

decision on whether the order should be amended to lower the pooling standard in the manner proposed. In the absence of a suspension, costly and inefficient movements of producer milk would have to be made solely for the purpose of pooling the milk of dairy farmers who have historically supplied the fluid milk needs of the market.

It is hereby found and determined that thirty days' notice of the effective date hereof is impractical, unnecessary and contrary to the public interest in that:

(a) This suspension is necessary to reflect current marketing conditions and to maintain orderly marketing conditions in the marketing area in that without the suspension costly and inefficient movements of milk would have to be made solely for the purpose of pooling the milk of dairy farmers who have historically supplied the fluid milk needs of the market.

(b) This suspension does not require of persons affected substantial or extensive preparation prior to the effective date; and

(c) The marketing problems that provide the basis for this suspension action were fully reviewed at a public hearing held on November 9-10, 1982, where all interested parties had an opportunity to be heard on this matter.

Therefore, good cause exists for making this order effective upon publication in the Federal Register.

List of Subjects in 7 CFR Part 1131

Milk marketing orders, Milk, Dairy products.

PART 1131—[AMENDED]

§ 1131.7 [Amended]

It is therefore ordered, That the aforesaid provisions in § 1131.7(c) of the order are hereby suspended for the months of August and September 1983.

Effective date: July 25, 1983.

(Sec. 1-19, 48 Stat. 31, as amended (7 U.S.C. 601-674))

Signed at Washington, D.C. on: July 21, 1983.

C. W. McMillan,

Assistant Secretary, Marketing and Inspection Service.

[FR Doc. 83-20167 Filed 7-25-83; 8:45 am]

BILLING CODE 3410-02-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 50

Licensee Event Report System

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to require the reporting of operational experience at nuclear power plants by establishing the Licensee Event Report (LER) system. The final rule is needed to codify the LER reporting requirements in order to establish a single set of requirements that apply to all operating nuclear power plants. The final rule applies only to licensees of commercial nuclear power plants. The final rule will change the requirements that define the events and situations that must be reported, and will define the information that must be provided in each report.

EFFECTIVE DATE: January 1, 1984. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 1, 1984.

FOR FURTHER INFORMATION CONTACT: Frederick J. Hebdon, Chief, Program Technology Branch, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone (301) 492-4480.

SUPPLEMENTARY INFORMATION:

I. Background

On May 6, 1982, the NRC published in the Federal Register (47 FR 19543)¹ a Notice of Proposed Rulemaking that would modify and codify the existing Licensee Event Report (LER) system. Interested persons were invited to submit written comments to the Secretary of the Commission by July 6, 1982. Numerous comments were received. After consideration of the comments and other factors involved, the Commission has amended the proposed requirements published for public comment by clarifying the scope and content of the requirements, particularly the criteria that define which operational events must be reported.

The majority of the comments on the proposed rule: (1) Questioned the meaning and intent of the criteria that defined the events which must be reported, (2) questioned the need for reporting certain specific types of events, and (3) questioned the need for certain information that would be required to be included in an LER. Section III of this notice discusses the comments in more detail.

¹ Copies of the documents are available for public inspection and copying for a fee at the Public Document Room at 1717 H Street NW, Washington, D.C.

II. Rulemaking initiation

The Nuclear Plant Reliability Data (NPRD) system is a voluntary program for the reporting of reliability data by nuclear power plant licensees. On January 30, 1980 (45 FR 6793),¹ the NRC published an Advance Notice of Proposed Rulemaking that described the NPRD system and invited public comment on an NRC plan to make it mandatory. Forty-four letters were received in response to the advanced notice. These comments generally opposed making the NPRD system mandatory on the grounds that reporting of reliability data should not be made a regulatory requirement.

In December 1980, the Commission decided that the requirements for reporting of operational experience data needed major revision and approved the development of an Integrated Operational Experience Reporting (IOER) system. The IOER system would have combined, modified, and made mandatory the existing Licensee Event Report (LER) system and the NPRD system. SECY 80-507¹ discusses the IOER system.

As a result of the Commission's approval of the concept of an IOER system, the NRC published another advance notice on January 15, 1981 (46 FR 3541). This advance notice explained why the NRC needed operational experience data and described the deficiencies in the existing LER and NPRD systems.

