will the Conservation Helium Be Offered for Sale?**

The BLM, Amarillo Field Office, will accept requests for purchase of Conservation Helium from final publication of this notice until March 3, 2003. On the next business day after this notice closes, requests to purchase Conservation Helium will be opened and evaluated. Thereafter, volumes of this Conservation Helium sale will be apportioned and allocated according to the sale rules described in this notice.

### **1.07 What Must I Do To Submit a Request for Purchase?**

You must submit the following information to the BLM, Amarillo Field Office:

- Billing address information and name(s) of principle officers of the company.
- Proof of being an entity qualified to purchase Conservation Helium at this sale as defined in part 1.05 above. Documents such as invoices for sale or purchase of helium, helium storage contracts, or other relevant documents may be submitted as proof of qualification.
- The amount (in Mcf) of Conservation Helium requested.
- Certified check or money order in the amount of \$1,000 made payable to the Bureau of Land Management. This money will be used to cover administrative expenses to conduct this sale and is nonrefundable.

### **1.08 Where Do I Send My Request for Purchase?**

All requests for purchase of helium as part of this sale must be sent by certified mail to: Bureau of Land Management, Amarillo Field Office, 810 S. Fillmore, Suite 500, Amarillo, TX 79101, Attention: Crude Helium Sale.

### **1.09 When Do I Need To Submit Payment For Any Conservation Helium Sold To Me?**

Successful purchasers will submit payments according to the following schedule: 25% by February 28, 2003, or 30 days after notification of the award volumes, whichever is later; 25% by April 30, 2003; 25% by June 30, 2003; 25% by September 30, 2003.

Conservation Helium will not be transferred to the purchaser's storage account until payment is received for that portion. Successful purchasers may, at their option, accelerate the purchase schedule.

### **1.10 To Whom Do I Make Payments for Awarded Conservation Helium Volumes?**

Make checks payable to the Bureau of Land Management at the address listed in part 1.08 in this notice.

### **1.11 What Are the Penalties for Not Paying for the Conservation Helium in a Timely Manner?**

If a payment is not received by the due date, the purchaser will forfeit the remainder of its allotment unless the purchaser can show that payment was late through no fault of its own. However, penalty interest will be assessed in accordance with the Debt Collection Act of 1982, 31 U.S.C. 951–953.

### **1.12 How Will I Know if I Have Been Successful in My Purchase Request?**

Successful purchasers will be notified in writing by BLM no later than 2 weeks after the close of this notice with the awarded volumes and payment schedule.

### **Allocated Sale**

#### **2.01 What Is the Allocated Sale?**

That portion of the annual sale volume of Conservation Helium that will be set aside for purchase by the crude helium refiners.

#### **2.02 Who Will Be Allowed To Purchase Conservation Helium in the Allocated Sale?**

Only those who meet the definition of crude helium refiners as defined in part 1.02 in this notice.

#### **2.03 What Volume of Conservation Helium Is Available in the Allocated Sale?**

The amount available will be 90 percent of the total volume of the annual Conservation Helium sale—1,890 MMcf.

#### **2.04 How Will the Conservation Helium Be Apportioned Among the Refiners?**

The apportionment to each crude helium refiner will be based on its percentage share (rounded to the nearest 1/10th of 1 percent) of the total refining capacity as of October 1, 2000, connected to the BLM crude helium pipeline.

#### **2.05 What Will Happen if a Refiner or Refiners Request an Amount Other Than Their Share of What Is Offered for Sale?**

- If one or more refiners request less than their allocated share, any other refiner(s) that requested more than their share will be allowed to purchase the

excess volume based on proportionate shares of remaining refining capacities.

- Requests by the Crude Helium Refiners that are in excess of the amount available above will be carried over to the Non-allocated Sale and considered a separate bid under the Non-allocated Sale rules.

### 2.06 What Will Happen if the Total Amount Requested by the Crude Helium Refiners Is Less Than the 1,890 MMcf Offered in the Allocated Sale?

Any excess volume not sold to the crude helium refiners will be added to the non-allocated sale volume.

### 2.07 Do You Have a Hypothetical Example of How an Allocated Sale Would Be Conducted?

2,100 MMcf available for total sale with 90 percent available for allocated sale (1,890 MMcf).

| Bidder-allocated sale | Installed refining capacity (percent) | Refiner bid volume* | Allocated volume* | Excess volume requested* | Proration percent | Excess allocated* | Total allocated* | Carry over to non-allocated sale* |
|-----------------------|---------------------------------------|---------------------|-------------------|--------------------------|-------------------|-------------------|------------------|-----------------------------------|
| Refiner A .....       | 10                                    | 225                 | 189               | 36                       | 20                | 36                | 225              | 0                                 |
| Refiner B .....       | 50                                    | 750                 | 750               | 0                        | 0                 | 0                 | 750              | 0                                 |
| Refiner C .....       | 40                                    | 985                 | 756               | 229                      | 80                | 156 + 3           | 915              | 70                                |
| Total .....           | 100                                   | 1,960               | 1,695             | 265                      | 100               | 195               | 1,890            | 0                                 |

\*All volumes in MMcf.

