

§ 211.1 Scope.

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(d)(1) The Director of the Center for Drug Evaluation and Research (CDER) and the CDER Director of the Office of Compliance each may approve a request from a manufacturer of positron emission tomography (PET) drug products for an exception or alternative to any requirement of this part pertaining to current good manufacturing practice for PET drug products.

(2) An approval under paragraph (d)(1) of this section may be withdrawn if either Director finds that such exception or alternative is no longer justified. Withdrawal of such approval shall be accomplished by providing written notice of such withdrawal, and the reasons for the withdrawal, to the original requestor.

Dated: April 15, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR**Minerals Management Service****30 CFR Part 218**

RIN 1010-AC01

**Amendments to Regulations
Governing Collection of Royalties,
Rentals, Bonuses, and Other Monies
Due the Federal Government**

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rulemaking.

SUMMARY: MMS is amending its regulations that specify how payments are made for mineral lease royalties, rentals, and bonuses. The changes are needed to incorporate revised U.S. Treasury requirements. Also, MMS has clarified language for other parts of this regulation.

DATES: Effective date May 22, 1997.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The principal authors of this rule are David J. Menard of the Reports and Financial Division, Financial Branch, Jim McNamee of the Office of Policy and Management Improvement, and David S. Guzy of the Rules and Procedures Staff, Lakewood, Colorado.

I. Background

The purpose of this final rule is to comply with the U.S. Treasury's final rule amending 31 CFR Part 206, Management of Federal Agency Receipts, Disbursements, and Operation of the Cash Management Improvement Fund (59 FR 4536, 1/31/94). That rule requires executive agencies to use effective, efficient disbursement mechanics, principally Electronic Funds Transfer (EFT), in making their payments. That rule also requires executive agencies to use EFT for collecting funds.

MMS has written this rule in plain English.

II. Comments on Proposed Rule

MMS published a proposed rule on April 19, 1996, at 61 FR 17267. The proposed rulemaking provided for a 60-day comment period, which ended June 18, 1996, and was extended to July 19, 1996, by a **Federal Register** Notice (61 FR 28829, June 6, 1996).

General Comments

Commenters believe writing the rule in plain English improves clarity and makes the rule easier to understand. Commenters stated they will continue to work with MMS to identify the most efficient and practical way to make payments to MMS.

Response. We appreciate these comments and will continue the plain English concept in all future rulemakings.

Specific Comments

Comment on § 218.51(a). One commenter did not think it is necessary to define person or payment when used in their common or ordinary meaning.

Response. MMS has determined that these definitions lend clarity and conform with other MMS rules. No change will be made in the final rule.

Comment on § 218.51(b). The same commenter pointed out that the word *general* was misspelled.

Response. We will correct the spelling in the final rule.

Comment on § 218.51(b)(1). Five commenters responded as follows:

(1) The section is vague and arbitrary. Sentence is circular and describes a discretionary standard. As written, the payer must use EFT anytime MMS requires EFT regardless of the reasoning or criteria or basis for the decision. They suggested alternative language.

(2) The requirement is in conflict with the preamble. Their opinion is that making all payments by EFT is neither cost effective nor practicable. They said many Indian payments cost more to process than the invoice they are paying

and adding the cost of making these payments by EFT would not be cost effective. They recommend a threshold of \$10,000.

(3) They feel there is a conflict with § 218.51(b) which says "to the extent it is cost effective and practicable," and this section which says if instructed you must pay by EFT. They recommend a threshold of \$10,000.

(4) They feel the statement of "If MMS instructs you to use * * *," conflicts with the general spirit of the preamble. They feel the additional cost of making EFT payments is not justifiable from the company standpoint. They recommend the \$10,000 limit be maintained.

(5) They do not believe the additional cost of making EFT payments is justifiable from the company standpoint. They recommend retaining the current \$10,000 threshold.

Response. MMS does not intend to be arbitrary in implementing the Treasury EFT requirement. The Treasury rule does not allow for any type of stated threshold. Our elimination of the threshold is based on Treasury's requirement that we increase our efficiency in collecting Government monies. We feel the new rule is consistent with the Treasury rule.