On June 8, 1981, the Institute of Nuclear Power Operations (INPO) announced that because of its role as an active user of NPRDs data it would assume responsibility for management and funding of the NPRD system. Further, INPO decided to develop criteria that would be used in its management audits of member utilities to assess the adequacy of participation in the NPRD system.

The two principal deficiencies that had previously made the NPRD system an inadequate source of reliability data were the inability of its committee management structure to provide the necessary technical direction and a low level of participation by the utilities. The commitments and actions by INPO provided a basis for confidence that these two deficiencies would be corrected. For example, centralizing the management and funding of NPRDs within INPO should overcome the previous difficulties associated with management by a committee and funding from several independent organizations. Further, with INPO focusing upon a utility's participation in

NPRDS as a specific evaluation parameter during routine management and plant audit activities, the level of utility participation, and therefore, the quality and quantity of NPRDS data, should significantly increase. However, the Commission will continue to have an active role in NPRDS by participating in an NPRDS User's Group, by periodically assessing the quality and quantity of information available from NPRDS, and by auditing the timely availability of the information to the NRC.

Since there was a likelihood that NPRDS under INPO direction would meet the NRC's need for reliability data, it was no longer necessary to proceed with the IOERS. Hence, the collection of detailed technical descriptions of significant events could be addressed in a separate rulemaking to modify and codify the existing LER reporting requirements. See SECY 81-494 for additional details concerning IOERS.

However, the Commission wishes to make it explicitly clear that it is relaxing the reporting requirements with the expectation that sufficient utility participation, cooperation, and support of the NPRD system will be forthcoming. If the NPRD system does not become operational at a satisfactory level in a reasonable time, remedial action by the Commission in the form of additional rulemaking may become necessary.

On October 6, 1981, the NRC published an advanced notice (46 FR 49134) that deferred development of the IOER system and sought public comment on the scope and content of the LER system. Six comment letters were received in response to this ANPRM. All of the comments received were reviewed by the staff and were considered in the development of the proposed LER rule. See SECY 82-3 for additional details.

This rule identifies the types of reactor events and problems that are believed to be significant and useful to the NRC in its effort to identify and resolve threats to public safety. It is designed to provide the information necessary for engineering studies of operational anomalies and trends and patterns analysis of operational occurrences. The same information can also be used for other analytic procedures that will aid in identifying accident precursors.

The Commission believes that the NRC should continue to seek an improved operational data system that will maximize the value of operational data. The system should encompass and integrate operational data of events and problem sequences identified in this rule, NPRDS data, and such other information as is required for a

comprehensive integrated analytically-versatile system.

The Brookhaven Study, published as BNL/NUREG 51609, NUREG/CR 3206, discusses data collection and storage procedures to support multivariate, multicase analysis. While the range of reactor configurations in the U.S. nuclear industry presents some methodological and interpretative problems, these difficulties should not be insurmountable. The Commission believes that the NRC should have as a specific objective the development, demonstration, and implementation of an integrated system for collecting and analyzing operational data that will employ the predictive and analytical potential of multicase, multivariate analyses. Accordingly, the staff has been directed to undertake the work necessary to develop and demonstrate such a cost-effective integrated system of operational data collection and analyses.

If the design of the system demonstrates that such a system is feasible and cost-effective, development of the system to the point of initiating rule should be completed by July 1986.

III. Analysis of Comments

The Commission received forty-seven (47) letters commenting on the proposed rule. Copies of those letters and a detailed analysis of the comments are available for public inspection and copying for a fee at the NRC Public Document Room at 1717 H Street, NW., Washington, D.C. A number of the more substantive issues are discussed below.

Licensee Resources

Of particular concern to the Commission was the impact that the proposed rule would have on the resources used by licensees to prepare LERs. The Commission's goal was to assure that the scope of the rule would not increase the overall level of effort above that currently required to comply with the existing LER requirements. Thirty letters of the 47 received contained comments on the overall acceptability of the proposed rule or commented directly on the question of scope and/or resources associated with the proposed rule. The views of the commenters can be characterized as follows:

1. Five commenters felt that the scope and level of effort would be greatly expanded by the proposed rule. Estimates included an increase of 100 man-years for the entire industry, an increase of three times the current effort, and an increase of \$100,000 and 2 man-years annually for each plant.

