that the new animal drug will be effective for the intended use at all doses within the range suggested in the proposed labeling for the intended use.

(ii) [Reserved]

(3) *Studies*—(i) *Number.* Substantial evidence of the effectiveness of a new animal drug for each intended use and associated conditions of use shall consist of a sufficient number of current adequate and well-controlled studies of sufficient quality and persuasiveness to permit qualified experts:

(A) To determine that the parameters selected for measurement and the measured responses reliably reflect the effectiveness of the new animal drug;

(B) To determine that the results obtained are likely to be repeatable, and that valid inferences can be drawn to the target animal population; and

(C) To conclude that the new animal drug is effective for the intended use at the dose or dose range and associated conditions of use prescribed, recommended, or suggested in the proposed labeling.

(ii) *Types.* Adequate and well-controlled studies that are intended to provide substantial evidence of the effectiveness of a new animal drug may include, but are not limited to, published studies, foreign studies, studies using models, and studies conducted by or on behalf of the sponsor. Studies using models shall be validated to establish an adequate relationship of parameters measured and effects observed in the model with one or more significant effects of treatment.

(c) *Substantial evidence for combination new animal drugs*—(1) *Definitions.* The following definitions of terms apply to this section:

(i) *Combination new animal drug* means a new animal drug that contains more than one active ingredient or animal drug that is applied or administered simultaneously in a single dosage form or simultaneously in or on animal feed or drinking water.

(ii) *Dosage form combination new animal drug* means a combination new animal drug intended for use other than in animal feed or drinking water.

(iii) *Antibacterial* with respect to a particular target animal species means an active ingredient or animal drug: That is approved in that species for the diagnosis, cure, mitigation, treatment, or prevention of bacterial disease; or that is approved for use in that species for any other use that is attributable to its antibacterial properties. But, antibacterial does not include ionophores or arsenicals intended for use in combination in animal feed or drinking water.

(iv) *Appropriate concurrent use* exists when there is credible evidence that the conditions for which the combination new animal drug is intended can occur simultaneously.

(2) *Combination new animal drugs that contain only active ingredients or animal drugs that have previously been separately approved.*

(i) For dosage form combination new animal drugs, except for those that contain a nontopical antibacterial, that contain only active ingredients or animal drugs that have previously been separately approved for the particular uses and conditions of use for which they are intended in combination, a sponsor shall demonstrate:

(A) By substantial evidence, as defined in this section, that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the effectiveness of the combination new animal drug;

(B) That each active ingredient or animal drug intended for at least one use that is different from all the other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target animal population; and

(C) That the active ingredients or animal drugs are physically compatible and do not have disparate dosing regimens if FDA, based on scientific information, has reason to believe the active ingredients or animal drugs are physically incompatible or have disparate dosing regimens.

(ii) For combination new animal drugs intended for use in animal feed or drinking water that contain only active ingredients or animal drugs that have previously been separately approved for the particular uses and conditions of use for which they are intended in combination, the sponsor shall demonstrate:

(A) By substantial evidence, as defined in this section, that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the effectiveness of the combination new animal drug;

(B) For such combination new animal drugs that contain more than one antibacterial ingredient or animal drug, by substantial evidence, as defined in this section, that each antibacterial makes a contribution to labeled effectiveness;

(C) That each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target animal population; and

(D) That the active ingredients or animal drugs intended for use in drinking water are physically compatible if FDA, based on scientific information, has reason to believe the active ingredients or animal drugs are physically incompatible.

(3) *Other combination new animal drugs.* For all other combination new animal drugs, the sponsor shall demonstrate by substantial evidence, as defined in this section, that the combination new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling and that each active ingredient or animal drug contributes to the effectiveness of the combination new animal drug.

4. Section 514.111 is amended by revising paragraph (a)(5) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence as defined in § 514.4.

* * * * *

Dated: July 21, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–19193 Filed 7–27–99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Parts 1200 and 1205

[Docket No. NHTSA–99–6011]

RIN 2127–AH53

Uniform Procedures for State Highway Safety Programs

AGENCY: National Highway Traffic Safety Administration and Federal Highway Administration, DOT.

ACTION: Final rule.

SUMMARY: This final rule announces that amendments to the regulation establishing uniform procedures for

State highway safety programs, published in an interim final rule, will remain in effect, with minor changes for clarification in response to comments. The amendments implemented the provisions of a two-year pilot highway safety program, providing a more flexible performance-based system for States to follow in conducting their highway safety programs.

EFFECTIVE DATE: August 27, 1999.

FOR FURTHER INFORMATION CONTACT: In NHTSA, Marlene Markison, Office of State and Community Services, 202–366–2121; John Donaldson, Office of the Chief Counsel, 202–366–1834. In FHWA, Daniel Hartman, Office of Highway Safety, 202–366-2131; Raymond Cuprill, Office of the Chief Counsel, 202–366–0834.