We are aware of the cost and technical issues associated with making EFT payments. The U.S. Treasury is working with the banking industry to broaden the use of EFT. MMS believes our record of working with payors in implementing EFT has not been arbitrary or burdensome. It has not been our policy nor will it be our policy to unduly burden industry with EFT payment requirements. As EFT becomes more widespread, the cost should decrease; therefore, EFT will be more beneficial to industry and the Government.

Comment on § 218.51(b)(3). One commenter stated that the paragraph is confusing and should be rewritten to clearly define intent. The commenter asked two questions: (1) "Does this statement mean that separate reports or report lines are required? (2) Are separate checks or separate lines on the check stub or other payment document needed?"

Response. The intent of this paragraph is to emphasize the fact that you must not mix Federal and Indian lease payments on a payment document. In other words, you must not include any Indian lease payments in your Federal payment documents or any Federal lease payments in your Indian payment documents. This proposed rule deals only with payments and does not change any reporting requirements.

Comment on § 218.51(b)(5). One commenter recommended adding the word *document* to the end of the sentence.

Response. We do not believe the suggested change adds to or clarifies the sentence.

Comment on § 218.51(c)(2). One commenter thought the word "it" was vague and open to more than one interpretation and that the sentence contained repetitive statements. They suggested alternative language.

Response. Because this word was not clear in its meaning, we replaced the word "it" with the words "your payment."

Comment on § 218.51(c)(4). One commenter pointed out that the proposed wording does not agree with § 218.51(d)(1) which says use the address supplied by a tribe. Section 218.51(c)(4) says to use address supplied by MMS.

Response. MMS agrees that the proposed rule is not consistent on the source of the address. There may be instances where the tribe will change banks or have to change the lockbox address. MMS intends to notify payors of this change as promptly as possible, but you may receive your first notification from the tribe. The lockbox agreements are with the tribes and their banks and payors should follow the tribe's instructions for a lockbox address. We will change § 218.51(d)(1) to eliminate the inconsistency.

Comment on § 218.51(f). One commenter felt that the word *document* should be added to the end of the first sentence.

Response. We do not believe the suggested change adds to or clarifies the sentence.

Comment on § 218.51 (e) through (g). One commenter pointed out that the first sentence repeats what is in the title. The commenter felt that any address change for courier deliveries would require a rulemaking because the address is included in the regulation. The commenter also suggested using declarative sentences for (c), (f), and (g).

Comment on § 218.51(f)(3)(ii). One commenter stated that the section has been oversimplified; similarly, paragraphs (f) and (g) have been oversimplified. The commenter recommends alternative language.

Comment on § 218.51(f)(4)(iii). One commenter recommended rewriting the paragraph to improve clarity.

Response. MMS agrees and reworded the paragraphs for clarification in the final rule. As to the comment on a change of address requiring a rulemaking, no policy nor procedure would be affected since MMS can notify

payors of an address change outside of the rulemaking process.

Comment on § 218.51(g)(3). One commenter stated that an entity is responsible for its own actions and a payor should not be responsible for banks' actions.

Response. MMS does and will continue to hold the payor responsible for the actions of your agent for making accurate and timely payments on your behalf.

III. Procedural Matters

The Regulatory Flexibility Act

The Department certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The rule is needed to comply with U.S. Treasury requirements.

Executive Order 12630

The Department certifies that the rule is not a governmental action capable of interference with constitutionally protected property rights. Thus, a Takings Implication Assessment need not be prepared under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights."

Executive Order 12988

The Department has certified to the Office of Management and Budget that these proposed regulations meet the applicable standards provided in section 2(a) and (b)(2) of Executive Order 12988.

Executive Order 12866

This document has been reviewed under Executive Order 12866 and is not a significant regulatory action.

Paperwork Reduction Act

The rule has been examined under the Paperwork Reduction Act of 1995 and has been found to contain no new reporting and information collection requirements.

Unfunded Mandate Reform Act of 1995

The Department has determined and certifies according to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rule will not impose a cost of \$100 million or more in any given year on State, local, and tribal governments, or the private sector.