2. Four commenters felt that the level of effort would be increased but not significantly.

3. One commenter felt that the proposed rule would have a minimal effect on the level of effort required.

4. Two commenters felt that the proposed rule would significantly reduce the number of LERs filed.

5. Thirteen commenters endorsed the objective of improving LER reporting but felt that changes in the proposed rule were needed. These commenters did not directly address the resource issue.

6. Five commenters endorsed the proposed rule and/or felt that it was a significant improvement over the existing reporting requirements.

Based on these comments and its own assessment of the impact of this rule, the Commission has concluded that the impact of this rule will be no greater than the impact of the existing LER requirements, and this rule will not place an unacceptable burden on the affected licensees.

Relationship Between the LER Rule (§ 50.73) and the Immediate Notification Rule (§ 50.72)

As a parallel activity to the preparation of § 50.73, the Commission is amending its regulations (§ 50.72) which require that licensees for nuclear power plants notify the NRC Operations Center of significant events that occur at their plants. On December 21, 1981, the Commission published in the *Federal Register* a proposed rule (46 FR 61894) that described the planned changes in § 50.72.

The *Federal Register* notice accompanying the proposed LER rule (i.e., § 50.73) stated that additional changes anticipated to § 50.72 would be made but they would be " * * * largely administrative and the revised § 50.72 would not be significantly modified nor would it be published again for public comment." Several commenters disagreed with this conclusion.

The commenters did, however, agree with the Commission's position that inconsistencies and overlapping requirements between the two rules need to be eliminated.

The Commission has carefully reviewed the proposed requirements in the LER and Immediate Notification rules and has concluded that although changes to both have been made (largely in response to public comments) to clarify the intent of the rules, the original intent and scope have not been significantly changed. Therefore, the Commission has concluded that these two rules need not be published again for public comment.

Engineering Judgment

In the Federal Register notice that accompanied the proposed rule, the Commission stated that licensee's engineering judgment may be used to decide if an event is reportable. Several commenters expressed the belief that some wording should be added to the rule of reflect that the NRC will also use judgment in enforcement of this regulation where the licensee is requested to use engineering judgment.

The Commission believes that the LER rule adequately discusses the need for and application of the concept of "engineering judgment." The concept itself includes the recognition of the existence of a reasonable range of interpretation regarding this rule, and consequently the Commission recognizes and hereby acknowledges the need for flexibility in enforcement actions associated with this rule. The Commission believes that this concept is sufficiently clear and that additional explicit guidance is not necessary.

Reporting Schedule

In the Federal Register notice that accompanied the proposed rule, the Commission stated that it had not yet decided if the reports should be submitted in fifteen days or thirty days following discovery of a reportable event. Many commenters stated that the time frame for reporting LERs should not be less than thirty days after the discovery of a reportable event.

One commenter estimated the impact of a requirement to submit a report sooner than 30 days following discovery of a reportable event would be an increase of approximately 40 man years per year for the currently operating plants. In addition the commenter estimated that if a summary report were also required the reporting burden would increase an additional 12 man years for the currently operating plants.

In response to these comments, the Commission has decided to require that LERs be submitted within 30 days of discovery of a reportable event or situation.

Reporting of Reactor Trips

Section 50.73(a)(1) of the proposed rule (§ 50.73(a)(2)(iv) of the final rule) required reporting of any event which results in an unplanned manual or automatic actuation of any Engineered Safety Feature (ESF) including the Reactor Protection System (RPS). Many commenters agreed that these events should be trended and analyzed, but disagreed that they deserve to be singled out as events of special significance (i.e., events reportable as

LERs). They noted that reports of RPS actuations are already reported to the NRC in the Monthly Operating Status Report, as well as telephoned to the NRC Operations Center.

In addition, the Institute of Nuclear Power Operations (INPO) analyzed the frequency of reactor scrams during a one-month period. This analysis indicated that an average of 55 reactor trips would be reportable each month under the proposed rule. INPO equated this to 660 additional LERs per year for all currently operating plants, or approximately 32 man-years of additional effort for all the currently operating plants based upon the assumption that each LER requires 100 man-hours of effort to prepare and analyze.