SUPPLEMENTARY INFORMATION:

A. Background

On June 26, 1997, the National Highway Traffic Safety Administration (''NHTSA'') and the Federal Highway Administration (''FHWA'') (''the agencies'') published an interim final rule (62 FR 34397) establishing new procedures governing the implementation of State highway safety programs conducted under the authority of the Highway Safety Act of 1966 (23 U.S.C. 401 *et seq.*). The new procedures changed the submission and approval requirements for State highway safety plans in the regulation at 23 CFR part 1200, Uniform Procedures for State Highway Safety Programs, and simplified certain funding requirements in the regulation at 23 CFR part 1205, Highway Safety Programs; Determinations of Effectiveness.

Under the provisions of the interim final rule, States assumed a new role in the planning and direction of their highway safety programs. In lieu of the earlier regulatory requirement that States submit comprehensive documents for Federal review and approval, States were now charged with setting their own highway safety goals, accompanied by performance measures to chart progress. These new procedures were based on almost two years of successful experience with a pilot highway safety program conducted by the agencies during fiscal years 1996 and 1997. The interim final rule incorporated most of the pilot program's provisions into its requirements.

The agencies requested comments on the interim final rule from all interested parties, and provided a 45-day comment period. Thereafter, because Congress was considering various changes to the Section 402 program in the course of reauthorizing NHTSA and FHWA programs, the agencies decided to delay responding to comments until after Congress had completed the reauthorization process. In today's notice, we respond to the comments received, and issue a final rule.

B. Statutory Requirements

The Section 402 program is authorized under the Highway Safety Act of 1966 (23 U.S.C. 401 *et seq.*). It is a formula grant program that was established to improve highway safety in the States. As a condition of the grant, the Act provides that the States must meet certain requirements contained in 23 U.S.C. 402.

Section 402(a) requires each State to have a highway safety program, approved by the Secretary of Transportation, which is designed to reduce traffic crashes and the deaths, injuries, and property damage resulting from those crashes. Section 402(b) sets forth the minimum requirements with which each State's highway safety program must comply. For example, the Secretary may not approve a program unless it provides that the Governor of the State is responsible for its administration through a State highway safety agency which has adequate powers and is suitably equipped and organized to carry out the program to the satisfaction of the Secretary. Additionally, the program must authorize political subdivisions of the State to carry out local highway safety programs and provide a certain minimum level of funding for these local programs each fiscal year. The enforcement of these and other continuing requirements is entrusted to the Secretary and, by delegation, to the agencies.

When it was originally enacted in 1966, the Highway Safety Act required the agencies to establish uniform standards for State highway safety programs to assist States and local communities in implementing their highway safety programs. Eighteen such standards were established and, during the early years, the Section 402 program was directed principally toward achieving State and local compliance with these standards. Over time, State highway safety programs matured and, in 1976, the Highway Safety Act was amended to provide for more flexible implementation of the program. States were no longer required to comply with every uniform standard or with each element of every uniform standard. As a result, the standards became more like guidelines for use by the States, and management of the program shifted from enforcing standards to using the standards as a framework for problem identification, countermeasure development, and program evaluation. In 1987, Section 402 of the Highway Safety Act was amended, formally changing the standards to guidelines.

Another amendment to the Highway Safety Act required the Secretary to determine, through a rulemaking process, those programs ''most effective'' in reducing crashes, injuries, and deaths, taking into account ''consideration of the States having a major role in establishing (such) programs.'' The Secretary was authorized to revise the rule from time to time. In accordance with this provision, the agencies have identified, over time, nine such programs, the ''National Priority Program areas'' (see discussion under Section C.2, below).

Until recently, the Act provided that only those programs established under the rule as ''most effective'' in reducing crashes, injuries and deaths (i.e., the National Priority Program areas) would be eligible for Federal financial assistance under the Section 402 program. However, the Transportation Equity Act for the 21st Century (Pub. L. 105–178) (TEA–21), enacted June 9, 1998, amended those provisions. The new requirement allows for periodic discretionary rulemaking to identify programs that are ''highly effective'' in reducing crashes, injuries, and deaths, and requires only that States ''consider'' these highly effective programs when developing their highway safety programs.

C. Regulations Prior to the Interim Final Rule

In recent years, the agencies have administered the Section 402 program in accordance with implementing regulations, the Uniform Procedures for State Highway Safety Programs (23 CFR part 1200) (''Part 1200'') and Highway Safety Programs; Determinations of Effectiveness (23 CFR part 1205) (''Part 1205''). Part 1200 sets forth requirements concerning submission and approval of State highway safety plans, apportionment and obligation of Federal funds, and financial accounting and program administration. Part 1205 identifies the National Priority Program areas and provides for the funding of program areas.

1. Part 1200

Part 1200, portions of which were amended by the interim final rule, contained detailed procedures governing the content and Federal approval of a ''Highway Safety Plan,'' to be submitted each fiscal year by the States. In particular, prior to its amendment, the regulation required

each State's highway safety plan to contain a ''problem identification summary,'' highlighting highway safety problems in the State, describing countermeasures planned to address those problems, and providing supporting statistical crash data. Additionally, in the highway safety plan, the State was required to describe and justify program areas to be funded, discuss planning and administration and training needs, and provide certain certifications and financial documentation.

