

**§ 640.74 Modification of Source Plasma.**

(a) Upon approval by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, of a supplement to the biologics license application for Source Plasma, a manufacturer may prepare Source Plasma as a liquid product for a licensed blood derivative manufacturer who has indicated a need for a liquid product.

(b) \* \* \*

(2) \* \* \* Such evidence may be submitted by either the licensed manufacturer of the Source Plasma Liquid or the manufacturer of the final blood derivative product who has requested the Source Plasma Liquid.

\* \* \* \* \*

**PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS**

62. The authority citation for 21 CFR part 660 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

63. Section 660.21 is amended by revising paragraphs (a)(3) and (d) to read as follows:

**§ 660.21 Processing.**

(a) \* \* \*

(3) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a subplot. If lots are to be subdivided, the manufacturer shall include this information in the biologics license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

\* \* \* \* \*

(d) *Volume of final product.* Each manufacturer shall identify the possible final container volumes in the biologics license application.

\* \* \* \* \*

64. Section 660.30 is amended by revising paragraph (b) to read as follows:

**§ 660.30 Reagent Red Blood Cells.**

\* \* \* \* \*

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

65. Section 660.33 is amended by revising the fifth sentence to read as follows:

**§ 660.33 Testing of source material.**

\* \* \* Where fewer than three donor sources of an antibody specificity are available, test discrepancies shall be resolved in accordance with the manufacturer's biologics license application. \* \* \*

Dated: August 30, 1999.

**Jane E. Henney,**

*Commissioner of Food and Drugs.*

**Donna E. Shalala,**

*Secretary of Health and Human Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 25**

**Environmental Impact Considerations**

*CFR Correction*

In Title 21 of the Code of Federal Regulations, parts 1 to 99, revised as of Apr. 1, 1999, page 240, § 25.32 is corrected by reinstating text missing from the end of paragraph (i) and the beginning of paragraph (j). In the eighth line of paragraph (i) "percdditive" is corrected to read "percent additive" and the following text is added between the words "percent" and "additive":

**§ 25.32 Foods, food additives, and color additives.**

\* \* \* \* \*

(i) \* \* \* -by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food \* \* \*

\* \* \* \* \*

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**DEPARTMENT OF THE INTERIOR**

**Minerals Management Service**

**30 CFR Parts 202 and 206**

**RIN 1010-AB57**

**Training Sessions on Gas Valuation for Indian Leases**

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of training sessions.

**SUMMARY:** The Minerals Management Service is offering six training sessions

on our revised Indian gas valuation regulations that are effective January 1, 2000.

**DATES:** See SUPPLEMENTARY INFORMATION section for meeting dates.

**ADDRESSES:** See SUPPLEMENTARY INFORMATION section for meeting addresses.

**FOR FURTHER INFORMATION CONTACT:** Ms. Vicki Skinner, Royalty Valuation Division, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3152, Denver, CO 80225-0165; telephone number (303) 275-7241, fax number (303) 275-7227.

**SUPPLEMENTARY INFORMATION:** The dates and locations of the training sessions are as follows:

1. *Oklahoma City, OK:* November 1, 1999, 9 a.m. to 4 p.m., Central time. Clarion Airport West Hotel, 737 S. Meridian, Oklahoma City, OK 73108; telephone number (405) 942-8511.

2. *Tulsa, OK:* November 3, 1999, 9 a.m. to 4 p.m., Central time. Radisson Inn, 2201 N. 77th East Ave., Tulsa, OK 74115; telephone number (918) 835-9911.

3. *Farmington, NM:* November 16, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 600 E. Broadway, Farmington, NM 87401; telephone number (505) 327-9811.

4. *Houston, TX:* November 30, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Hotel, 9090 Southwest Freeway, Houston, TX 77074; telephone number (713) 995-0123.

5. *Dallas, TX:* December 6, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Market, 2727 Stemmons Freeway, Dallas, TX 75207; telephone number (214) 630-5332.

6. *Denver, CO:* December 15, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 14707 W. Colfax Ave., Golden, CO 80401; telephone number (303) 279-7611.

MMS published revised Indian gas valuation regulations in the **Federal Register** on August 10, 1999 (64 FR 43506). The revised regulations add alternative valuation methods to existing regulations to ensure that Indian lessors receive maximum revenues from their mineral resources as required by the unique terms of Indian leases and MMS's trust responsibility to Indian lessors. The revised regulations will also improve the accuracy of royalty payments at the time royalties are due.

If you produce gas from Indian lands, the new regulations affect you, and we strongly encourage you to attend one of these training sessions. Some of the topics that will be covered include:

- How do you value gas in an index zone using the index-based formula?
- How do you value gas not in an index zone?
- How do you make a dual accounting election?
- What are the changes to transportation and processing allowances?

MMS is offering these training sessions at no cost to oil and gas industry representatives and members of the public who have an interest in the valuation of gas produced from Indian lands. You must make your own travel and hotel reservations for the training. MMS will not reserve blocks of rooms.

If you plan to attend training, please register for the session by calling or sending a fax to Vicki Skinner at the telephone or fax numbers in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Seating is limited, and we need to know the number in your party.