The Commission still believes that ESF actuations, including reactor trips, frequently are associated with significant plant transients and are indicative of events that are of safety significance. In addition, if the ESFs are being challenged during routine transients, that fact is of safety significance and should be reported.

In addition, the Commission does not agree with the estimate that each LER submitted for a routine reactor trip would require, on the average, 100 man-hours to prepare and analyze. Licensees are already required to make internal evaluation of and document significant events, including reactor trips. Therefore, the incremental impact of preparing and analyzing the LER should be significantly less than 100-man hours. In addition, the actual increase in burden would be offset by reductions in the burden of reporting less significant events that would no longer be reportable.

Coordination With Other Reporting Requirements

Several commenters noted that the proposed rule did not appear to be coordinated with other existing reporting requirements, and that duplication of licensee effort might result. They recommended that LER reporting be consolidated to eliminate potential duplication of other existing reporting requirements.

The Commission has reviewed existing NRC reporting requirements (e.g., 10 CFR Parts 20 and 21, § 50.55(e), § 50.72, § 50.73, § 73.71, and NUREG-0654) and has attempted, to the extent practicable, to eliminate redundant reporting and to ensure that the various reporting requirements are consistent. Many of the changes in the final LER rule are as a result of this effort. These changes resulted in extensive revisions in the wording of criteria contained in

this rule, but did not change the original scope of intent of the requirements. In addition, in order to make the requirements in §§ 50.72 and 50.73 more compatible, the order (i.e., numbering) of the criteria in § 50.73 has been changed. The changes are noted in the discussion of each paragraph below.

Finally, conforming amendments are being made to various sections of Parts 20 and 50 in order to reduce the redundancy in reporting requirements that apply to operating nuclear power plants. In general, these amendments will require that:

1. Licensees that have an Emergency Notification System (ENS) make the reports required by the subject sections via the ENS. All other licensees will continue to make the reports to the Administrator of the appropriate NRC Regional Office.

2. Written reports required by the subject sections be submitted to the NRC Document Control Desk in Washington, D.C., with a copy to the appropriate Regional Offices.

3. Holders of licenses to operate a nuclear power plant submit the written reports required by the subject sections in accordance with the procedures described in § 50.73(b).

The criteria contained in the subject sections which define a reportable event have not been modified.

Similar changes are also planned as part of current activities to make more substantive changes to Part 21, § 50.55(e), and § 73.71.

Nonconservative Interdependence

Several commenters expressed difficulty in understanding the meaning of the phrase "nonconservative interdependence" as used in the proposed § 50.73(a)(3). The wording of § 50.73(a)(3) (§ 50.73(a)(2)(vii) of this final rule) has been changed to eliminate the phrase "non conservative interdependence" by specifically defining the types of events that should be reported. The revised paragraph does not, however, change the intent of the original paragraph.

Sabotage and Threats of Violence

Several commenters noted that the security-related reporting requirements of § 50.73(a)(6) (§ 50.73(a)(2)(iii) of this final rule) were already contained in greater detail in 10 CFR 73.71. For instance, § 73.71 requires an act of sabotage to be reported immediately, followed by a written report within 15 days. The proposed rule would have required an LER to be filed within 30 days. Although distribution of reports is somewhat different, redundant reporting

would have occurred. The commenters recommended that the Commission ensure consistency between §§ 50.73 and 73.71.

In response to these comments the Commission has deleted the reporting of sabotage and threats of violence from § 50.73 because these situations are adequately covered by the reporting requirements contained in § 73.71.

Evacuation of Rooms or Buildings

Many commenters stated that the reporting of in-plant releases of radioactivity that require evacuation of individual rooms (§ 50.73(a)(7) in the proposed rule or (§ 50.73(a)(2)(x) of this final rule) was inconsistent with the general thrust of the rule to require reporting of significant events. They noted that minor spills, small gaseous waste releases, or the disturbance of contaminated particulate matter (e.g., dust) may all require the temporary evacuation of individual rooms until the airborne concentrations decrease or until respiratory protection devices are utilized. They noted that these events are fairly common and should not be reportable unless the required evacuation affects the entire facility or a major portion thereof.

In response to these comments the wording of this criterion (§ 50.73(a)(2)(x) in the final rule) has been changed to significantly narrow the scope of the criterion to include only those events which significantly hamper the ability of site personnel to perform safety-related activities (e.g., evacuation of the main control room).