National Environmental Policy Act of 1969

We have determined that this rulemaking is not a major Federal action significantly affecting the quality of the human environment, and a detailed

statement under section 102(2)(C) of the National Environmental Policy Act of 1969 [42 U.S.C. 4332 (2)(C)] is not required.

List of Subjects in 30 CFR Part 218

Coal, Continental shelf, Electronic funds transfers, Geothermal energy, Government contracts, Indian lands, Mineral royalties, Oil and gas exploration, Public lands—mineral resources.

Dated: April 14, 1997.

Bob Armstrong,

Assistant Secretary—Land and Minerals Management.

For the reasons set out in the preamble, 30 CFR Part 218 is amended as follows:

PART 218—COLLECTION OF ROYALTIES, RENTALS, BONUSES AND OTHER MONIES DUE THE FEDERAL GOVERNMENT

1. The authority citation for part 218 is revised to read as follows:

Authority: 25 U.S.C. 396 *et seq.*, 396a *et seq.*, 2101 *et seq.*; 30 U.S.C. 181 *et seq.*, 351 *et seq.*, 1001 *et seq.*, 1701 *et seq.*; 31 U.S.C.A. 3335; 43 U.S.C. 1301 *et seq.*, 1331 *et seq.*, 1801 *et seq.*

2. Section 218.51 is revised to read as follows:

§ 218.51 How to make payments.

(a) *Definitions.*

ACH—Automated Clearing House. A type of EFT using the ACH network.

Courtesy Notice—An MMS-issued notice of rental or bonus due.

Deferred Bonus Payment—Lease bonus paid in equal annual installments over a specified number of years.

EFT—Electronic Funds Transfer. Any paperless transfer of funds a bank initiates through an electronic terminal. For MMS purposes, EFT is limited to FEDWIRE and ACH transfers.

FEDWIRE—A type of EFT using the Federal Reserve Wire network.

Invoice Document Identification—The MMS-assigned invoice document identification (four alpha and eight numeric characters).

Payment—Any monies for royalty, bonus, rental, late payment charge, assessment, penalty, or other money sent to MMS.

Person—Any individual, firm, corporation, association, partnership, consortium, or joint venture (when established as a separate entity). The term does not include Federal agencies.

Report—Form MMS-2014, *Report of Sales and Royalty Remittance.*

RIK—Royalty in kind.

(b) *General Instructions.* You must make all payments to MMS

electronically to the extent it is cost effective and practical. If you pay money to MMS or to an Indian tribe or allottee, you must follow these procedures:

(1) If MMS instructs you to use EFT, you must use EFT for all payments to MMS and/or a tribe.

(2) Contact MMS before using EFT. MMS will provide you with EFT payment instructions.

(3) Separate any payments on a Federal lease from any payments on an Indian lease.

(4) If you are not required to use EFT, use one of the following types of payment documents. MMS prefers that you use these payment documents in the order presented:

(i) Commercial check drawn on a solvent bank;

(ii) Certified check;

(iii) Cashier's check;

(iv) Money order;

(v) Bank draft drawn on a solvent bank; or

(vi) Federal Reserve check.

(5) You must include your payor code on all payments.

(6) You must pay in U.S. dollars.

(c) *How to complete a non-EFT payment.* (1) Make any payment on a Federal lease payable to: "Department of the Interior-Minerals Management Service" or "DOI-MMS."

(2) For an Indian allottee payment, send a separate payment for each Bureau of Indian Affairs (BIA) agency or area office represented by the leases on your report or invoice document. You must include the name of the applicable BIA agency or area office on your payment. Make your payment document payable to: "Department of the Interior-Minerals Management Service for BIA [Name] Agency (allotted)" or "DOI-MMS for BIA [Name] Agency (allotted)."

(3) For an Indian tribal payment other than a lockbox payment, send a separate payment for each tribe represented by the leases on your report or invoice document. You must include the name of the Indian tribe on your payment. Make it payable to: "Department of the Interior-Minerals Management Service for BIA [Name of Tribe]" or "DOI-MMS for BIA [Name of Tribe]."

