Dated: Issued in Des Plaines, Illinois, on March 13, 2003.

Nancy B. Shelton,

Manager, Air Traffic Division, Great Lakes Region.

[FR Doc. 03–7663 Filed 3–28–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 204

RIN 1010–AC30

Accounting and Auditing Relief for Marginal Properties

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Supplementary proposed rule.

SUMMARY: MMS is proposing new regulations to implement certain provisions in the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996. These regulations would explain how lessees and their designees could obtain accounting and auditing relief for Federal oil and gas leases and unit and communitization agreements that qualify as marginal properties.

EFFECTIVE DATE: Comments must be submitted on or before May 30, 2003.

ADDRESSES: Address your comments, suggestions, or objections regarding this proposed rule to:

By regular U.S. mail. Minerals Management Service, Minerals Revenue Management, Regulations and FOIA Team, P.O. Box 25165, MS 320B2, Denver, Colorado 80225–0165; or

By overnight mail or courier. Minerals Management Service, Minerals Revenue Management, Building 85, Room A–614, Denver Federal Center, Denver, Colorado 80225; or

By e-ail. MRM.comments@mms.gov. Please submit Internet comments as an ASCII file and avoid the use of special characters and any form of encryption. Also, please include ''Attn: RIN 1010–AC30'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, call the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Paul A. Knueven, Chief, Regulation and FOIA Team, Minerals Revenue Management, MMS, telephone (303) 231–3316, fax (303) 231–3385, or e-mail *Paul.Knueven@mms.gov.*

SUPPLEMENTARY INFORMATION: The principal authors of this rule are Sarah L. Inderbitzin of the Office of the Solicitor and David A. Hubbard of Minerals Revenue Management, MMS, Department of the Interior.

I. Background

On August 13, 1996, the President signed into law the Federal Oil and Gas Royalty Simplification and Fairness Act (RSFA).[1] RSFA amends the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA).[2] Section 7 of RSFA allows MMS and the State concerned (defined under RSFA as ''a State which receives a portion of royalties or other payments under the mineral leasing laws from [a Federal onshore or OCS oil and gas lease]'')[3] to provide royalty prepayment and regulatory relief for marginal properties for Federal onshore and Outer Continental Shelf (OCS) oil and gas leases.[4] The stated purpose of granting relief to marginal properties under RSFA is to promote production, reduce administrative costs, and increase net receipts to the United States and the States.[5] Specifically, paragraph (c) of the new 30 U.S.C. 1726 enacted by RSFA section 7 directed the Secretary (and States that had received a delegation of audit authority) to ''provide accounting, reporting, and auditing relief that will encourage lessees to continue to produce and develop'' marginal properties, ''provided that such relief will only be available to lessees in a State that allows.'' (There is an exception to the requirement for State allowance if royalty payments from a lease are not shared with a State under applicable law.)

In response to the RSFA section 7 amendments, MMS conducted three workshops to receive input from a wide variety of constituent groups to develop a proposed rule. The workshops were held at MMS offices in Denver, Colorado, on October 31, 1996, January 23, 1997, and November 5, 1997. Representatives from several Federal and State government organizations participated along with industry organizations representing both small and large Federal oil and gas lessees. The input received during these workshops was instrumental in developing the proposed rule that was published in the **Federal Register** on January 21, 1999 (64 FR 3360).

Public comments received in response to the proposed rule were sharply contradictory. The comments fell into two general categories:

1. The States believed that MMS was offering too much relief to industry; and

2. Industry believed that the rule was too complicated and did not offer enough relief.

Because of the contradictory opinions, the Associate Director for Minerals Revenue Management asked the Royalty Policy Committee (RPC) of the Department of the Interior's Minerals Management Advisory Board to form a subcommittee to review the marginal property issue and make recommendations to the Department on how MMS should proceed. The RPC appointed a subcommittee with members from several industry associations and the major States affected by the relief provisions. MMS employees and a representative of the Office of the Solicitor served as technical advisors to the subcommittee.

The RPC subcommittee prepared a report that was submitted to the RPC on March 27, 2001. The RPC accepted the subcommittee's recommendations. On August 2, 2001, the Acting MMS Director—on behalf of the Secretary of the Interior—approved the report and advised MMS to proceed with a second proposed rule incorporating the subcommittee's recommendations. This second proposed rule includes the RPC subcommittee's recommendations with one exception described below.

II. Comments on the 1999 Proposed Rule

MMS received comments on the initial proposed rule published on January 21, 1999 (64 FR 3360) from the following nine entities:

- 3 States;
- 1 State and Indian audit organization;
- 2 oil and gas producers;
- 2 industry associations; and
- 1 law firm representing 1 industry association and 11 oil and gas companies.

These comments are analyzed and discussed below:

Definition of Base Period

1999 Proposed Rule. In § 204.2, MMS proposed to define the base period as the 12-month period from October 1 through September 30 immediately preceding the calendar year in which the lessee takes or requests marginal property relief.

Public Comments. One State commented that the base period should track as closely as possible to the beginning of the applicable calendar year in which the lessee takes marginal property relief. One producer requested that the base period be moved from October 1 through September 30 to

[1] Pub. L. 104–185, as corrected by Pub. L. 104–200.

[2] 30 U.S.C. 1711 *et seq.*

[3] 30 U.S.C. 1701(31).

[4] 30 U.S.C. 1726.

[5] 30 U.S.C. 1726(a).

September 1 through August 31 because the proposed period did not allow sufficient time for producers to report. One industry association also requested that the base period be moved back to give industry more time for calculations.

RPC Subcommittee Recommendation. The subcommittee members discussed the need to change the proposed base period. Producer groups indicated that the base period needed to be moved back at least 1 or 2 months. However, one State representative said that the base period needed to be as close to the calendar year as possible, but the State could accept moving it back to September 1 through August 31. The subcommittee ultimately recommended changing the base period to July 1 through June 30. The subcommittee felt that it was necessary to move the base period back in order for MMS to publish a **Federal Register** notice before the first of the calendar year listing which States were participating in the marginal property relief options. The subcommittee believes that the following schedule should meet the needs of all parties (industry, States, and MMS):

August 15: Operators submit production reports for June production.

October 1: MMS furnishes States a report of marginal properties for July-June base period.

November 1: States notify MMS if they wish to opt in or out of marginal property accounting and auditing relief (if a State fails to notify MMS, they are deemed to have opted out).

December 1: MMS publishes a **Federal Register** notice listing which States are opting in or out.

MMS Response. We agree with the RPC subcommittee recommendation to change the period to July 1 through June 30.

Definition of ''Marginal Property''

1999 Proposed Rule. In § 204.4, MMS proposed to define a ''marginal property'' as a property having average daily well production of less than 15 barrels of oil equivalent (BOE) per well per day during the base period.

Public Comments. The law firm and the two industry associations suggested that MMS establish separate production levels for different situations, particularly offshore and onshore properties. One State was concerned that using all producing wells in the calculation could result in classifying properties with very prolific wells as marginal. The same State also objected to MMS delegating to itself the determination of what marginal production is because RSFA stated that MMS and the States should determine the definition jointly.

RPC Subcommittee Recommendation. The subcommittee members discussed the comment that separate qualification rates should be established for offshore and onshore. MMS representatives advised the subcommittee that industry had previously formed an operational group to establish a rate for offshore, but the group could not agree and the idea was dropped. Subcommittee members also discussed whether the States could set their own individual qualification rates. The subcommittee members decided this was not acceptable because of the administrative burden associated with tracking and auditing different rates for different States. One State representative was concerned that some States might want to offer some relief but not at 15 BOE. The RPC subcommittee did not recommend any changes in the definition of ''marginal property.''

MMS Response. We propose to retain the definition of ''marginal property'' contained in the 1999 proposed rule. MMS agrees with the subcommittee's conclusion that using different State production levels to define ''marginal property'' would be too administratively onerous for use. Such an approach also would result in a Federal law having different meanings in different States, which would raise serious legal concerns.

Although using all producing wells in the calculation to determine whether a property is marginal may result in some leases or units with high-producing wells being classified as marginal properties, we believe it would be too administratively burdensome to allow relief for individual wells, rather than by lease or unit or communitization agreement (hereinafter referred to as ''agreement'' in this context) as the rule provides. MMS believes that the proposed rule does allow the Secretary (acting through MMS) and the State to ''jointly determine, on a case-by-case basis, the amount of what marginal production from a lease or leases or well or wells, or parts thereof'' may obtain royalty accounting and auditing relief, as the statute provides (30 U.S.C. 1726(a)). Several State representatives on the subcommittee ultimately recommended using the production level in the proposed rule. Moreover, any State that does not agree with the production levels MMS ultimately adopts under this rule may decline to allow accounting, reporting, and auditing relief under § 204.208.

Statutory Requirements for Relief

1999 Proposed Rule. In § 204.5, MMS reiterated the RSFA statutory requirements that any relief granted for marginal properties must promote production, reduce administrative costs, and increase net receipts to the Federal Government and the States.