Energy Industry Identification System

Many commenters noted that the requirement to report the Energy Industry Identification System (EIIS) component function identifier and system name of each component or system referred to in the LER description would be a significant burden on the licensee.

They suggested instead that the NPRDS component identifiers be used in place of the EIIS component identifiers which are not yet widely used by the industry.

The Commission continues to believe that EIIS system names and component function identifiers are needed in order that LERs from different plants can be compared. We do not, however, suggest that the EIIS identifiers be used throughout the plant, but only that they be added to the LER as it is written. A simple, inexpensive table could be used to translate plant identifiers into equivalent EIIS identifiers.

The Commission considered the system and component identifiers used

in NPRDS as an alternative. It is our understanding, however, the NPRDS will soon adopt the EIIS system titles, so a distinction should no longer exist. In addition, LERs frequently include systems that are not included in the scope of NPRDS (i.e., an NPRDS system identification does not exist) while EIIS, on the other hand, includes all of the systems commonly found in commercial nuclear power plants. Further, NPRDS includes only 39 component identifiers (e.g., valve, pump). The Commission believes that this limited number does not provide a sufficiently detailed description of the component function involved.

Function of Failed Components and Status of Redundant Components

Many commenters said that information required in (§ 50.73(b)(2) (vi) and (vii) of the proposed rule should not be a requirement in the LER. They argued that this information is readily available in documents previously submitted to the NRC by licensees and are available for reference.

The final rule (§ 50.73(b)(2)(i)(G)) has been modified to narrow the scope of the information requested by the Commission.

While this general information may be available in licensee documents previously submitted to the NRC, the Commission believes that a general understanding of the event and its significance should be possible without reference to additional documentation which may not be readily or widely available, particularly to the public.

The Commission continues to believe that the licensee should prepare an LER in sufficient depth so that knowledgeable readers who are conversant with the design of commercial nuclear power plants, but are not familiar with the details of a particular plant, can understand the general characteristics of the event (e.g., the cause, the significance, the corrective action). As suggested by the commenters, more detailed information to support engineering evaluations and case studies will be obtained, as needed, directly from the previously submitted licensee documents.

Engineering Evaluations

The overview discussion of the proposed rule contains the following statement: "If the NRC staff decides that the event was especially significant from the standpoint of safety, the staff may request that the licensee perform an engineering evaluation of the event and describe the results of that evaluation."

Several commenters argued that the inclusion of the requirement that the licensee perform an engineering evaluation of certain events at the staff's request appeared unjustified and would add substantially to the burden of reporting. They argued that the licensee should be required to submit only the specific additional information required for the necessary engineering evaluation rather than to perform the evaluation.

The rule has been modified to require only the submittal of any necessary additional information requested by the Commission in writing.

IV. Specific Findings

Overview of the LER System

When this final LER rule becomes effective, the LER will be a detailed narrative description of potentially significant safety events. By describing in detail the event and the planned corrective action, it will provide the basis for the careful study of events or conditions that might lead to serious accidents. If the NRC staff decides that the event was especially significant from the standpoint of safety, the staff may request that the licensee provide additional information and data associated with the event.

The licensee will prepare an LER for those events or conditions that meet one or more of the criteria contained in § 50.73(a). The criteria are based primarily on the nature, course, and consequences of the event. Therefore, the final LER rule requires that events which meet the criteria are to be reported regardless of the plant operating mode or power level, and regardless of the safety significance of the components, systems, or structures involved. In trying to develop criteria for the identification of events reportable as LERs, the Commission has concentrated on the potential consequences of the event as the measure of significance. Therefore, the reporting criteria, in general, do not specifically address classes of initiating events or causes of the event. For example, there is no requirement that all personnel errors be reported. However, many reportable events will involve or have been initiated by personnel errors.

Finally, it should be noted that licensees are permitted and encouraged to report any event that does not meet the criteria contained in § 50.73(a), if the licensee believes that the event might be of safety significance, or of generic interest or concern. Reporting requirements aside, assurance of safe operation of all plants depends on accurate and complete reporting by each

licensee of all events having potential safety significance.

Paragraph-by-Paragraph Explanation of the LER Rule

The significant provisions of the final LER rule are explained below. The explanation follows the order in the proposed rule.