Part 1200 required Federal approval for proposed expenditures within program areas, both under the State's initially submitted Highway Safety Plan and subsequently for any proposed changes in expenditures exceeding ten percent of the total amount in a given program area. Federal approval was also required, on a year-by-year basis, if a State sought to continue a NHTSA project beyond three years. Such approval was conditioned on a showing that the project had demonstrated great merit or the potential for significant long-range benefits, and was subject to increased cost assumption by the State. The regulation provided the agencies with broad discretion to approve, conditionally approve, or disapprove a highway safety plan or any portion of the document, and required the States to submit a comprehensive and detailed annual evaluation report.

2. Part 1205

Part 1205 lists each highway safety program area that the agencies have determined, in accordance with the Highway Safety Act, to be most effective in reducing crashes, injuries, and deaths. The agencies have, through a series of rulemaking actions over the years, identified these program areas as ''National Priority Program Areas.'' There are currently nine National Priority Program Areas: Alcohol and Other Drug Countermeasures; Police Traffic Services; Occupant Protection; Traffic Records; Emergency Medical Services; Motorcycle Safety; Roadway Safety; Pedestrian and Bicycle Safety; and Speed Control.

Prior to its amendment by the interim final rule, part 1205 provided for expedited funding approval of programs developed in any of the National Priority Program Areas. Part 1205 provided that programs developed under other program areas could also be funded, but they were subject to a more detailed approval process. As further described under Section E, below, the amendments that the interim final rule made to part 1205 provided States with more flexibility with regard to their ability to fund these latter programs.

D. The Pilot Program

In the years since the original enactment of Section 402, States have developed the expertise necessary to conduct effective highway safety programs. Just as Congress earlier recognized the desirability of changing the mandatory standards to more flexible guidelines, the agencies recognized that the time was right to provide the States with added flexibility to set their own goals, define their own performance measures, and determine the best means of accomplishing their goals, subject to the existing statutory parameters requiring overall program approval.

Consistent with efforts to relieve burdens on the States under the President's regulatory reform initiative, the agencies took the first step in providing more flexibility for the States by establishing a pilot program in fiscal years 1996 and 1997 for highway safety programs conducted under section 402. The pilot program was announced in the **Federal Register** on September 12, 1995 (60 FR 47418) for fiscal year 1996 and on September 6, 1996 (61 FR 46895) for fiscal year 1997.

1. Procedures

The pilot program waived the requirement for State submission and Federal approval of the Highway Safety Plan required under then-existing part 1200 for those States that chose to participate, and instead provided for a benchmarking process by which the States set their own highway safety goals and performance measures. Under the benchmarking process, participating States were required to submit a planning document and a benchmark report, rather than the previously required highway safety plan. The planning document, which described how Federal funds would be used, consistent with the guidelines, priority areas, and other requirements of Section 402, was required to be approved by the Governor's Representative for Highway Safety.

The States were required to submit the benchmark report to the agencies for approval by August 1 prior to the fiscal year for which the highway safety program was to be conducted. The benchmark report was required to contain three components: a Process Description; Performance Goals; and a Highway Safety Program Cost Summary. Under the Process Description component, States were required to describe the processes used to identify highway safety problems, establish performance goals, and develop the programs and projects in their plans. Under the Performance Goals component, States were required to identify highway safety performance goals (developed through a problem identification process) and to identify performance measures to be used to track progress toward each goal. Under the Highway Safety Program Cost Summary component, States submitted HS Form 217, a financial accounting form that has been a longstanding requirement under part 1200.

The focus of the Federal review and approval process under the pilot program shifted away from a review of the substantive details of the program, on a project-by-project basis, as required under then-existing part 1200. Instead, the process focused on verification that the State had committed itself, through a performance-based planning document approved by the Governor's Representative for Highway Safety and a benchmark report, to a highway safety program that targeted identified State highway safety concerns. The agencies waived the requirement under then-existing part 1200 that States seek approval for changes in expenditures exceeding ten percent in a given program area.

Under the pilot program, the requirements governing the annual evaluation report were changed to accommodate the shift to a performance-based process. States were required to report on their progress toward meeting goals, using performance measures identified in the benchmark report, and the steps they took toward meeting goals. States were also required to describe State and community projects funded during the year.

In other respects, the pilot program followed the requirements of then-existing part 1200 without change. Provisions concerning the submission of certifications and assurances, the apportionment and obligation of Federal funds, financial accounting (including submission of vouchers, program income, and the like), and the closeout of each year's program continued to apply to the pilot program.

2. Experience Under the Pilot Program

Over the two-year period during which the pilot program was in place prior to issuance of the interim final rule, it received increasing support from States. Sixteen States participated in the pilot program during fiscal year 1996, and 41 States, the District of Columbia, Puerto Rico, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands participated during fiscal year

1997. Most participating States expressed enthusiasm about the goal-setting process used in the pilot program, and felt a greater sense of ''ownership'' of their highway safety programs under the pilot procedures. Prior to their participation in the pilot program, many of these States already had adopted performance measures in their State budgeting and management processes, which eased the transition for these States to a performance-based process under the pilot program. The majority of participating States reported that the pilot program procedures resulted in reduced Federally-imposed burdens and increased State flexibility in administering their highway safety programs.