Public Comments. One State stated that the proposed rule was contrary to law because it was unlikely to promote production or increase net receipts. Further, the State argued that there is no way to determine if the relief will increase net receipts. The State also noted that we must take into account the loss of the time value of royalty receipts if we allow delayed reporting.

RPC Subcommittee Recommendation. The subcommittee discussed numerous times the difficulty in finding possible relief options that would meet all three RSFA objectives. The subcommittee recommended that two relief options be retained—cumulative reporting and ''other'' relief.

MMS Response. We understand the State's concerns, but do not agree that the relief offered will not promote production or increase net receipts. Because use of the annual reporting option is limited to properties producing 1,000 BOE or less annually, we believe there will be little loss of time value of the royalties. Moreover, we believe the administrative savings to the lessee will promote production, and the administrative savings to MMS and the States will more than offset any possible loss of interest. A member of MMS's reengineering team informed the subcommittee that each different relief option would require modifications to MMS's compliance programs and thus add cost. We propose to limit our relief options to those recommended by the subcommittee to avoid being cost-prohibitive.

State Liability for Denials of Requests for Relief

1999 Proposed Rule. In § 204.6, MMS proposed that if MMS denied a request for relief based on a State's denial, then the decision was final for the Department of the Interior and could not be appealed administratively.

Public Comments. One State believed that MMS's interpretation of RSFA was incorrect and left the States open to litigation in Federal court. Another State indicated that the proposed rule did not clearly acknowledge that nothing in RSFA serves to waive a State's immunity from suit.

RPC Subcommittee Recommendation. All of the State representatives on the subcommittee expressed grave concern

over the language in the proposed rule that said if a decision not to grant relief is based on a State's denial, the decision would not be subject to administrative appeal. This would put any challenge to a decision not to grant relief directly into Federal District Court. The States were not willing to accept that risk. Based on this discussion, the subcommittee sent a request to seven State agencies asking their opinion on the comments raised by State representatives on the subcommittee. Only one agency responded, stating that it agreed with the other States' concerns. Consequently, the subcommittee recommended that each State be given the ability to determine, before each calendar year, whether it will allow either the notification-based relief option or the request-based relief option, or both. If a State decides to allow the request-based relief option, the State would thereby agree to let MMS make the final decision on the relief request. That decision could be appealed administratively within the Department of the Interior.

MMS Response. We agree with the subcommittee's recommendation. We also believe that modifying the proposed rule at § 204.207(b) to read as follows would eliminate the States' concerns:

> If, for your marginal property, there is a State concerned that has determined in advance that it will allow either or both of the relief options under this subpart, MMS will decide whether to approve, deny, or modify your relief request after consulting with the State concerned.

Thus, the approval process under this proposed rule is like the current process for issuance of orders where the State has performed the audit. Although the State is consulted regarding whether to grant, deny or modify relief, MMS would ultimately issue the decision and the State would not be subject to suit in Federal District Court. Moreover, any State that does not wish to allow accounting and reporting relief may opt out.

Who May Request Relief

1999 Proposed Rule. In § 204.201, MMS proposed that a lessee or the lessee's designee of a Federal property could obtain relief if the property qualified as marginal. Further, the lessee or lessee's designee could request relief only for the lessee's fractional interest in the property.

Public Comments. One industry association liked the fact that not all lessees in a property have to seek relief in order for an individual lessee to take relief on the lessee's portion. One State commented that RSFA did not allow designees to apply for relief in place of the lessee.

RPC Subcommittee Recommendation. The subcommittee suggested retaining the original proposed language concerning designees.

MMS Response. We agree with the State that RSFA does not specifically state that designees may seek relief on behalf of lessees. However, it also does not specifically preclude such action. Indeed, 30 U.S.C. 1726(c) merely authorizes the Secretary and delegated States to provide relief ''to encourage lessees to continue to produce and develop properties'' and that relief will only be ''available to lessees in a State that allows'' such relief. The statute is silent about who may request relief. Therefore, because the statute is silent, and designees are acting as the lessee's agent, we believe that it is reasonable and consistent with RSFA to authorize designees to request relief under this rulemaking.

Cumulative Reporting and Payment Relief

1999 Proposed Rule. In § 204.203, MMS proposed to allow lessees to report quarterly, semi-annually, or annually depending upon the volume of royalty BOE produced on the property.

Public Comments. One State objected to allowing payments less often than monthly because that is what is required by lease terms. The law firm commented that cumulative reporting should not be less often than annual. One industry association suggested that the thresholds for the lessee to be allowed to submit cumulative reports should be higher. The other industry association was concerned that lessees could not perform the complicated calculations to determine the level of relief and suggested MMS establish a consistent production level for eligibility for relief. The industry association also stated that the calculations to determine cumulative royalty reporting relief were too narrow and too burdensome and all marginal properties should get the same relief. The association also suggested that MMS eliminate the requirement to report allowances separately on marginal properties and explain how estimates would work with reporting less often than monthly. One State was concerned that MMS would have to develop a separate database to track reporting dates and royalty rates by lessee.

RPC Subcommittee Recommendation. A representative of the MMS financial reengineering team was invited to a subcommittee meeting on cumulative reporting. The reengineering team representative stated that MMS would have to make some modifications to its financial system in order to process reporting on a periodic, cumulative basis. She explained that each reporting frequency would require funding for system modifications; thus, we would probably have to limit the available relief options to avoid being cost-prohibitive. Consequently, the subcommittee recommended that only annual cumulative reporting be retained as a notification-based relief option and that this option be limited to marginal properties producing 1,000 BOE or less annually.

MMS Response: We agree with the subcommittee's recommendations. Moreover, with respect to one State's concern regarding the lease instrument's requirement that lessees pay monthly, the Government may by rule waive an obligation under the lease terms if doing so does not change the lessee's position to its detriment.

Complex Calculations

1999 Proposed Rule. In §§ 204.203, 204.204, and 204.205, the level of relief in each reporting option was based on various levels of marginal production. The calculations required lessees to multiply the BOE attributable to a marginal property by the applicable lease royalty rate.

Public Comments. One State pointed out that MMS did not provide any rationale for the volume cut-offs for relief. Another State commented that it was unclear how MMS derived production levels for the levels of relief.

RPC Subcommittee Recommendation. Discussion in the subcommittee centered on the complexity of the calculations required to determine whether a marginal property qualified for a particular form of accounting relief. The proposed rule included five different production levels for the five different forms or levels of accounting relief. The subcommittee ultimately decided to recommend volume limits based on total BOE rather than royalty BOE. The subcommittee also reduced the number of volume levels from five to one. This simplified the calculations significantly.

MMS Response. We agree with the subcommittee's recommendations.

Net Adjustment Reporting

1999 Proposed Rule. In § 204.204, MMS proposed to allow net adjustment reporting as one of the notification-based relief options. In this reporting scenario, lessees could adjust a previously-reported royalty line in a one-line net entry on the Report of Sales and Royalty Remittance, Form MMS–

2014, rather than using MMS's traditional two-line adjustment process.

Public Comments. One State objected to allowing net adjustments. One industry association thought net adjustment reporting should be allowed for all leases under MMS's reengineered system. The law firm, however, commented that net adjustments would not be ''relief'' for marginal properties if it is allowed for all reporters in the reengineered system.

RPC Subcommittee Recommendation. The subcommittee members discussed the problems MMS's financial reengineering team had encountered in trying to implement net adjustment reporting. Because of very specific requirements in FOGRMA for certain data elements to be displayed on the Explanation of Payments (EOP) sent to States and tribes, the reengineering team and MMS's industry partners found net adjustment reporting unworkable. However, MMS continues to look for acceptable net adjustment reporting options for reengineering purposes. Based on MMS's continuing efforts to offer net adjustment reporting for all reporters, the subcommittee recommended that the net adjustment reporting relief option be dropped from the proposed rule.

MMS Response. We agree with the subcommittee's recommendation.

''Rolled-Up'' Reporting Relief Option

1999 Proposed Rule. In § 204.205, MMS proposed to allow ''rolled-up'' reporting as one of the notification-based relief options. In this reporting scenario, lessees could report all selling arrangements for a revenue source under a single selling arrangement on the Form MMS–2014.

Public Comments. The law firm stated that ''rolled-up'' reporting was not significant relief. One of the industry associations agreed that if all product codes could not be rolled up, this was not significant relief.

RPC Subcommittee Recommendation. The subcommittee recommended that the rolled-up reporting relief option be dropped from the proposed rule. This recommendation was, again, associated with the problem of accommodating required EOP information and the fact that selling arrangements were dropped from the revised Form MMS–2014 effective October 1, 2001.

MMS Response. We agree with the subcommittee's recommendation.

Alternate Valuation Relief Option

1999 Proposed Rule. In § 204.206, MMS proposed to allow lessees to request approval to report and pay royalties using a valuation method other than that required under 30 CFR part 206.