After the initial allocation, Refiner B has received all requested. However, 265 MMcf is deemed excess of the total in the first iteration of the allocated sale and reallocated to the two remaining refiners based on the refining capacity between them. With the reallocation, Refiner A gets all requested, but Refiner C is still short by 73 MMcf. Additionally, 3 MMcf remains unallocated and without any other Refiners is awarded to Refiner C, who now has a remaining request of 70 MMcf that is posted into the non-allocated sale. All percentages used in the calculation will be rounded to the nearest 1/10th of 1 percent. All volumes calculated will be rounded to the nearest 1 Mcf.

### Non-allocated Sale

#### 3.01 What Is the Non-Allocated Sale?

That portion of the annual sale volume of conservation helium that will be offered to all qualified bidders.

#### 3.02 What Is the Minimum Volume I Can Request?

The minimum request is 5 MMcf.

#### 3.03 What Volume of Conservation Helium Is Available for the Non-allocated Sale?

The total volume of Conservation Helium available for this portion of the sale is 210 MMcf plus any additional helium that is not sold as part of the allocated sale.

#### 3.04 How Is the Ratio of Allocated to Non-Allocated Sale Volumes Determined?

According to the terms of the HPA, the BLM must conduct the annual Conservation Helium sales in a manner not to cause undue helium market disruptions; and therefore, the majority of the Conservation Helium is being offered as part of the allocated sale. Currently, the crude helium refiners have refining capacity roughly double what can be supplied through the annual Conservation Helium sales. Although there are other crude helium supplies available to the crude helium refiners, these supplies are declining each year. The BLM must be sensitive to the crude helium refiners requirements while maintaining a balance with other helium industry requirements. The exact ratio of allocated to non-allocated sale volumes may change for subsequent annual Conservation Helium sales.

#### 3.05 How Will the Non-Allocated Conservation Helium Be Apportioned Among the Bidders?

The Conservation Helium will be apportioned equally in 1 Mcf increments among the bidders with no prospective bidder receiving more than its request.

#### 3.06 What Will Happen if the Bidders Request More Than What Is Made Available for Sale in Part 3.03 of This Notice?

- If one or more bidders request less than their apportioned amount, any

other bidder(s) that requested more than its apportioned amount will be allowed to purchase equally apportioned amounts of the remaining volume available for this sale.

- If all bidders request more than their apportioned amount each bidder will receive its apportioned amount as determined in part 3.05 in this notice.

#### 3.07 What Will Happen if a Bidder Requests Less Than Its Apportioned Amount?

Any bidder requesting less than the calculated apportioned volume, will receive the amount of its request and amounts remaining will be reapportioned in accordance with part 3.05 in this notice.

#### 3.08 What Will Happen if the Total Requests From All Bidders Are Less Than That Offered for Sale in the Non-Allocated Sale?

If the total non-allocated volume requested is less than the non-allocated volume offered for this portion of the sale, the excess amount will not be sold and will be held in storage for future sales.

#### 3.09 Do You Have a Hypothetical Example of How a Non-Allocated Sale Would Be Conducted?

2,100 MMcf available for total sale with 10 percent available for non-allocated sale (210 MMcf).

| Bidder—non-allocated sale | Bid volume* | Apportioned volume* | Excess volume requested* | Proration percent | Excess apportioned* | Total apportioned* | Amount requested not received* |
|---------------------------|-------------|---------------------|--------------------------|-------------------|---------------------|--------------------|--------------------------------|
| Refiner C .....           | 70          | 52.5                | 17.5                     | 50                | 15                  | 67.5               | 2.5                            |
| Company D .....           | 100         | 52.5                | 47.5                     | 50                | 15                  | 67.5               | 32.5                           |

| Bidder—non-allocated sale | Bid volume* | Apportioned volume* | Excess volume requested* | Proration percent | Excess apportioned* | Total apportioned* | Amount requested not received* |
|---------------------------|-------------|---------------------|--------------------------|-------------------|---------------------|--------------------|--------------------------------|
| Company E .....           | 50          | 50                  | 0                        | 0                 | 0                   | 50                 | 0                              |
| Company F .....           | 25          | 25                  | 0                        | 0                 | 0                   | 25                 | 0                              |
| Total .....               | 245         | 180                 | 65                       | 100               | 30                  | 210                | 35                             |

\* All volumes in MMcf.