In December 1996, the 16 States that participated in the pilot program during its initial year submitted their annual reports regarding their highway safety accomplishments under the pilot program. Overall, the reports revealed improvements in data systems, goal-setting, and project selection. They also reported reductions in costs and time expended for the administration of the program, and a broadening of highway safety partnerships. In addition, the reports revealed that pilot States were making steady progress toward achieving established goals. Experience during that initial year confirmed that the pilot procedures resulted in the implementation of successful highway safety programs, consistent with national highway safety goals and Federal goals for regulatory reform, streamlining procedures, and improvements in performance.

In January 1997, during the second year of the pilot program, the agencies held a meeting that was attended by representatives of all States and territories. State representatives identified concerns and offered suggestions in an effort to make further improvements in the pilot program procedures. States generally expressed a desire for more flexibility, such as by extending the due date for submission of application documents, permitting a multi-year planning process, and accommodating short and long range goals in the goal-setting process. States generally agreed that, if progress toward meeting goals did not occur in a State, both State and Federal officials should cooperate to develop an improvement plan for the State.

E. Interim Final Rule

Based on the success of the pilot program during its first two years of operation, the agencies published an interim final rule on June 26, 1997, revising the regulations governing State highway safety programs to implement the pilot procedures. The interim final rule also addressed issues raised during the January 1997 meeting. It extended the due date for submission of application documents from August 1 to September 1 and accommodated the States' desire for flexibility to plan and set goals covering time periods that best meet State needs. It also provided for a joint effort by Federal and State officials to develop an improvement plan, where a State fails to progress to meet goals.

The interim final rule replaced the previously-existing procedures under part 1200 governing the preparation, submission, review, and approval of State Highway Safety Plans (discussed generally under Section C.1, above), with new procedures modeled after those used in the pilot program. The interim final rule required the States to submit information detailing their highway safety programs in the same format as required under the pilot program, but made some adjustments to the pilot program procedures, as noted above.

In addition, the interim final rule changed some of the terminology used in the pilot program. The more descriptive terms ''performance plan'' and ''highway safety plan'' replaced the terms ''benchmark report'' and ''planning document,'' which were used in the pilot program to describe State highway safety goals and planned activities. However, the functions of these documents remained essentially unchanged from those existing under the pilot program, as described under Section D, above. In the preamble to the interim final rule, the agencies explained that States were free to prepare their Performance Plan and Highway Safety Plan as comprehensive documents which also included goals and activities for highway safety programs other than the Section 402 program. The agencies explained that, in such cases, the Highway Safety Plan should identify those programs or activities funded from other sources in a separate section or should identify them clearly in some other manner.

The interim final rule changed the nature of the Federal approval process, consistent with the procedures used during the pilot program. Instead of approving a highway safety plan based on a project-by-project justification, the interim final rule provided for review of the State's highway safety program as a whole, to verify that the State had developed a goal-oriented highway safety program that was approved by the Governor's Representative for Highway Safety, and that identified the State's highway safety problems, established goals and performance measures to effect improvements in highway safety, and described activities designed to achieve those goals.

The interim final rule left unchanged the requirement that States must submit an annual report. However, the contents of the annual report changed from those required under the previously-existing part 1200. Under the interim final rule, the States were required to describe their progress in meeting State highway safety goals, using performance measures identified in the Performance Plan, and the projects and activities funded during the fiscal year. They also were required to include in these reports an explanation of how these projects and activities contributed to meeting the State's highway safety goals. No substantive changes were made to provisions relating to the apportionment and obligation of Federal funds, financial accounting, and the like.

Finally, the interim final rule made conforming changes to the funding procedures for National Priority Program Areas and other program areas contained in Part 1205. These changes allowed States to pursue activities in program areas identified either by the agencies as National Priority Program areas or by the States as State priorities. In pursuing activities under the latter category, States were given more flexibility in the processes they could follow to identify program areas that were State priorities, and the level of Federal oversight was reduced.

A more detailed discussion of the changes appears in the preamble to the interim final rule (62 FR 34397).

F. Comments

The interim final rule solicited comments from all interested parties, and noted that the agencies would respond to all comments and, if appropriate, amend the provisions of the rule. The agencies received comments from State agencies in Florida, Maryland, Michigan, and Washington and from two organizations, the National Association of Governors' Highway Safety Representatives and Advocates for Highway and Auto Safety.

1. In General

Many commenters expressed general approval of the interim final rule. In the State of Washington, the Traffic Safety Commission and the Department of Transportation both supported the interim final rule without change. The Traffic Safety Commission lauded the ''change in attitude and method,'' adding that it was certain to improve the already good working relationship

between NHTSA and the States. The Michigan Office of Highway Safety Planning (Michigan) identified the flexibility for quick response to changing issues, the outcome-based evaluation (which it noted was already being performed at the State level), the opportunity to offer programming flexibility to local communities, and the reduction in paperwork as welcome results of the interim final rule. The National Association of Governors' Highway Safety Representatives (NAGHSR) expressed strong support for the rule, commending the agencies for reflecting State concerns and codifying the flexibility desired by States in the interim final rule. NAGHSR was especially supportive of the change in submission date for the State's application documents from August 1 to September 1 of the fiscal year, stating that this would provide the States with time to obtain additional input from their safety constituencies and to refine their performance plans.