Public Comments. One State and one industry association did not think alternative valuation relief was necessary because lessees already have that option under current valuation regulations. The law firm was troubled by the provision that the proposed valuation method should ''approximate 30 CFR part 206.'' The law firm stated that with all the litigation currently in progress, it would be difficult for someone to determine what that value should be. Another State commented that the proposed rule invited litigation because there was no way for a State or MMS to determine whether an alternate valuation method would ''approximate'' royalties in the future. The State further added that alternate valuation relief was not accounting, reporting or auditing relief but really royalty relief.

RPC Subcommittee Recommendation. The subcommittee recommended dropping this option from the proposed rule.

MMS Response. We agree with removal of this option for the reasons stated by the commenters. Moreover, alternative valuation is still an option a lessee may request under the other relief option in § 204.203 of this second proposed rule.

1999 Proposed Rule. In § 204.211, MMS proposed how it would review requests for alternative relief. MMS did not propose time frames within which it would review requests.

RPC Subcommittee Recommendation. The subcommittee recommended that MMS have 120 days to review alternative relief requests. The subcommittee recommended that if MMS did not complete the review within the prescribed 120 days, requests would be deemed ''approved.''

MMS Response. MMS has not determined whether to adopt the RPC subcommittee's recommendations. We are concerned about deeming a request ''approved'' based solely on the length of time elapsed after receipt of the request without any Department review. One alternative is to deem the request denied if MMS does not approve or disapprove a lessee's request within 120 days after MMS received the request. Because denial of a request may be appealed, that would give the Department the opportunity to review the request and make an informed decision. The other alternative is to have no timing requirements by not including any provision at all.

Because of these concerns we are specifically requesting comments on:

- Whether there should be a time limit on MMS approval after it receives a request for reporting, accounting, and auditing relief;
- Whether the request should be deemed approved or denied after some time period, and what that period should be; and
- Any other alternative approaches.

Audit Relief Option

1999 Proposed Rule. In § 204.207, MMS proposed to allow audit relief such as audits of limited scope, audits coordinated with other State or Federal agencies, or audits by independent public accountants.

Public Comments. One State objected to any limit on the scope of audits. The State further added that independent auditors do not review whether royalties are paid correctly. Another State stated that it did not believe that audit relief was warranted and would not participate in it. The third State wanted to remove the audit relief option related to ''coordinated royalty and severance tax audits'' because it compromised the State's right to audit. The law firm stated that audit relief was not much relief because under the current strategy marginal properties are seldom audited. One industry association agreed that audit relief was not much relief because the States and MMS already practice coordinated audits. The other industry association, however, strongly supported audit relief.

RPC Subcommittee Recommendation. The subcommittee recommended dropping this option from the proposed rule.

MMS Response. We agree with removal of this option for the reasons stated by the State commenters. Moreover, audit relief is still an option a lessee may request under the ''other'' relief option in § 204.203 of this second proposed rule.

Other Relief Option

1999 Proposed Rule. In § 204.208, MMS proposed to allow a lessee to request any type of accounting and auditing relief that was appropriate for a specific marginal property provided that it was not specifically prohibited.

Public Comments. One State opposed the other relief option because the burden to evaluate the request was too great for a meaningless level of cost savings.

RPC Subcommittee Recommendation. The subcommittee members discussed all three approval-based relief options contained in the 1999 proposed rule. Because of the sensitivities surrounding what was in the original proposal, the subcommittee decided to recommend an approval-based relief option called ''other'' relief. Other relief would apply

to all marginal properties and could be anything within MMS authority that the lessee or his/her designee believes would be marginal property relief. The lessee would need to submit a proposal to MMS for approval. After consultation with the State or States concerned, MMS would decide whether to grant the requested relief. Examples of what might be considered are payments made more than annually but less than monthly or an alternative valuation method.

MMS Response. We agree with the subcommittee's recommendation. Further, we disagree with one State's comment that such an option is too great a burden relative to any savings. As this second proposed rule states, any relief requested must meet the statutory requirements in RSFA to promote production, increase net receipts, and reduce administrative costs.

Disallowed Relief Options

1999 Proposed Rule. In § 204.209, MMS listed relief items that MMS would not approve if requested by lessees.

Public Comments. One State wanted to add three items to the types of relief that MMS would not approve. The items were any relief request that (1) decreases royalty income below true market value, (2) increases allowances, or (3) reduces royalty-bearing volumes.

RPC Subcommittee Recommendation. The subcommittee recommended retaining the list of disallowed items with no changes.

MMS Response. We believe that § 204.203(a)(1) in this second proposed rule, which provides that any alternative valuation methodology must approximate royalties payable under 30 CFR part 206, addresses the State's concern.

Notification-Based Relief

1999 Proposed Rule. In § 204.210(a), MMS described the information a lessee must submit to MMS before taking any notification-based relief.

Public Comment. One industry association supported notification-based relief rather than request-based relief. The other industry association did not want any required notification for taking relief in §§ 204.203, 204.204, and 204.205.

Two States opposed the automatic relief options. One of those States indicated that all relief should be gained through an approval process. One industry association liked the provision that would allow lessees to file a single notification for multiple marginal properties.

RPC Subcommittee Recommendation. The subcommittee recommended only one type of notification-based relief—cumulative annual reporting.

MMS Response. We agree with the subcommittee recommendation to allow only notification-based relief for annual reporting.

Approval Process

1999 Proposed Rule. In §§ 204.212 and 204.213, MMS described the approval process for request-based relief.

Public Comments. All three States thought that the approval process placed too much administrative burden on the States. One State objected to MMS telling the States what the scope, timing or process should be for its review of a request. The same State noted that MMS cannot tell a State who in the State will make determinations on relief or how long they have to make the determinations. One industry association suggested that authority to approve alternative valuation should be delegated to someone below the Assistant Secretary for Land and Minerals Management (ASLM). The other industry association wanted approval authority for all properties to be with the ASLM. The law firm, one State, and one industry association commented that they did not agree with the fact that the regulation required States to do things within specified time periods but not MMS. One State did not agree with the provision that if the State did not notify MMS of its decision within 30 days then the State is deemed to agree with MMS's determination. One industry association was concerned that States might be given more than 30 days to review and decide relief options. The same industry association supported publication of States' decisions to allow or disallow certain types of relief and wanted MMS and the States to develop criteria for analyzing relief requests.

RPC Subcommittee Recommendation. The subcommittee recommended that MMS consult with the State concerned about a request for relief rather than requiring a decision from the State in a specific period of time.

MMS Response. The State's concerns regarding timing are no longer an issue because this proposed rule now requires consultation with the State concerned, rather than specific timing requirements. See discussion on proposed § 204.207(b) under the topic ''State Liability'' above.

Length of Relief

1999 Proposed Rule. In § 204.217, MMS proposed that any approved relief would remain in effect for as long as the property qualified as marginal.

Public Comments. One State opposed continuous relief throughout the life of a lease and thought the marginal properties should be monitored periodically. One industry association supported relief for the life of the lease.

RPC Subcommittee Recommendation. The subcommittee did not recommend any changes in § 204.217 (redesignated as § 205.209).

MMS Response. We agree that properties should have relief for the life of the lease only if they continue to qualify as marginal. Moreover, nothing in this proposed rulemaking precludes MMS from monitoring and auditing leases for compliance with other MMS regulations and lease terms.

Relationship to Other Incentive Programs

1999 Proposed Rule. In § 204.218, MMS proposed that a lessee could obtain accounting and auditing relief for a marginal property even if the property benefited from other Federal or State production incentive programs.

Public Comments. One State commented that lessees should be required to disclose other types of relief they are receiving. One industry association supported the provision allowing lessees to get marginal property relief even if they benefit from other incentive programs.

RPC Subcommittee Recommendation. The subcommittee did not recommend any changes in this provision.

MMS Response. We agree that lessees should get marginal property accounting and auditing relief even if they benefit from other relief programs. Nothing in RSFA precludes obtaining marginal property relief if a lessee obtains other relief.

Fees

1999 Proposed Rule. In § 210.210(b), MMS listed the information that lessees must submit in their requests for accounting and auditing relief and the requirement to submit a $50 fee with each request.

Public Comments. One State stated that the items to be included in the written request for relief were inadequate. Two States said the $50 fee is too low compared to the cost incurred by States and MMS to process requests. Two States thought the fees should be shared with the States. Both industry associations opposed the fee. One industry association said that small independent producers could not afford it and did not like the fact that MMS would not refund the fee for any reason.

RPC Subcommittee Recommendation. The subcommittee recommended elimination of the fee for request-based relief.

MMS Response. After further legal review, we have decided that it is reasonable not to recover a processing fee for requests or notices under this proposed rule. MMS recovers its costs under the Independent Offices Appropriations Act of 1952 (IOAA),[6] for Federal offshore leases, and the Federal Land Policy and Management Act of 1976(FLPMA),[7] for Federal onshore leases. Thus, as part of the previously-proposed rulemaking, we analyzed the proposed marginal property relief's cost recovery fees for reasonableness according to the factors in FLPMA section 304(b).[8] In that proposed rulemaking, we examined the ''reasonableness factors'' which FLPMA requires to be considered: (a) Actual costs (exclusive of management overhead); (b) the monetary value of the rights or privileges sought by the applicant; (c) the efficiency to the Government processing involved; (d) that portion of the cost incurred for the benefit of the general public interest rather than for the exclusive benefit of the applicant; (e) the public service provided; and (f) other factors relevant to determining the reasonableness of the costs.