In this example, three companies submit a request and there is a carryover amount from one of the crude helium refiners in the allocated sale that is considered as a separate request. Each bidder would be apportioned 52.5 MMcf, (*i.e.*, 210 MMcf of non-allocated Conservation Helium ÷ 4 bidders = 52.5 MMcf per bidder). After the initial allocation, Companies E and F have received all they requested. However, 30 MMcf is deemed excess in the first iteration of the non-allocated sale and reallocated to the two remaining bidders. With the reallocation, Refiner C and Company D each receives an additional 15 MMcf. No more helium is available, Refiner C and Company D do not receive all that they requested, and the sale is complete. All percentages used in the calculation will be rounded to the nearest 1/10th of 1 percent. All volumes calculated will be rounded to the nearest 1 Mcf.

Dated: December 13, 2002.

**Timothy R. Spisak,**

*Acting State Director, New Mexico.*

[FR Doc. 03-2048 Filed 1-29-03; 8:45 am]

**BILLING CODE 4310-FB-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[AK-023-03-1310-PB-018L-241A]

#### National Petroleum Reserve—Alaska Research and Monitoring Advisory Team (RMT) Public Meeting

**AGENCY:** Northern Field Office, Bureau of Land Management, Interior.

**ACTION:** Notice of the National Petroleum Reserve—Alaska Research and Monitoring Advisory Team Public Meeting.

**SUMMARY:** A joint public meeting of the National Petroleum Reserve—Alaska Research and Monitoring Advisory Team and the NPR-A Subsistence Advisory Panel (SAP) will be held in Barrow, Alaska, on March 18–19, 2003, to discuss research and monitoring needs in the NPR-A and to make recommendations to the Authorized Officer on priority projects to be implemented by the BLM. This will also

be the first joint meeting of the RMT and SAP as stipulated in the charter of the RMT.

**DATES:** The public meeting will be held at the Iñupiat Heritage Center in Barrow, Alaska, on March 18–19, 2003. A field trip to view a winter seismic operation is tentatively planned for March 20. Hours of the meeting have not yet been set. Please call the phone number below for a time update.

**PUBLIC PARTICIPATION:** This meeting is open to the public.

**FOR FURTHER INFORMATION CONTACT:** Additional information concerning the NPR-A Research and Monitoring Advisory Team may be obtained from Herb Brownell, Arctic Team Manager, BLM Northern Field Office, 1150 University Avenue, Fairbanks, Alaska 99709–3844. Mr. Brownell may be reached at (907) 474–2333 or at 1–800–437–7021, x2333, or at [Herb\\_Brownell@ak.blm.gov](mailto:Herb_Brownell@ak.blm.gov).

**SUPPLEMENTARY INFORMATION:** The RMT's membership represents the BLM, Minerals Management Service, Department of Energy, U.S. Fish and Wildlife Service, U.S. Geological Survey—Biological Resources Division, the North Slope Borough, the oil and gas industry, environmental/resource conservation organizations, natural resource management/science academicians, and the public at large. The RMT advises the BLM in assessing the effectiveness and appropriateness of mitigative stipulations established in the Northeast NPR-A Integrated Activity Plan/Environmental Impact Statement, Record of Decision, 1998. The team focuses on assessing NPR-A research and monitoring needs, developing and recommending research priorities, and applying improved technology and operating practices to oil and gas exploration and development in the NPR-A.

The Subsistence Advisory Panel advises the BLM on how subsistence resources, uses, and users may be impacted by oil and gas exploration and development in the NPR-A.

Dated: January 23, 2003.

**Robert W. Schneider,**

*Field Manager, Northern Field Office, Bureau of Land Management.*

[FR Doc. 03-2153 Filed 1-29-03; 8:45 am]

**BILLING CODE 4310-JA-P**

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Notice of extension of an information collection (1010-0128).

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), we are inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR 250, Subpart O, "Well Control and Production Safety Training."

**DATES:** Submit written comments by March 31, 2003.

**ADDRESSES:** Mail or hand carry comments to the Department of the Interior; Minerals Management Service; Attention: Rules Processing Team; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170-4817. If you wish to e-mail comments, the address is: [rules.comments@mms.gov](mailto:rules.comments@mms.gov). Reference "Information Collection 1010-0128" in your e-mail subject line and mark your message for return receipt. Include your name and return address in your message.

**FOR FURTHER INFORMATION CONTACT:** Arlene Bajusz, Rules Processing Team, (703) 787-1600. You may also contact Arlene Bajusz to obtain a copy, at no cost, of the regulations that require the subject collection of information.

#### SUPPLEMENTARY INFORMATION:

*Title:* 30 CFR 250, Subpart O, Well Control and Production Safety Training.  
*OMB Control Number:* 1010-0128.