2. Specific Issues

Commenters raised a number of specific issues, all related to the interim final rule's changes to part 1200. The agencies received no comments concerning the interim final rule's changes to part 1205.

a. Federal Approval Procedures

The Florida Department of Transportation (Florida) sought clarification of Federal approval procedures. Noting the discussion that Federal approval of the annual Highway Safety Plan was no longer required, Florida asked why the interim final rule contained references to an ''Approving Official'' (§ 1200.3), ''delayed approval'' (§ 1200.12) if due dates are not met, and a ''letter of Approval'' (§ 1200.13).

The statute under which the Section 402 program operates requires each State to have a highway safety program ''approved by the Secretary (of Transportation),'' and further specifies certain conditions under which the Secretary may not approve a program. Consequently, some approvals continue to be required but, as the agencies explained in the preamble to the interim final rule, the nature of the Federal approval process changed. The interim final rule provided that the contents of the Highway Safety Plan no longer need to be approved on a project-by-project basis. Rather, the State's highway safety program is to be reviewed as a whole, to verify that the State has developed a goal-oriented highway safety program that is approved by the Governor's Representative for Highway Safety, and that identifies the State's highway safety problems, establishes goals and performance measures to effect improvements in highway safety, and describes activities designed to achieve those goals. The agencies believe that this new program level approval process was reflected in the interim final rule without ambiguity. Consequently, the agencies have made no change to the rule in response to this comment.

b. Financial Reporting

To effect a further reduction in paperwork burdens on State highway safety offices, Michigan recommended that changes in the allocation of funds, under § 1200.22, be reported on a quarterly basis rather than within 30 days of the change.

In the interim final rule, the agencies took the significant step of removing the requirement for prior approval of changes during program implementation. The agencies believe that removing the prior approval requirement, coupled with retention of the monthly reporting requirement, strikes the appropriate balance between alleviating burdens to the States and retaining the agencies' ability to monitor, on an ongoing basis, the expenditure of Federal funds. Consequently, the agencies have not adopted the suggestion for quarterly reporting of changes.

Florida noted that the interim final rule prescribes the use of HS Form 217 for financial reporting, despite the transition by some States (including Florida) to paperless electronic reporting through NHTSA's Grant Tracking System. Florida asked which format (i.e., hard copy or electronic) was intended by the interim final rule.

For many States, use of the electronic Grant Tracking System has replaced the use of paper forms to report grant finances. However, even with the electronic system, there is an ''HS 217'' screen for recording the information concerning allocations of federal and State funds to specific program areas, which is then transmitted electronically to NHTSA. This form, either in its electronic or hard copy format, would meet the requirements of the interim final rule. To clarify this point, the agencies have included language in appropriate places in the rule explaining that either HS Form 217 or its electronic equivalent is acceptable.

c. Goal-Setting and Program Evaluation

Advocates for Highway and Auto Safety (Advocates) submitted lengthy comments, expressing the view that the interim final rule ''devolves all essential aspects of the 402 program to state authorities.'' According to Advocates, this more flexible approach will result in the selection of highly subjective safety program goals, the inability to assess cost-effectiveness properly, and the submission of State reports based on ''anecdotal experience and generalized, amorphous information.'' Advocates questioned whether this approach satisfies the statutory requirement that State highway safety programs be based on ''uniform guidelines [which] shall be expressed in terms of performance criteria.''

In support of this concern, Advocates cited the report, ''Evaluation of the section 402 Pilot Process, NHTSA (May, 1997)'' and the separate reports submitted by the 16 original pilot States. According to Advocates, the NHTSA report elaborates only on positive information drawn from the State reports, ignoring the deficiencies. Among the deficiencies Advocates identified in the State reports are the lack of substantive information about goals and accomplishments; and the lack of data, or reliance on old or subjective data, or brushing aside of contradictory data in efforts to demonstrate progress toward meeting State goals. Advocates asserted that some State reports are ''in essence, public relations documents,'' and concluded that if this continues, most State reports will be of no use in assessing the status of the individual State programs as well as the national 402 program as a whole. Advocates also asserted that, with a unique goal-selection process for each State, States might select easily achieved goals at the expense of safety issues that need to be addressed. Advocates questioned whether the new approach met the statutory goal of improving highway safety or provided a credible means for evaluating the effectiveness of the Section 402 program.