For marginal property relief taken or requested under § 204.210, the method used to evaluate the factors under the previously-proposed rulemaking was twofold. First, we estimated actual costs and evaluated each of the remaining FLPMA reasonableness factors (b) through (f) individually to decide whether the factor might reasonably lead to an adjustment in actual costs. If so, that factor was then weighed against the remaining factors to determine whether another factor might reasonably increase, decrease, or eliminate any contemplated reduction. On the basis of that twofold analysis, although MMS's total estimated actual costs were $2,370 to process an average request, MMS determined that a fee of $50 to process relief requests was reasonable.

MMS determined a reduced fee was reasonable primarily based on its evaluation of FLPMA factor (f) Other Factors. MMS's primary consideration under this factor was RSFA's purpose with respect to marginal properties. Congress enacted RSFA to ''promote production,''[9] by ''encourag[ing] lessees to continue to produce and develop marginal properties.''[10] Congress stated that ''certain regulatory * * * obligations should be waived if it can be demonstrated such a waiver could aid in maintaining production that might otherwise be abandoned.''[11] However, RSFA also mandated that any relief should ''reduce administrative costs, and increase net receipts to the United States and the States.''[12] Congress stated that granting relief for marginal properties should ''result in additional receipts from oil and gas production that would otherwise be abandoned, and would * * * increase oil and gas production on Federal lands by creating economic efficiencies to make Federal leases more competitive with private leases.''[13] Thus, as part of its FLPMA reasonableness analysis, MMS considered (1) whether the benefit from the increase in royalties to be gained from continued production from marginal properties and the decreased administrative burden to MMS from granting such relief merited a reduction in fee charges; and (2) whether recovering the fee would defeat the Congressional intent to provide relief by discouraging companies from requesting relief.

MMS has reexamined the analysis under factor (f) in the previously-proposed rule to determine whether those factors warranted elimination of the proposed fee. We believe they do. We do not believe that the administrative savings to industry that may be afforded if they are granted relief will be significant enough for them to pay to request relief. Moreover, we believe that the companies that most need the relief are small independents who would be discouraged from applying for relief by even the nominal $50 fee previously proposed. Because the purpose of RSFA is to grant relief to producers so that they will continue to produce, we believe it is counterproductive to include a fee that will discourage many of the smaller marginal producers from requesting relief. Thus, we are not proposing to require payment of a processing fee for relief requests.

III. Procedural Matters

1. Public Comment Policy

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours and on our Internet site at www.mrm.mms.gov. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comments. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

2. Summary Cost and Benefit Data

We have summarized below the estimated costs and benefits of this proposed rule to all potentially-affected groups: industry, State and local governments, and the Federal Government. Indian tribes and allottees are not affected by this rule. The cost and benefit information in this Item 2 of Procedural Matters is used as the basis for the Departmental certifications in Items 3 through 11 below.

A. Industry

(1) *Cost—Notification-based relief—Submitting notifications.* Approximately 3,000 Federal oil and gas properties produce 1,000 or less BOE annually. In the first year after this rule becomes effective, we estimate that lessees of 1,000 of these properties will submit notifications that they will take cumulative reporting and payment relief. We do not anticipate that all lessees of qualifying properties will submit notifications because not all States will allow reporting and payment relief, and large corporations may find that modifying their computer systems to report and pay on a few leases annually rather than monthly will not be cost effective.

We further estimate that a lessee will require 2 hours to determine if a property qualifies for cumulative reporting and payment relief and then prepare and submit the notification to MMS. Consequently, the total estimated burden for all notifications in the first year is 2,000 hours (1,000 properties × 2 hours). Using an estimated $50 per hour cost, the total cost for all lessees to submit these notifications is $100,000 (2,000 burden hours × $50).

Because the reporting and payment relief for a qualified property is for the life of the property as long as the property produces less than 1,000 BOE per year, a notification need only be

[6] 31 U.S.C. 9701 *et seq.*

[7] 43 U.S.C. 1701.

[8] 64 FR 3366–69.

[9] RSFA section 7(a).

[10] S. Rep. 260, 104th Cong., 2d Sess. 20 (1996); H.R. 667, 104th Cong., 2d Sess. 20 (1996).

[11] H.R. 667, 104th Cong., 2d Sess. 20 (1996).

[12] RSFA section 7(a).

[13] *Id.* at 20–21.

filed one time. However, we estimate that MMS will receive notifications for approximately 100 newly-qualifying properties in each subsequent year. The total estimated burden for each subsequent year is 200 hours (100 properties × 2 hours) for a total cost of $10,000 (200 hours × $50).

(2) *Benefit—Notification-based relief—Reporting fewer lines.* We estimate that an average of 1,000 properties (500 leases and 500 Agreements) will involve cumulative reporting and payment relief annually. This means that royalties on these properties will be reported and paid annually rather than monthly. We further estimate that lessees will submit 5,500 fewer lines for leases (1 line per month × 11 months × 500 leases) and 16,500 fewer lines for Agreements (3 lines per month × 11 months × 500 Agreements) on Form MMS–2014, each year for a total of 22,000 fewer lines per year. Because each line averages 3 minutes to submit, we estimate that lessees will save 1,100 burden hours (22,000 lines × 3 minutes ÷ 60 minutes/hour) or a total of $55,000 (1,100 hours × $50/hour) in the first year this rule is effective and for each year thereafter.

(3) *Cost—Request-based relief—Requesting approval.* MMS expects approximately 10 requests per year for other accounting and auditing relief. We estimate each request will require 4 hours for a lessee to prepare and submit. This estimate also includes providing information originally omitted from the request and lessee approval of MMS modifications, if any. The estimated cost to lessees to request other relief is approximately $2,000 per year (10 requests × 4 hours per request × $50 per hour).

(4) *Benefit—Request-based relief—Taking request-based relief.* We are unable to quantify the benefits of the request-based relief category at this time because we do not know what types of relief industry will request or how many MMS will approve.

(5) *Cost—Both types of relief—Notifying MMS that relief has ceased.* When a property ceases to qualify for previously granted relief, the lessee or designee is required to notify MMS. MMS expects that 24 properties will cease to qualify for relief each year and that each notification will require ¼ hour to prepare and submit. The estimated cost to lessees for these notifications is approximately $300 (24 properties × .25 hours × $50).

Small Business Issues. Approximately 2,500 companies report and pay royalties to MMS. We estimate that over 97 percent of these companies are small businesses as defined by the U.S. Small Business Administration because they have 500 or fewer employees. We anticipate that most of the relief granted under this proposed rule will benefit small companies. Typically, as properties near the end of their productive life, larger companies with higher overhead, sell their marginal properties to small companies who can operate them more profitably. We expect most small companies will avail themselves of the cumulative reporting and payment relief option. Generally, larger companies may not use this option because of the expense of modifying their large, complex computer systems to report a few leases on an annual rather than a monthly basis. However, we expect that most request-based relief will be sought by larger companies having more sophisticated and complex accounting considerations. If any company, large or small, chooses not to take the accounting and auditing relief offered in this proposed rule, it will incur no additional expense or burden.

B. State and Local Governments

This rule will not impose any additional burden on local governments. MMS estimates that States impacted by this rule would incur costs and benefits as calculated below:

(1) *Cost—Notification-based relief—Determining State participation.* Burden hours for review and development of a blanket State policy on accounting and auditing relief is estimated to be 40 hours at the beginning of each year. Only 4 States have sufficient numbers of marginal properties to require an in-depth analysis of the economic impact of offering accounting and auditing relief. Consequently, we estimate the total annual burden to establish blanket policies for all States to be approximately 160 hours (4 primary States × 40 hours) or a total cost of $8,000 (160 hours × $50).

(2) *Cost—Request-based relief—Consulting with MMS.* Consultation with MMS on individual requests for other accounting and auditing relief is estimated to be 4 hours per property. As noted previously, MMS expects approximately 10 requests for individual accounting and auditing relief each year for a total burden of 40 hours for all States (10 requests × 4 hours per request) or a total cost of $2,000 (40 hours × $50).

(3) *Benefit—Notification-based relief—Prolonging life of marginal wells.* As discussed in item 2.A., we estimate that after the first year, cumulative reporting will save industry approximately $45,000 annually ($55,000–$10,000). We believe this reduced cost of operations will prolong the life of marginal wells. If the reporting relief encourages industry to continue to produce oil and gas from marginal properties, States will benefit in the additional receipts. The States generally would receive 50 percent of the royalties collected on additional production plus additional severance and ad valorem taxes. The States also would benefit from continued employment and economic activity resulting from production that would otherwise be abandoned. We cannot determine the length and dollar benefit of this additional well life at this time. However, we believe that if States choose to participate in this reporting relief, the net benefits to the States will be positive.