Paragraph 50.73(a)(2)(iv) (proposed paragraph 50.73(a)(1)) requires reporting of: "Any event or condition that resulted in manual or automatic actuation of any Engineered Safety Feature (ESF), including the Reactor Protection System (RPS). However, actuation of an ESF, including the RPS, that resulted from and was part of the preplanned sequence during testing or reactor operation need not be reported."

This paragraph requires events to be reported whenever an ESF actuates either manually or automatically, regardless of plant status. It is based on the premise that the ESFs are provided to mitigate the consequences of a significant event and, therefore: (1) They should work properly when called upon, and (2) they should not be challenged frequently or unnecessarily. The Commission is interested both in events where an ESF was needed to mitigate the consequences (whether or not the equipment performed properly) and events where an ESF operated unnecessarily.

"Actuation" of multichannel ESF Actuation Systems is defined as actuation of enough channels to complete the minimum actuation logic (i.e., activation of sufficient channels to cause activation of the ESF Actuation System). Therefore, single channel actuations, whether caused by failures or otherwise, are not reportable if they do not complete the minimum actuation logic.

Operation of an ESF as part of a planned operational procedure or test (e.g., startup testing) need not be reported. However, if during the planned operating procedure or test, the ESF actuates in a way that is not part of the planned procedure, that actuation must be reported. For example, if the normal reactor shutdown procedure requires that the control rods be inserted by a manual reactor trip, the reactor trip need not be reported. However, if conditions develop during the shutdown that require an automatic reactor trip, such a reactor trip must be reported.

The fact that the safety analysis assumes that an ESF will actuate automatically during certain plant conditions does not eliminate the need to report that actuation. Actuations that need not be reported are those initiated for reasons other than to mitigate the

consequences of an event (e.g., at the discretion of the licensee as part of a planned procedure or evolution).

Sections 50.73(a)(2) (v) and (vi) (proposed § 50.73(a)(2)) require reporting of:

(v) Any event or condition that alone could have prevented the fulfillment of the safety function of structures or systems that are needed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more personnel errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

The wording of this paragraph has been changed from the proposed rule to make it easier to read. The intent and scope of the paragraph have not been changed.

The intent of this paragraph is to capture those events where there would have been a failure of a safety system to properly complete a safety function, regardless of when the failures were discovered or whether the system was needed at the time.

This paragraph is also based on the assumption that safety-related systems and structures are intended to mitigate the consequences of an accident. While § 50.73(a)(2)(iv) of this final rule applies to actual actuations of an ESF, § 50.73(a)(2)(v) of this final rule covers an event or condition where redundant structures, components, or trains of a safety system could have failed to perform their intended function because of: one or more personnel errors, including procedure violations; equipment failures; or design, analysis, fabrication, construction, or procedural deficiencies. The event must be reported regardless of the situation or condition that caused the structure or systems to be unavailable, and regardless of whether or not an alternate safety system could have been used to perform the safety function (e.g., High Pressure Core Cooling failed, but feed-and-bleed or Low Pressure Core Cooling were available to provide the safety function of core cooling).

The applicability of this paragraph includes those safety systems designed to mitigate the consequences of an

accident (e.g., containment isolation, emergency filtration). Hence, minor operational events involving a specific component such as valve packing leaks, which could be considered a lack of control of radioactive material, should not be reported under this paragraph. System leaks or other similar events may, however, be reportable under other paragraphs.

It should be noted that there are a limited number of single-train systems that perform safety functions (e.g., the High Pressure Coolant Injection System in BWRs). For such systems, loss of the single train would prevent the fulfillment of the safety function of that system and, therefore, must be reported even though the plant Technical Specifications may allow such a condition to exist for a specified limited length of time.

It should also be noted that, if a potentially serious human error is made that could have prevented fulfillment of a safety function, but recovery factors resulted in the error being corrected, the error is still reportable.

The Commission recognizes that the application of this and other paragraphs of this section involves the use of engineering judgment on the part of licensees. In this case, a technical judgment must be made whether a failure or operator action that did actually disable one train of a safety system, could have, but did not, affect a redundant train within the ESF system. If so, this would constitute an event that "could have prevented" the fulfillment of a safety function, and, accordingly, must be reported.