The agencies have described, above, the evolution of the Highway Safety Act of 1966, from a framework of enforcing standards to using standards for problem identification, countermeasure development, and program evaluation, and ultimately to using guidelines as an aid in fashioning highway safety programs. We have also noted, above, that since publication of the interim final rule, Congress further amended the Highway Safety Act, allowing the States to consider highly effective programs that may from time to time be identified in a rule by the agency, in lieu of requiring adherence to only those programs specifically designated as most effective in a rule by the agency. In short, the statutory framework has moved away from requiring a centralized, uniform program, with each

State pursuing a set of common goals. Consequently, we do not agree with Advocates' criticism that a goal selection process that is unique to each State overlooks important safety issues. Rather, we believe that this new process provides States with the additional flexibility and ability to tailor their programs that was intended by the Congress.

The agencies agree with Advocates that there was variability in the quality and usefulness of data among the 16 initial annual reports submitted by the States under the pilot process. This is to be expected under any new process. However, for the first time, reports began to address performance goals in highway safety and measures of progress in reaching those goals. Under the previous procedures, this important goal-setting and tracking information was largely unavailable. The agencies fully expect that the process, the data, and the reports will improve over time (although there will always be a time-lag in the data). We believe that the annual reports under the new process will provide an effective means of evaluating progress under the Section 402 program, as more experience is developed. Should this not materialize, the agencies will consider necessary changes to the reporting process in a future action. The agencies do not believe that any change to the rule is necessary at this time to address this comment.

The agencies also do not believe that the concern that States may select only goals that are easy to achieve, overlooking other important areas of highway safety, is warranted. In the course of establishing goals and performance measures, the interim final rule requires a State to describe in its Performance Plan the problem identification process followed and the participants in that process. In addition, the State must issue a public report (the Annual Report) each year. With this public process, we do not believe that States will address only easily-achieved goals. A more likely limitation on the goal-setting process will be the initial absence of effective performance measures and data for certain problem areas. This limitation should be mitigated over time by improvement of the performance-based management process and the data upon which it depends. Consequently, we have made no change to the rule in response to this comment.

Florida questioned the value of the Annual Report (§ 1200.33). According to Florida, the requirement for an Annual Report (as well as the requirement for an Improvement Plan, discussed in the next section) assumes that projects from a Highway Safety Plan can be evaluated against the State's goals within three months of their completion, whereas data to support an evaluation are actually not likely to be available for a year or more after project completion. Florida also stated that it is unclear from § 1200.10 (Application) whether the intent is for the State to have short-term or longer-term safety goals for the program. Florida noted that short term goals exhibit data availability problems.

The agencies agree with Florida that many projects will not produce measurable results within the three-month period between the end of the fiscal year and the due date for submission of the Annual Report. However, the performance-based process implemented by the interim final rule recognizes that the Section 402 program is ongoing, as are the State highway safety programs that it supports. These State programs do not begin and end with the fiscal year, even if certain projects do. Progress toward meeting goals in major highway safety program areas will occur across fiscal years and be attributable to more than one project or activity. Therefore, in the Annual Report, States should report the most recent data available concerning each of their identified performance measures and describe the projects that have contributed to that progress. The agencies have made changes to the ''Annual Report'' section of the rule to clarify these points. With respect to Florida's concern about § 1200.10, that section specifies neither short-term nor long-term goals as requirements in the goal-setting process. Either approach or a mix of both approaches is acceptable, as deemed necessary or appropriate by the State. In all cases, the State should include the most recent and best available data in the annual report.

d. Improvement Plans

Two commenters expressed opposing views about the value of Improvement Plans. Florida recommended elimination of the interim final rule's requirement for an Improvement Plan where a State's broad goals are not met, reasoning that Federal highway safety funds provide only ''seed money'' for a few projects, and should not be assumed to have an ''immediate quantifiable effect on a statewide problem.'' In contrast, NAGHSR supported the requirement for joint development of an Improvement Plan by Federal and State officials where a State has not made sufficient progress to meet goals (§ 1200.25). NAGHSR believed this approach to be a ''reasonable and prudent one'' if a State fails to make progress or does not act in good faith in implementing its plan.

The agencies agree with NAGHSR about the value of Improvement Plans. Florida's recommendation to eliminate the requirement stems from concerns about the lack of contemporaneous data to track progress. The agencies are mindful of these data limitations, and intend to exercise appropriate restraint in the use of Improvement Plans. For example, it is not the agencies' intent to require an Improvement Plan if, in a single year, some of a State's projects or activities do not appear to ''have an immediate quantifiable effect on a statewide problem,'' based on available data. Rather, an improvement plan would be employed if a State demonstrates a pattern that indicates little or no progress toward meeting goals, taking account of all relevant circumstances. The agencies believe that this approach strikes an appropriate balance in ensuring that the expenditure of Section 402 funds ultimately results in measurable traffic safety benefits, and that no changes to the rule are necessary.

e. Use of the Term ''Highway Safety Plan'

The Office of Traffic Safety of the Maryland State Highway Administration (Maryland) objected to the agencies' ''preemption'' of the title ''Highway Safety Plan'' for the program document required under the Section 402 program. Maryland explained that States have comprehensive, multi-year plans that set forth goals and strategies for addressing highway traffic safety problems, and that these State plans typically are called Highway Safety Plans or Strategic Highway Safety Plans. In Maryland's view, the Federally-prescribed Highway Safety Plan under the interim final rule cannot serve as a State's comprehensive Highway Safety Plan because it does not include goals, objectives, strategies, and performance measures and it covers only projects and activities that are supported by Section 402 funds or other Federal funds. Maryland recommends that the interim final rule be amended to redesignate the Highway Safety Plan as the ''Implementation Plan.''