(4) *Cost—Notification-based relief—Lost time value of money.* Because payments would be made annually rather than monthly, States will lose the time value of money on sales made in the 11 months before the royalty payment is due. Generally, States receive 50 percent of the royalties collected for onshore leases.

For example, New Mexico has the largest number of properties qualifying for cumulative reporting and payment relief—approximately 1,280. Using a value of $21 per barrel of oil and $2.20 per Mcf of gas and a 7 percent interest rate, we estimate that if all 1,280 qualifying properties take cumulative reporting and payment relief, New Mexico would lose a maximum of $14,000 annually in the time value of money. The calculation for New Mexico marginal properties producing 1,000 BOE per year or less is as follows:

Action	Gas (Mcf)	Oil (bbl)	Total
Total qualifying volume	1,741,829	154,101	
Multiplied by estimated unit value	× $2.20	× $21.00	
Total estimated value	$3,832,023	$3,236,121	$7,068,144
Multiplied by royalty rate [1]			× .125
Total royalty due for year			$ 883,518

Action	Gas (Mcf)	Oil (bbl)	Total
Divided by 12 months [2]			÷12
Average royalty due per month			$ 73,626
Multiplied by est. interest rate			× .07
Interest on 1 mo. royalty for 1 yr.			5,153
Multiplied by 66/12 [3]			× 66/12
Interest (time value) lost for yr. [4]			28,341

[1] The royalty rate for Federal onshore leases is most often 12½ percent. However, many of these marginal properties may also qualify for lower royalty rates under the stripper oil royalty rate reduction program (30 CFR 216.57). Consequently, the royalty value in this calculation could be less.

[2] To simplify this calculation, we divided the total royalty due for the year by 12 months on the assumption that the royalties would be evenly produced throughout the year.

[3] This factor reflects the fact that different amounts of interest would accrue for each production month, beginning with 11/12 of 7 percent for the first month; 10/12 of 7 percent for the second month; 9/12 of 7 percent for the third month, etc. for a total of 66/12.

[4] The New Mexico State share is 50 percent; the Federal share is 50 percent. We rounded each share to $14,000.

As noted above, we calculated the time value of money lost for qualifying properties in New Mexico to be approximately $28,000 annually (the New Mexico share is $14,000 and the Federal government's share is $14,000). Because New Mexico has 43 percent of all marginal properties producing 1,000 BOE or less per year, we extrapolated the total loss for qualifying properties in all States to be $65,000 annually ($28,000 ÷. 43 = $65,000). The share of the lost time value of money for all States would be $32,500 and the Federal government's share would be $32,500.

C. Federal Government

(1) *Benefit—Notification-based relief—Processing fewer lines.* As noted in item 2.A.(2) above, lessees will report—and MMS will process—approximately 22,000 fewer lines under the cumulative reporting and payment relief option. We estimate that MMS will save approximately $8,360 per year (22,000 lines X $.38 processing cost per line). We determined the cost per line using cost data from OMB Control Number 1010–0140 ($958,229 cost to MMS to process lines received from industry on the Form MMS–2014 divided by 2,496,000 expected lines per year).

(2) *Cost—Notification-based relief—Processing notifications.* In the first year, MMS expects to receive 1,000 notifications from lessees who wish to report annually on their marginal properties. We estimate that recording each notification in MMS's automated records will require 5 minutes per notice. Total time to record the notifications is 83 hours (1,000 notices X 5 minutes/notice 60 minutes/hour). Using an average cost of $50 per hour, the total cost to the Government is estimated to be $4,150.

In the second year and each year thereafter, MMS expects to receive only 100 notifications. Total time to record the notifications is 8 hours (100 notices X 5 minutes/notice 60 minutes/hour) or a total cost of $400 (8 hours X $50/hour).

(3) *Cost—Request-based relief—Evaluating requests for other relief.* As noted in item 2.A.(3) above, MMS expects to receive 10 individual accounting and auditing relief requests from lessees annually. We estimate that each request will require 40 hours to analyze for a total cost of $20,000 (10 requests X 40 hours per request X $50 per hour).

(4) *Benefit—Notification-based relief—Prolonging life of marginal wells.* As discussed in item 2.A. above, we estimate that after the first year cumulative reporting will save industry approximately $45,000 annually ($55,000—$10,000). We believe this reduced cost of operations will prolong the life of marginal wells. We cannot determine the length and dollar benefit of this additional well life at this time. The Federal government would generally receive 50 percent of the royalties collected on additional production. We believe the net benefit to the Federal government will be positive.

(5) *Cost—Notification-based relief—Lost time value of money.* The Federal government will lose the time value of money on sales made in the 11 months before the royalty payment is due. Generally, the Federal government receives 50 percent of the royalties collected for onshore leases. We believe the amount lost to the Federal government for the time value of money would be the same as for all States or $32,500 annually (see item B.4. above for the calculation).

D. Summary of Costs and Benefits

Description	Benefit / <COST>	
	First Year	Subsequent Years
A. Industry		
(1)<Cost>—Notification-based relief—Submitting notifications	$<100,000>	$<10,000>
(2) Benefit—Notification-based relief— Reporting fewer lines	55,000	55,000
(3) Cost—Request-based relief—Requesting approval	<2,000>	<2,000>
(4) Benefit—Request-based relief—Taking request-based relief and prolonging the life of marginal wells	Unknown	Unknown
(5) Cost—Both types of relief—Notifying MMS that relief has ceased	<300>	<300>
B. State and Local Governments		
(1) Cost—Notification-based relief—Determining State participation	<8,000>	<8,000>
(2) Cost—Request-based relief—Consulting with MMS	<2,000>	<2,000>
(3) Benefit—Notification-based relief—Prolonging life of marginal wells	Unknown	Unknown
(4) Cost—Notification- based relief—Lost time value of money	<32,500>	<32,500>

Description	Benefit / <COST>	
	First Year	Subsequent Years
C. Federal Government		
(1) Benefit—Notification-based relief—Processing fewer lines	8,360	8,360
(2) Cost—Notification-based relief—Processing notifications	<4,150>	<400>
(3) Cost—Request-based relief—Evaluating requests for relief	<20,000>	<20,000>
(4) Benefit—Notification based relief—Prolonging the life of marginal wells	Unknown	Unknown
(5) Cost—Notification-based relief—Lost time value of money	<32,500>	<32,500>

3. Regulatory Planning and Review (Executive Order 12866)

This document is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866.

(1) This proposed rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This proposed rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This proposed rule will not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This proposed rule does not raise novel legal or policy issues.

4. The Regulatory Flexibility Act

The Department of the Interior 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.*). See the discussion of small business effects in Item 2.A. above.

Your comments are important. The Small Business and Agricultural Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions in this rule, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Disciplinary action for retaliation by an MMS employee may include suspension or termination from employment with the Department of the Interior.

5. Small Business Regulatory Enforcement Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Will not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

6. Unfunded Mandates Reform Act

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

7. Takings (Executive Order 12630)

In accordance with Executive Order 12630, this proposed rule does not have significant takings implications. This rule does not impose conditions or limitations on the use of any private property; consequently, a takings implication assessment is not required.

8. Federalism (Executive Order 13132)

In accordance with Executive Order 13132, this proposed rule does not have Federalism implications. This rule does not substantially or directly affect the relationship between Federal and State governments or impose costs on States or localities.

9. Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this proposed rule will not unduly burden the judicial system and does meet the requirements of sections 3(a) and 3(b)(2) of the Order.

10. Paperwork Reduction Act of 1995

This proposed rule contains new information collection requirements that we have submitted to the Office of Management and Budget (OMB) for review and approval under section 3507(d) of the Paperwork Reduction Act of 1995. As part of our continuing effort to reduce paperwork and respondent burden, we invite the public and other Federal agencies to comment on any aspect of the reporting burden.

Submit your comments to the Office of Information and Regulatory Affairs, OMB, Attention Desk Officer for the Department of the Interior (OMB Control Number 1010–NEW), 725 17th Street, Washington, DC 20503.

Send copies of your comments to Paul A. Knueven, Chief, Regulations and FOIA Team, Minerals Management Service, Minerals Revenue Management, P.O. Box 25165, MS 320B2, Denver, Colorado 80225. If you use an overnight courier service, the MMS courier address is Building 85, Room A–614, Denver Federal Center, Denver, Colorado 80225. You may also e-mail your comments to us at *mrm.comments@mms.gov*. Include the title of the information collection and the OMB Control number in the ''Attention'' line of your comment. Also include your name and return address. Submit electronic comments as an ASCII file avoiding the use of special characters and any form of encryption. If you do not receive a confirmation that we have received your e-mail, contact Mr. Knueven at (303) 231–3316.

OMB has up to 60 days to approve or disapprove this collection of information but may respond after 30 days. Therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration. However, we will consider all comments received during the comment period for this notice of proposed rulemaking.

Information Collection Burden. The annual reporting burden for this information collection in the first year after this rule is effective is 2,206 hours.