**Joan Killgore,**

*Acting Associate Director for Royalty Management.*

[FR Doc. 99-27311 Filed 10-19-99; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### National Park Service

#### 36 CFR Part 13

RIN 1024-AB99

#### Glacier Bay National Park, AK; Commercial Fishing Regulations

**AGENCY:** National Park Service (NPS), Interior.

**ACTION:** Final rule.

**SUMMARY:** This final rule represents a major step towards a comprehensive resolution of commercial fishing issues in Glacier Bay National Park. In accordance with the provisions of Section 123 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for FY 1999 (Section 123), as amended, the rule establishes special regulations for commercial fishing in the marine waters of Glacier Bay National Park. The rule implements provisions in Section 123 by: closing specifically identified areas of non-wilderness waters in Glacier Bay proper and all wilderness waters within Glacier Bay National Park to commercial fishing; limiting commercial fishing in Glacier Bay proper to three specific commercial fisheries; establishing a "grandfathering" process to allow qualifying fishermen in the three authorized commercial fisheries to continue fishing in the remaining waters

of Glacier Bay proper under nontransferable lifetime permits; and, clarifying that the marine waters of Glacier Bay National Park outside of Glacier Bay proper will remain open to various existing commercial fisheries. Section 123 also directs that authorized commercial fisheries be managed in accordance with a cooperatively developed state/federal fisheries management plan. The cooperative state/federal fisheries management plan is being developed independent of this rule and will be announced at a later date.

**DATES:** This rule is effective on October 20, 1999, with the exception of paragraphs (a)(10)(i)-(iii) which take effect on January 1, 2000.

**ADDRESSES:** Tomie Lee, Superintendent, Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, Alaska 99826.

E-mail address is *glba-administration@nps.gov*.

**FOR FURTHER INFORMATION CONTACT:**

Tomie Lee, Superintendent, Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, Alaska, 99827, Phone (907) 697-2230; fax (907) 697-2654.

**SUPPLEMENTARY INFORMATION:**

#### Background

The background section in the re-proposed rule of August 2, 1999 (64 FR 41854), includes a comprehensive chronology of Glacier Bay's commercial fishing history that outlines the circumstances and events leading to this final rule. That information is unchanged and has continuing applicability. The National Park Service (NPS) wishes to note that numerous extensions to the public comment period on the 1997 proposed rule afforded the public a prior opportunity to comment on Section 123 (see *e.g.*, 63 FR 68655, December 11, 1998; 64 FR 1573, January 11, 1999). The re-proposed rule was published, in part, to fulfill the requirement of Section 123, as amended by Pub. L. 106-31 (May 21, 1999), which directed the Secretary of the Interior to re-publish the rule and provide an opportunity for the public to comment for not less than 45 days.

To comply with Section 123, the rule, in part, amends the general regulatory prohibition on commercial fishing activities in units of the National Park System, and authorizes various existing commercial fisheries to continue in most marine waters of Glacier Bay National Park subject to a cooperatively developed state/federal fisheries management plan.

The other provisions of the rule also conform to the requirements of Section 123. The rule limits commercial

fisheries in Glacier Bay proper to pot and ring net fishing for Tanner crab, longlining for halibut, and trolling for salmon. The rule describes eligibility criteria that allow certain fishermen with a sufficient, recent, reoccurring history of participation in Glacier Bay proper fisheries to continue fishing in Glacier Bay proper for their lifetimes. The final rule adopts October 1, 2000, as the deadline to apply for a lifetime permit. Beginning October 1, 2000, a lifetime permit is needed in order to fish in Glacier Bay proper. To qualify, fishermen must be able to document that they have fished in Glacier Bay proper in one of the three authorized commercial fisheries as follows: For the halibut fishery, 2 years of participation are required in Glacier Bay proper during the 7-year period, 1992 through 1998. For the salmon and Tanner crab fisheries, 3 years of participation are required in Glacier Bay proper during the 10-year period, 1989 through 1998. The 7-year qualifying period for halibut is based, in large part, on the establishment of a statistical sub-area for Glacier Bay proper in 1992. Use of this qualifying period specific to this sub-area will assist fishermen in documenting, and NPS in identifying, a history of fishing within Glacier Bay proper. A 10-year qualifying period is used for the Tanner crab and salmon fisheries. These qualifying periods (of 7 and 10 years, respectively) are intended to provide a better opportunity for fishermen with a variable but reoccurring history of participation in these fisheries, in Glacier Bay proper, to qualify for the lifetime access permits. Essentially, these criteria require fishermen to have fished in Glacier Bay proper for approximately 30% of the years during the 7 and 10-year base periods to qualify for lifetime access to an authorized fishery.

The rule also describes the application requirements and procedures for fishermen to follow to apply for a lifetime access permit for an authorized fishery in Glacier Bay proper. The rule requires that applicants: demonstrate that they hold a valid state limited entry commercial fishing permit, and for halibut an International Pacific Halibut Commission quota share, for the fishery in Glacier Bay proper; provide a sworn and notarized affidavit attesting to their history and participation in the fishery within Glacier Bay proper; and, provide other documentation that corroborates their participation in the fishery in Glacier Bay proper during the qualifying years. The rule requires applicants to