In contrast, NAGHSR supported the name changes for the application documents (i.e., from ''Benchmark Report'' and ''Planning Document'' to ''Performance Plan'' and ''Highway Safety Plan'') , finding them to be less confusing.

As noted in the preamble to the interim final rule, the familiar term ''Highway Safety Plan'' was used for convenience, and many of those most

involved in the Section 402 program continued to use it even during the pilot program. The agencies further explained that States were free to prepare both their Performance Plan and Highway Safety Plan as comprehensive documents that include goals and activities for highway safety programs other than the Section 402 Program. (In fact, since the enactment of the Transportation Equity Act for the 21st Century, Pub. L. 105–178, implementing regulations for a number of new highway safety grant programs have included provisions requiring States to document activities related to these other grant programs in the Highway Safety Plan.) Moreover, the interim final rule does not preclude a State from combining the elements of the Performance Plan and the Highway Safety Plan into one document called a Highway Safety Plan, as long as the substantive content requirements of the interim final rule are met. The interim final rule also does not restrict the amount of information or detail included in the Highway Safety Plan, and does not preclude the identification in the plan of projects or activities that do not receive Federal funds. The only requirement is that the source of funding for other projects or activities be identified, so that the agencies are able to distinguish clearly the programs for which Section 402 funds are being sought. The agencies have added language to the rule clarifying that this is permissible. Finally, a State may, for its own administrative purposes, choose to call the Highway Safety Plan required under this rule by another name, so long as the document satisfies the requirements of the rule. In view of the flexibility afforded by this process, the agencies have made no other change to the rule in response to these comments.

f. Effect of Interim Final Rule

Florida requested clarification of the discussion in the preamble to the interim final rule, which described the material as ''guidance'' for 1998 highway safety plans, but noted that ''this regulation is fully in effect and binding upon its effective date.'' Florida believed that these statements led to confusion about the status of the interim final rule.

The Section 402 program is operated in accordance with published regulations, so that all States will have a clear understanding of the procedures and requirements that accompany the grant funds. When referring to the procedures of the interim final rule as providing ''guidance'' to the States, the agencies did not intend to convey that these procedures were optional or otherwise not fully in effect. As noted in the preamble to the interim final rule, that document (and hence the provisions contained therein) became effective and binding upon publication.

Advocates objected to the publication of an interim final rule to implement the new process, arguing that dispensing with prior public notice and comment is permissible only under the most extreme circumstances, and that no such circumstances existed here.

The agencies previously explained the need to provide prompt guidance to the States about impending grant procedures. We explained that States needed this information well in advance of the start of the fiscal year to which the highway safety program applied in order to comply with application procedures and to allow sufficient time for program planning activities. For these reasons, the agencies concluded that there was good cause for finding that providing notice and comment in connection with this action was impracticable, unnecessary, and contrary to the public interest. The agencies noted that the amendments made by the interim final rule were consistent with the provisions of a pilot program whose procedures were already known to the States. During the two years covered by the pilot programs, these procedures were also announced to the public, in two **Federal Register** notices (60 FR 47418 and 61 FR 46895). The agencies believe that the decision to issue an interim final rule was appropriate and in the public interest.

G. Regulatory Analyses and Notices

Executive Order 12612 (Federalism)

We have analyzed this action in accordance with the principles and criteria contained in Executive Order 12612, and have determined that it does not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. This action increases the flexibility of the States by implementing a performance-based process under which the States bear the responsibility for setting highway safety goals, in accordance with their individual needs.

Executive Order 12778 (Civil Justice Reform)

This rule does not have any preemptive or retroactive effect. It merely revises existing requirements imposed on States to afford States more flexibility in implementing a grant program. The enabling legislation does not establish a procedure for judicial review of final rules promulgated under its provisions. There is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceedings before they may file suit in court.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

We have determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of Department of Transportation Regulatory Policies and Procedures. This rule does not impose any additional burden on the public, but rather reduces burdens and improves the flexibility afforded to States in implementing highway safety programs. This action does not affect the level of funding available in the highway safety program. Accordingly, neither a Regulatory Impact Analysis nor a full Regulatory Evaluation is required.

Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

This rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and it does not concern an environmental, health, or safety risk that may have a disproportionate effect on children.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we have evaluated the effects of this action on small entities. We hereby certify that this action will not have a significant economic impact on a substantial number of small entities. States are the recipients of any funds awarded under the Section 402 program. Accordingly, the preparation of a Regulatory Flexibility Analysis is unnecessary.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) directs us to use voluntary consensus standards (i.e., technical standard concerning materials specifications, test methods, sampling procedures, and business practices) in regulatory activities unless doing so would be inconsistent with applicable law or otherwise impracticable. We have determined that no voluntary consensus standards apply to this action.