We expect approximately 1,034 responses from 1,010 Federal lessees or designees and approximately 4 responses from 4 States annually. The table below shows the breakdown of burden in the first year by proposed CFR section and paragraph:

30 CFR section	Reporting requirement	Burden hours per response	Annual number of responses	Annual burden hours
204.202(b); 204.205(a)	You must notify MMS under § 204.205(a) before taking [cumulative reporting] relief under this option * * * To take accounting relief under § 204.202, you must notify MMS in writing * * *.	2	1,000	2,000
204.202(c), (e), (f), (g); 204.210(c).	Submit your royalty report and payment * * * by the end of February * * * Submit your royalty report and payment by the end of March if you have an estimate on file * * * Report one line of cumulative royalty information on the Report of Sales and Royalty Remittance, Form MMS–2014 * * * If you take relief you are not qualified for, you must * * * amend your Form MMS–2014 * * * You must report allowances on Form MMS–2014 on the same annual basis as the royalties for your marginal property * * * You must report and pay royalties for the portion of the calendar year * * * by the end of the month after you dispose of the marginal property * * * You must adjust your royalty payments if they are affected by any required BLM or OMM reallocation under the nonqualifying Agreement.	Burden covered under OMB Control Number 1010–0140		
204.203(b); 204.205(b)(1); 204.206(a)(3), (b).	You must request approval from MMS under § 204.205(b) before taking relief under this [other relief] option * * * To obtain [other] accounting or auditing relief under § 204.203, you must file a written request * * * You have 60 days from your receipt of MMS's notice to either accept or reject any modifications in writing * * * If your request for relief is not complete * * * you must submit the missing information within 60 days * * * You may submit a new request for relief * * * at any time after MMS returns your incomplete request.	4	10	40
204.208(c), (d)	* * * The State must notify the Associate Director for [MRM], in writing of its intent to allow or disallow one or both of the relief options * * * [and] specify in its notice of intent * * * which relief options it will allow or disallow * * * If it so decides * * * that it will allow one or both of the relief options previously denied * * * the State must notify the Associate Director * * * in writing * * * its intent to allow one or both of the relief options * * * [and] specify in its notice of intent * * * which relief options it will allow..	40	4	160
204.209(b)	You must notify MMS in writing by December 31 that the relief for your property has terminated.	.25	24	6
Total			1,038	2,206

As noted in the table above, the total burden hours for this information collection is 2,206 hours in the first year. Using an average cost of $50 per hour, the total cost to respondents is $110,300.

In the second year after this rule is effective and each year thereafter, the annual burden for this information collection will be substantially reduced to 406 hours and a total cost of $20,300 (406 hours × $50/hour). Because the reporting and payment relief for a qualified property is for the life of the property as long as the property produces less than 1,000 BOE per year, a notification under §§ 204.202(b) and 204.205(a) need only be filed one time. Consequently, we expect only 100 notifications for newly-qualifying properties in each subsequent year. The total estimated burden for notifications will decrease from 2,000 hours (1,000 responses × 2 hours) to 200 hours (100 responses × 2 hours) for a total decrease of 1,800 hours. MMS will notify OMB of this burden adjustment at the appropriate time. There are no additional recordkeeping costs associated with this information collection.

Effects on OMB Control Number 1010–0140, Report of Sales and Royalty Remittance, Form MMS–2014. We estimate that as a result of cumulative reporting, lessees will submit, and MMS will receive, a total of 22,000 fewer lines on Forms MMS–2014 each year. However, because this rule potentially impacts less than 0.9 percent of the total expected lines (22,000 lines ÷ 2,496,000 lines = .0088) each year, we are not revising our burden estimates for OMB Control Number 1010–0140 at this time. Our burden estimates for Form MMS–2014 are based on a combination of historical information and informed but subjective judgments about future occurrences. Thus, our estimates are not sufficiently precise to project a measurable difference in burden for a potential minor decrease in reported lines.

Public Comment Policy. The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Before submitting an ICR to OMB, PRA Section 3506(c)(2)(A) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *.'' Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is

necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

The PRA also requires agencies to estimate the total annual reporting ''non-hour cost'' burden to respondents or recordkeepers resulting from the collection of information. We have not identified non-hour cost burdens for this information collection. If you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information; monitoring, sampling, and testing equipment; and record storage facilities. Generally, your estimates should not include equipment or services purchased: (i) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Government; or (iv) as part of customary and usual business or private practices.

We will summarize written responses to this proposed information collection and address them in our final rule. We will provide a copy of the ICR to you without charge upon request and the ICR will also be posted on our Web site at *http://www.mrm.mms.gov/Laws_R_D/FRNotices/FRInfColl.htm.*

We will post all comments in response to this proposed information collection on our Web site at *http://www.mrm.mms.gov/Laws_R_D/InfoColl/InfoColCom.htm.* We will also make copies of the comments available for public review, including names and addresses of respondents, during regular business hours at our offices in Lakewood, Colorado. Individual respondents may request that we withhold their home address from the public record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you request that we withhold your name and/or address, state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

11. National Environmental Policy Act

This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required.

12. Clarity of this Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, *etc.*) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (A ''section'' appears in bold type and is preceded by the symbol ''§ '' and a numbered heading; for example, § 204.200 What is the purpose of this part?) (5) Is the description of the rule in the ''Supplementary Information'' section of the preamble helpful in understanding the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street NW, Washington, DC 20240. You may also e-mail the comments to this address: *Exsec@ios.doi.gov.*

13. Energy Supply, Distribution, or Use (Executive Order 13211)

This rule is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866. The primary purpose of this rule is to provide accounting and auditing relief to certain lessees of Federal oil and gas properties, largely in the form of reduced records submittal requirements. This rule does not have a significant effect on energy supply, distribution, or use because while it should promote some additional production on a subset of Federal oil and gas leases, the additional production would not be significant in comparison to total production from Federal oil and gas leases.

List of Subjects in 30 CFR Part 204

Continental shelf, Government contracts, Mineral royalties, Natural gas, Petroleum, Public lands—mineral resources, Reporting and recordkeeping requirements.

Dated: February 19, 2003.

Rebecca W. Watson,

Assistant Secretary for Land and Minerals Management.

For reasons set out in the preamble, 30 CFR part 204 is proposed to be added as follows:

PART 204—ALTERNATIVES FOR MARGINAL PROPERTIES

Subpart A—General Provisions

Sec.

204.1 What is the purpose of this part?
204.2 What definitions apply to this part?
204.3 What alternatives are available for marginal properties?
204.4 What is a marginal property under this part?
204.5 What statutory requirements must I meet to obtain royalty prepayment or accounting and auditing relief?
204.6 May I appeal if MMS denies my request for prepayment or accounting and auditing relief?

Subpart B—Prepayment of Royalty [Reserved]

Subpart C—Accounting and Auditing Relief

204.200 What is the purpose of this subpart?
204.201 Who may obtain accounting and auditing relief?
204.202 What is the cumulative royalty reports and payments relief option?
204.203 What is the other relief option?
204.204 What accounting and auditing relief will MMS not allow?
204.205 How do I obtain accounting and auditing relief?
204.206 What will MMS do when it receives my request for accounting and auditing relief?
206.207 Who will approve, deny, or modify my request for accounting and auditing relief?
204.208 May a State decide that it will or will not allow one or both of the relief options under this subpart?
204.209 What if my property ceases to qualify for relief obtained under this subpart?
204.210 What if BLM approves my property as part of a nonqualifying agreement?
204.211 When may MMS retroactively rescind relief for a property?

204.212 What if I took relief for which I was ineligible?
204.213 May I obtain relief for a property that benefits from other Federal or State incentive programs?
204.214 Are the information collection requirements in this subpart approved by the Office of Management and Budget?

Authority: 30 U.S.C. 1701 *et seq.*

Subpart A—General Provisions

§ 204.1 What is the purpose of this part?

This part explains how you as a lessee or lessee's designee of a Federal onshore or Outer Continental Shelf (OCS) oil and gas lease may obtain prepayment or accounting and auditing relief for certain marginal properties.

§ 204.2 What definitions apply to this part?

Agreement means a federally approved communitization Agreement or unit participating area.

Barrels of oil equivalent (BOE) means the combined equivalent production of oil and gas stated in barrels of oil. Each barrel of oil production is equal to one BOE. Also, each 6,000 cubic feet of gas production is equal to one BOE.

Base period means the 12-month period from July 1 through June 30 immediately preceding the calendar year in which you take or request marginal property relief. For example, if you request relief in January 2006, your base period will be July 1, 2004 through June 30, 2005.

Combined equivalent production means the total of all oil and gas production for the marginal property, stated in BOE.

Designee means the person designated by a lessee under § 218.52 of this chapter to make all or part of the royalty or other payments due on a lease on the lessee's behalf.

Producing wells means only those producing oil or gas wells that contribute to the sum of BOE used in the calculation under § 204.4(c). Producing wells do not include injection or water wells.

State concerned (State) means the State that receives a statutorily-prescribed portion of the royalties from a Federal onshore or OCS lease.

§ 204.3 What alternatives are available for marginal properties?