(4) For an Indian tribal lockbox payment, follow the instructions MMS provides you on how to report and make the lockbox payment. These instructions are specific to each tribe's lockbox written agreement with the bank authorized to receive payments on the tribe's mineral leases. You will receive these instructions from MMS when you are required to use a tribal lockbox for reports and payments.

(d) *Where to send a non-EFT payment when you use the U.S. Postal Service.* (1) For a payment to an Indian tribal lockbox, send your payment to the appropriate tribal lockbox address.

(2) For a Federal nonproducing lease rental or deferred bonus payment, send it to:

Minerals Management Service, Royalty Management Program, P.O. Box 5640, Denver, CO 80217-5640.

(3) For all other Federal and Indian lease payments other than those going to an Indian tribal lockbox, send them to:

Minerals Management Service, Royalty Management Program, P.O. Box 5810, Denver, CO 80217-5810.

(e) *Where to send a non-EFT payment when you use a courier or overnight delivery service.* You should send this type of payment to:

Minerals Management Service, Royalty Management Program, Building 85, Denver Federal Center, Room A-212, Denver, CO 80225-0165.

(f) *How to prepare and what to include on your payment document.* (1) For Form MMS-2014 payments, you must include both your payor code (block 2) and your payor-assigned document number (block 3a).

(2) For invoice payments, including RIK invoice payments, you must include both your payor code and invoice document identification (four-letter prefix and eight-digit number).

(3) For bonus payments:

(i) For one-fifth bonus payments for offshore oil, gas, and sulphur leases, follow the instructions in the Notice of Lease Offering.

(ii) For payment of the four-fifths bonus for an offshore lease, use EFT and follow the instructions in § 218.155(c).

(iii) For the successful bidder's bonus in the competitive sale of a coal, geothermal, or offshore mineral (other than oil, gas or sulfur) lease, follow the instructions and terms of the Notice of Competitive Lease Sale.

(iv) For installment payments of deferred bonuses, you must use EFT.

(4) If you are paying a lease rental you must:

(i) See 30 CFR 218.155(c) for instructions on how to pay first-year rentals of an offshore oil, gas, or sulfur lease; (ii) See the Notice of Lease Offering for instructions on how to pay first-year rentals other than those covered in paragraph (f)(4)(i) of this section.

(iii) Include the MMS Courtesy Notice, when provided, or write your payor code and government-assigned lease number on the payment document when paying a rental that is not

reported on Form MMS-2014 and not paid by EFT.

(g) *When is a payment to MMS due?*

(1) All payments are due to MMS at the time law, regulation, or lease terms require unless MMS approves a change according to 30 CFR 243.2,

"Suspensions of orders or decisions pending appeal." If you file an appeal, and the requirement to submit payment is suspended, the original payment due date for purposes such as calculating late payment interest is not changed.

(2) If you use the U.S. Postal Service, courier, or overnight mail to send your payment, it is due at the MMS addresses in paragraphs (d) and (e) of this section before 4 p.m. Mountain Time on the due date, regardless of when you sent it.

(3) If you use EFT to send your payment, it is due in the MMS account by the payment due date. You are responsible for your actions or your bank's actions that cause a late or incorrect payment. You will not be held responsible for mechanical or system failures of EFT payments.

(h) *What happens if payments are late or overdue?*

(1) If MMS receives your payment late, MMS will impose a late-payment interest charge under 30 CFR 218.54.

(2) If you do not pay an amount you owe, MMS may assess civil penalties under 30 CFR 241.20 and 241.51 or other applicable regulations.

3. Paragraph (b)(1) of § 218.155 is amended by revising the last sentence to read as follows:

§ 218.155 Method of payment.

* * * * *

(b)(1) * * * EFT may be used as a method of payment for the one-fifth bonus bid amount.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Chapter V

Blocked Persons, Specially Designated Nationals, Specially Designated Terrorists, Specially Designated Narcotics Traffickers, and Blocked Vessels: Removal of Entry

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment.

SUMMARY: The Office of Foreign Assets Control is removing from appendix C to 31 CFR chapter V an entry for a vessel