Unfunded Mandates Reform Act

This action does not impose any unfunded mandates under the Unfunded Mandates Reform Act of

1995. It would not result in costs of $100 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector. Accordingly, neither a written assessment of its costs, benefits, and other effects nor a consideration of regulatory alternatives is required.

Paperwork Reduction Act

The requirement relating to this action, that each State must submit certain documents to receive Section 402 grant funds, is considered to be an information collection requirement, as that term is defined by OMB. This information collection requirement has been previously submitted to and approved by OMB, pursuant to the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The requirement has been approved through September 30, 2001; OMB Control No. 2127–0003.

National Environmental Policy Act

We have reviewed this action for the purpose of compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and have determined that it will not have a significant effect on the human environment.

Regulation Identifier Number

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

List of Subjects in 23 CFR Parts 1200 and 1205

Grant programs—transportation, Highway safety.

Accordingly, the interim final rule amending part 1205 of title 23 of the Code of Federal Regulations, published at 62 FR 34397, June 26, 1997, is adopted as final without change and the interim final rule amending part 1200 of title 23 of the Code of Federal Regulations, published at 62 FR 34397, June 26, 1997, is adopted as final with the following changes:

1. The authority citation for part 1200 continues to read as follows:

Authority: 23 U.S.C. 402; delegations of authority at 49 CFR 1.48 and 1.50.

2. In § 1200.10, paragraphs (b) and (d) are revised to read as follows:

§ 1200.10 Application.

* * * * *

(b) A Highway Safety Plan, approved by the Governor's Representative for Highway Safety, describing the projects and activities the State plans to implement to reach the goals identified in the Performance Plan. The Highway Safety Plan must, at a minimum, describe one year of Section 402 program activities (and may include activities funded from other sources, so long as the source of funding is clearly distinguished).

* * * * *

(d) A Program Cost Summary (HS Form 217 or its electronic equivalent), completed to reflect the State's proposed allocations of funds (including carry-forward funds) by program area, based on the goals identified in the Performance Plan and the projects and activities identified in the Highway Safety Plan. The funding level used shall be an estimate of available funding for the upcoming fiscal year.

* * * * *

3. In § 1200.13, paragraph (b) is revised to read as follows:

§ 1200.13 Approval

* * * * *

(b) The approval letter identified in paragraph (a) of this section will contain the following statement:

We have reviewed (STATE)'s _____ fiscal year 19__ Performance Plan, Highway Safety Plan, Certification Statement, and Cost Summary (HS Form 217), as received on (DATE) _____. Based on these submissions, we find your State's highway safety program to be in compliance with the requirements of the Section 402 program. This determination does not constitute an obligation of Federal funds for the fiscal year identified above or an authorization to incur costs against those funds. The obligation of Section 402 program funds will be effected in writing by the NHTSA Administrator at the commencement of the fiscal year identified above. However, Federal funds reprogrammed from the prior-year Highway Safety Program (carry-forward funds) will be available for immediate use by the State on October 1. Reimbursement will be contingent upon the submission of an updated HS Form 217 (or its electronic equivalent), consistent with the requirements of 23 CFR 1200.14(d), within 30 days after either the beginning of the fiscal year identified above or the date of this letter, whichever is later.

* * * * *

4. In § 1200.33, paragraphs (a) and (b) are revised to read as follows:

§ 1200.33 Annual Report.

* * * * *

(a) The State's progress in meeting its highway safety goals, using performance measures identified in the Performance Plan. Both Baseline and most current level of performance under each measure will be given for each goal.

(b) How the projects and activities funded during the fiscal year contributed to meeting the State's highway safety goals. Where data becomes available, a State should report progress from prior year projects that have contributed to meeting current State highway safety goals.

§§ 1200.14 and 1200.22 [Amended]

In addition to the amendments set forth above, in 23 CFR part 1200, remove the words ''HS Form 217'' and add, in their place, the words ''HS Form 217 (or its electronic equivalent)'' in the following places:

(a) Section 1200.14(d)(1) and (d)(2); and

(b) Section 1200.22.

Issued on: July 23, 1999.

Kenneth R. Wykle,

Administrator, Federal Highway Administration.

Ricardo Martinez,

Administrator, National Highway Traffic Safety Administration.

[FR Doc. 99–19321 Filed 7–27–99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 256

RIN 1010–AC49

Leasing of Sulphur or Oil and Gas in the Outer Continental Shelf—Bonus Payments With Bids

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This rule gives MMS the authority to require Federal offshore Outer Continental Shelf (OCS) lands lease bidders to use any single method for submitting ⅕ bonus payments with OCS bids.

EFFECTIVE DATE: The rule is effective August 27, 1999.

FOR FURTHER INFORMATION CONTACT: Jan Arbegast, Program Analyst, at (703) 787–1227.

SUPPLEMENTARY INFORMATION: On March 31, 1999, we published a Notice of Proposed Rulemaking (64 FR 15320), titled ''Leasing of Sulphur or Oil and Gas in the Outer Continental Shelf—Bonus Payments with Bids,'' revising 30 CFR 256.46(b). Our 30-day comment period closed on April 30, 1999. We received four comments. This final rule