If you have production from a marginal property, MMS and the State may allow you the following options:

(a) *Prepay royalty.* MMS and the State may allow you to make a lump-sum advance payment of royalties instead of monthly royalty payments for the remainder of the lease term.

(b) *Take accounting and auditing relief.* MMS and the State may allow various accounting and auditing relief options to encourage you to continue to produce and develop your marginal property. See subpart C for accounting and auditing relief requirements.

§ 204.4 What is a marginal property under this part?

To qualify as a marginal property eligible for royalty prepayment or accounting and auditing relief under this part, your property must meet the following requirements:

(a) Production must be from, or attributable to, a Federal onshore or OCS lease or Agreement. Indian leases are not eligible for the marginal property alternatives under this part, even though production from a qualifying marginal property may be attributable to an Indian lease. You must also meet the criteria shown in the following table:

If your lease is * * *	Then * * *	And * * *
(1) Not in an Agreement	The entire lease must qualify as a marginal property under paragraph (b) of this section..	
(2) Entirely or partly committed to one Agreement.	The entire Agreement must qualify as a marginal property under paragraph (b) of this section.	Agreement production allocable to your lease may be eligible for relief under this part. Any production from your lease that is not committed to the Agreement also may be eligible for separate relief under (a)(4) of this table.
(3) Entirely or partly committed to more than one Agreement.	The Agreement must qualify separately as a marginal property under paragraph (b) of this section.	Only the qualifying Agreement's production allocable to your lease may be eligible for separate relief under this part.
(4) Partly committed to an Agreement and you have production from the part of the lease that is not committed to the Agreement.	The part of the lease that is not committed to the Agreement must qualify separately as a marginal property under paragraph (b) of this section..	

(b) To qualify as a marginal property for a calendar year, the combined equivalent production of the property during the base period must equal an average daily well production of less than 15 barrels of oil equivalent (BOE) per well per day calculated under paragraph (c) of this section.

(c) To determine the average daily well production on or attributable to your property, divide the sum of the BOE for all producing wells on the property by the sum of the number of days that each of those wells actually produced during the base period. If your property is in an Agreement, your calculation under this section must include all wells included in the Agreement, even if they are not on a Federal onshore or OCS lease.

§ 204.5 What statutory requirements must I meet to obtain royalty prepayment or accounting and auditing relief?

(a) MMS and the State may allow royalty prepayment or accounting and auditing relief for your marginal property if MMS and the State jointly determine that the prepayment or relief is in the best interests of the Federal Government and the State to:

(1) Promote production;

(2) Reduce the administrative costs of MMS and the State; and

(3) Increase net receipts to the Federal Government and the State.

(b) MMS and the State may discontinue any prepayment or accounting and auditing relief options granted for your marginal property if MMS and the State jointly determine that the prepayment or relief no longer meets the criteria in paragraph (a) of this section.

§ 204.6 May I appeal if MMS denies my request for prepayment or accounting and auditing relief?

If MMS denies your request for prepayment or accounting and auditing relief under this part, you may appeal under part 290 of this chapter.

Subpart B—Prepayment of Royalty [Reserved]

Subpart C—Accounting and Auditing Relief

§ 204.200 What is the purpose of this subpart?

This subpart explains how you as a lessee or lessee's designee may obtain accounting and auditing relief for production from a marginal property. The two types of relief that you can receive under this subpart are cumulative reports and payment relief (explained in § 204.202) and other accounting and auditing relief appropriate for your property (explained in § 204.203).

§ 204.201 Who may obtain accounting and auditing relief?

(a) You may obtain accounting and auditing relief under this subpart:

(1) If you are a lessee or its designee for a Federal lease with production from a property that qualifies as a marginal property under § 204.4;

(2) If you meet any additional requirements for specific types of relief under this subpart; and

(3) Only for your fractional interest in the marginal property.

(b) You may not obtain one or both of the relief options specified in this subpart on any portion of a property if:

(1) The property covers multiple States; and

(2) One of the States determines under § 204.208 that it will not allow one or both of the relief options.

§ 204.202 What is the cumulative royalty reports and payments relief option?

(a) The cumulative royalty reports and payments relief option allows you to submit royalty reports and payments annually for the calendar year. You are eligible for this option only if the total volume produced from the marginal property is 1,000 BOE or less during the base period.

(b) You must notify MMS under § 204.205(a) before taking relief under this option.

(c) To use the cumulative royalty reports and payments relief option, you must do all of the following.

(1) Submit your royalty report and payment in accordance with § 218.51(g) of this chapter if you do not have an estimated payment on file for gas under 30 CFR 218.150(b). You must make this submission by the end of February of the year following the calendar year for which you are reporting annually.

(2) Submit your royalty report and payment by the end of March of the year following the year for which you are reporting annually if you have an estimate on file.

(3) Use as the sales month the month before the month that you will report and pay under this paragraph (c) to report royalty information for the entire calendar year. (For example, if you report and pay by the end of February, use January as the sales month.)

(4) Report one line of cumulative royalty information on the Report of Sales and Royalty Remittance, Form MMS–2014, for the calendar year, the same as if it were a monthly report.

(d) If you do not pay your royalty by the date due in paragraph (c) of this section, you will owe late payment interest determined under part 218 of this chapter from the date your payment was due under this section until the date MMS receives it.

(e) If you take relief you are not qualified for, you must:

(1) Pay MMS late payment interest determined under part 218 of this chapter from the date your payment was due until the date MMS receives it; and

(2) Amend your Form MMS–2014 to reflect the required monthly reporting.

(f) You must report allowances on Form MMS–2014 on the same annual basis as the royalties for your marginal property.

(g) If you dispose of a marginal property for which you have taken relief under this section, you must:

(1) Report and pay royalties for the portion of the calendar year for which you had an ownership interest; and

(2) Make the report and payment by the end of the month after you dispose of the marginal property.

§ 204.203 What is the other relief option?

(a) Under this relief option, you may request any type of accounting and auditing relief that is appropriate for your marginal property, provided it is not prohibited under § 204.204 and meets the statutory requirements of § 204.5. Examples of relief options you could request are:

(1) To report and pay royalties using a valuation method other than that required under part 206 of this chapter that approximates royalties payable under part 206 of this chapter; and

(2) To reduce your royalty audit burden. However, MMS will not consider any request that eliminates MMS's or the State's right to audit.

(b) You must request approval from MMS under § 204.205(b) before taking relief under this option.

§ 204.204 What accounting and auditing relief will MMS not allow?

MMS will not approve your request for accounting and auditing relief under this subpart if your request:

(a) Prohibits MMS or the State from conducting any form of audit;

(b) Permanently relieves you from making future royalty reports or payments;

(c) Provides for less frequent royalty reports and payments than annually;

(d) Provides for you to submit royalty reports and payments at separate times;

(e) Impairs MMS's ability to properly or efficiently account for or distribute royalties;

(f) Requests relief for a lease under which the Federal Government takes its royalties in-kind;

(g) Alters production reporting requirements;

(h) Alters lease operation or safety requirements;

(i) Conflicts with rent, minimum royalty, or lease requirements; or

(j) Requests relief for a marginal property located in a State that has determined in advance that it will not allow such relief under § 204.208.

§ 204.205 How do I obtain accounting and auditing relief?

(a) To take accounting relief under § 204.202, you must notify MMS in writing by January 31 of the calendar year for which you begin taking your relief.

(1) Your notification must contain:

(i) Your company name, MMS-assigned payor code, address, phone number, and contact name; and

(ii) The specific MMS lease number and Agreement number, if applicable.

(2) You may file a single notification for multiple marginal properties.

(b) To obtain accounting or auditing relief under § 204.203, you must file a written request for relief with MMS.

(1) Your request must contain:

(i) Your company name, MMS-assigned payor code, address, phone number, and contact name;

(ii) The MMS lease number and Agreement number, if applicable; and

(iii) A complete and detailed description of the specific accounting or auditing relief you seek.

(2) You may file a single request for multiple marginal properties if you are requesting the same relief for all properties.

§ 204.206 What will MMS do when it receives my request for accounting and auditing relief?

When MMS receives your request for accounting and auditing relief under § 204.205(b), it will notify you in writing as follows:

(a) If your request for relief is complete, MMS may either approve, deny, or modify your request in writing.

(1) If MMS approves your request for relief, MMS will notify you of the

effective date of your accounting or auditing relief and other specifics of the relief approved.

(2) If MMS denies your relief request, MMS will notify you of the reasons for denial and your appeal rights under § 204.6.

(3) If MMS modifies your relief request, MMS will notify you of the modifications.

(i) You have 60 days from your receipt of MMS's notice to either accept or reject any modification(s) in writing.

(ii) If you reject the modification(s) or fail to respond to MMS's notice, MMS will deny your relief request. MMS will notify you in writing of the reasons for denial and your appeal rights under § 204.6.

(b) If your request for relief is not complete, MMS will notify you in writing that your request is incomplete and identify any missing information.

(1) You must submit the missing information within 60 days of your receipt of MMS's notice that your request is incomplete.

(2) If you submit all required information, MMS and the State may approve, deny, or modify your request for relief. You may submit a new request for relief under this subpart at any time after MMS returns your incomplete request.

(3) If you do not submit all required information within 60 days of your receipt of MMS's notice that your request is incomplete, MMS will deny your relief request. MMS will notify you in writing of the reasons for denial and your appeal rights under § 204.6.

(c) [*The regulatory text in this paragraph concerning the time period, if any, within which MMS must either deny or approve your request will be determined after due consideration of public comments. See section II of the preamble titled ''Comments on the 1999 Proposed Rule, Alternate Valuation Relief Option.''*]

§ 204.207 Who will approve, deny, or modify my request for accounting and auditing relief?

(a) If there is not a State concerned for your marginal property, only MMS will decide whether to approve, deny, or modify your relief request.

(b) If there is a State concerned for your marginal property that has determined in advance that it may allow either or both of the relief options under this subpart, MMS will decide whether to approve, deny, or modify your relief request after consulting with the State concerned.

§ 204.208 May a State decide that it will or will not allow one or both of the relief options under this subpart?

(a) A State may decide in advance that it will or will not allow one or both of the relief options specified in this subpart for a particular calendar year.

(b) To help States decide whether to allow one or both of the relief options specified in this subpart, MMS will send States a Report of Marginal Properties by September 30 of the preceding calendar year.

(c) If a State decides under paragraph (a) of this section that it will or will not allow one or both of the relief options in this subpart, within 30 days of the State's receipt of the Report of Marginal Properties under paragraph (b) of this section, the State must:

(1) Notify the Associate Director for Minerals Revenue Management, MMS, in writing, of its intent to allow or not allow one or both of the relief options under this subpart; and

(2) Specify in its notice of intent to MMS which relief option(s) it will allow or not allow.

(d) If a State decides in advance under paragraph (a) of this section that it will not allow one or both of the relief options specified in this subpart, it may decide for subsequent calendar years that it will allow one or both of the relief options in this subpart. If it so decides, within 30 days of the State's receipt of the Report of Marginal Properties under paragraph (b) of this section, the State must:

(1) Notify the Associate Director for Minerals Revenue Management, MMS, in writing, of its intent to allow one or both of the relief options allowed under this subpart; and

(2) Specify in its notice of intent to MMS which relief option(s) it will allow.

(e) If a State does not notify MMS under paragraphs (c) or (d) of this section, the State will be deemed to have decided not to allow either of the relief options under this subpart.

(f) MMS will publish a notice of the State's intent to allow or not allow certain relief options under this section in the **Federal Register** no later than 30 days before the beginning of the applicable calendar year.

§ 204.209 What if my property ceases to qualify for relief obtained under this subpart?

(a) Your property must qualify for relief under this subpart for each calendar year based on production during the base period for that calendar year. The notice or request you provided to MMS under § 204.205 for the first calendar year that your property qualified for relief remains effective for successive calendar years if you continue to qualify.

(b) If your property is no longer eligible for relief for any reason during a calendar year other than the reason under § 204.210 or paragraph (c) of this section, the relief for your property terminates as of December 31 of that calendar year. You must notify MMS in writing by December 31 that the relief for your property has terminated.

(c) If you dispose of your property during the calendar year, your relief terminates as of the end of the sales month in which you disposed of the property.

§ 204.210 What if BLM approves my property as part of a nonqualifying Agreement?

If the Bureau of Land Management (BLM) or MMS's Offshore Minerals Management (OMM) retroactively approves your marginal property as part of a nonqualifying Agreement, the property no longer qualifies for relief under this subpart. In that case:

(a) MMS will not retroactively rescind the marginal property relief for your property under § 204.211;

(b) Your marginal property relief terminates as of December 31 of the calendar year that you receive the BLM or OMM approval of your marginal property as part of a nonqualifying Agreement; and

(c) You must adjust your royalty payments if they are affected by any required BLM or OMM reallocation under the nonqualifying Agreement.

§ 204.211 When may MMS retroactively rescind relief for a property?

MMS may retroactively rescind the relief for your property if MMS determines that your property was not eligible for the relief obtained under this subpart because:

(a) You did not submit a notice or request for relief under § 204.205;

(b) You submitted erroneous information in the notice or request for relief you provided to MMS under § 204.205 or in your royalty or production reports; or

(c) Your property is no longer eligible for relief because production increased, but you failed to provide the notice required under § 204.209(b).

§ 204.212 What if I took relief for which I was ineligible?

If you took relief under this subpart for a period for which you were not eligible, you may owe additional royalties and late payment interest determined under part 218 of this chapter from the date your additional

payments were due until the date MMS receives them.

§ 204.213 May I obtain relief for a property that benefits from other Federal or State incentive programs?

You may obtain accounting and auditing relief for your marginal property under this subpart even if the property benefits from other Federal or State production incentive programs.

§ 204.214 Are the information collection requirements in this subpart approved by the Office of Management and Budget?

The information collection requirements contained in this subpart have been approved by OMB under 44 U.S.C. 3501 *et seq.* and assigned OMB control number 1010–____. See part 210 of this chapter for details concerning your estimated reporting burden and how you may comment on the accuracy of the burden estimate.

[FR Doc. 03–6703 Filed 3–28–03; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 800

[Docket No. 03N–0056]

Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the sampling plans, test method, and acceptable quality levels (AQLs) for medical gloves contained in its medical device regulations. As prescribed by its regulation, FDA samples patient examination and surgeons' gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet the specified quality levels. The objective of the proposed regulation is to improve the barrier quality of medical gloves on the U.S. market. The updated regulation would accomplish this by reducing the acceptable level of defects observed during FDA testing of medical gloves. By reducing the AQLs for medical gloves, FDA would also harmonize the level with consensus standards developed by the International Organization for Standardization (ISO) and the American Society for Testing Materials (ASTM).

DATES: Submit written or electronic comments by June 30, 2003. See section VII of this document for the proposed effective date of a final rule based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Office of Compliance, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

With the advent of the human immunodeficiency virus (HIV) infections and the progression of infections into acquired immune deficiency syndrome (AIDS), scientists and medical and public health experts developed risk reduction strategies, including protective and preventive strategies for health care workers. These strategies were based on the etiology, and mechanisms and routes of transmission, of HIV infections.

A. Routes and Mechanisms of HIV Transmission

HIV is transmitted primarily through sexual contact. However, nonsexual transmission occurred in health care settings as a result of contact with infected blood. HIV was also isolated from other body fluids. The prevalence of HIV infections in health care settings and the risk of clinical transmission of other infections increased the importance of using effective procedures and barriers. The potential for infection heightened the importance of the quality of the barriers selected for protection.

B. The Need for Precautions in Health Care Settings

On August 21, 1987, the Centers For Disease Control (CDC) published a report emphasizing the need for all health care workers to routinely use appropriate universal precautions when they expect to come into contact with blood or other body fluids of any patient (Ref. 1). This report recommended that health care workers wear medical gloves when: (1) Touching blood or other body fluids, mucous membranes, or non-intact skin of patients; (2) handling items or surfaces soiled with blood or other bodily fluids; and (3) performing venipuncture and other vascular access procedures. The collective term, medical gloves, includes patient examination and surgeons' gloves (see 21 CFR 880.6250 and 878.4460).

C. The Need for Testing

After the publication of the CDC's recommendations, and the rise in HIV infections, health care workers increasingly relied on surgeons' gloves and patient examination gloves as a barrier to the transmission of HIV and other blood- and fluid-borne infectious agents. The CDC's recommendations clearly recognized that defects in medical gloves had the potential of resulting in transmission of HIV between patients and health care workers.

Consequently, FDA reviewed and evaluated the quality control procedures that manufacturers used in making medical gloves. FDA concluded that manufacturers could only meet reasonable expectations of barrier protection by establishing adequate specifications for medical gloves, and adequate test procedures to detect defects in gloves. Glove defects include rips, tears, embedded foreign objects in the glove that may cause the glove to rip or tear upon stretching, or holes that allow the passage of fluids and fluid-borne microorganisms. Each of these defects compromises the glove barrier integrity and may expose health care workers and patients to infectious agents. Articles written by health care professionals who studied glove quality and the use of gloves as a barrier to infectious agents noted that gloves with defects may not provide this protection (Refs. 2 through 6). In 1989, when FDA proposed § 800.20 (21 CFR 800.20), FDA's position was that existing consensus standards did not establish adequate test methods and acceptance criteria for patient examination or surgeons' gloves (54 FR 48218, November 21, 1989). Therefore, the agency concluded that it needed to communicate clearly the test procedures and the acceptance levels it would use to determine whether medical gloves were adulterated.

D. The Setting of Adulteration Levels

In the **Federal Register** of December 12, 1990 (55 FR 51254), FDA issued a final rule that identified minimum AQLs for both patient examination and surgeons' gloves, and established the sample plans and test method for determining whether a lot of gloves were acceptable. This rule defined defects as ''leaks, tears, mold, embedded foreign objects, etc.'' The definitions, sampling plans, test methods, and adulteration levels identified in the