If a component fails by an apparently random mechanism it may or may not be reportable if the functionally redundant component could fail by the same mechanism. Reporting is required if the failure constitutes a condition where there is reasonable doubt that the functionally redundant train or channel would remain operational until it completed its safety function or is repaired. For example, if a pump in one train of an ESF system fails because of improper lubrication, and engineering judgment indicates that there is a reasonable expectation that the functionally redundant pump in the other train, which was also improperly lubricated, would have also failed before it completed its safety function, then the actual failure is reportable and the potential failure of the functionally redundant pump must be discussed in the LER.

For safety systems that include three or more trains, the failure of two or more trains should be reported if, in the

judgement of the licensee, the functional capability of the overall system was jeopardized.

Interaction between systems, particularly a safety system and a non-safety system, is also included in this criterion. For example, the Commission is increasingly concerned about the effect of a loss or degradation of what had been assumed to be non-essential inputs to safety systems. Therefore, this paragraph also includes those cases where a service (e.g., heating, ventilation, and cooling) or input (e.g., compressed air) which is necessary for reliable or long-term operation of a safety system is lost or degraded. Such loss or degradation is reportable if the proper fulfillment of the safety function is not cannot be assured. Failures that affect inputs or services to systems that have no safety function need not be reported.

Finally the Commission recognizes that the licensee may also use engineering judgment to decide when personnel actions *could* have prevented fulfillment of a safety function. For example, when an individual improperly operates or maintains a component, he might conceivably have made the same error for all of the functionally redundant components (e.g., if he incorrectly calibrates one bistable amplifier in the Reactor Protection System, he could conceivably incorrectly calibrate all bistable amplifiers). However, for an event to be reportable it is necessary that the actions actually affect or involve components in more than one train or channel of a safety system, and the result of the actions must be undesirable from the perspective of protecting the health and safety of the public. The components can be functionally redundant (e.g., two pumps in different trains) or not functionally redundant (e.g., the operator correctly stops a pump in Train "A" and, instead of shutting the pump discharge valve in Train "A," he mistakenly shuts the pump discharge valve in Train "B").

Section 50.73(a)(2)(vii) (proposed § 50.73(a)(3)) requires the reporting of: "Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains channels or to become inoperable in a system designed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition,

(B) Remove residual heat,

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident."

This paragraph has been changed to clarify the intent of the phrase "nonconservative interdependence." Numerous comment letters expressed difficulty in understanding what this phrase meant; so the paragraph has been changed to be more specific. The new paragraph is narrower in scope than the original paragraph because the term is specifically defined, but the basic intent is the same.

This paragraph requires those events to be reported where a single cause produced a component or group of components to become inoperable in redundant or independent portions (i.e., trains or channels) of one or more systems having a safety function. These events can identify previously unrecognized common cause failures and systems interactions. Such failures can be simultaneous failures which occur because of a single initiating cause (i.e., the single cause or mechanism serves as a common input to the failures); or the failures can be sequential (i.e., cascade failures), such as the case where a single component failure results in the failure of one or more additional components.

To be reportable, however, the event or failure must result in or involve the failure of independent portions of more than one train or channel in the same or different systems. For example, if a cause or condition caused components in Train "A" and "B" of a single system to become inoperable, even if additional trains (e.g., Train "C") were still available, the event must be reported. In addition, if the cause or condition caused components in Train "A" of one system and in Train "B" of another system (i.e., a train that is assumed in the safety analysis to be independent) to become inoperable, the event must be reported. However, if a cause or condition caused components in Train "A" of one system and Train "A" of another system (i.e., trains that are not assumed in the safety analysis to be independent), the event need not be reported unless it meets one or more of the other criteria in this section.

In addition, this paragraph does not include those cases where one train of a system or a component was removed from service as part of a planned evolution, in accordance with an approved procedure, and in accordance with the plant's Technical Specifications. For example, if the licensee removes part of a system from service to perform maintenance, and the Technical Specifications permit the resulting configuration, and the system or component is returned to service

within the time limit specified in the Technical Specifications, the action need not be reported under this paragraph. However, if, while the train or component is out of service, the licensee identifies a condition that could have prevented the whole system from performing its intended function (e.g., the licensee finds a set of relays that is wired incorrectly), that condition must be reported.

Section 50.73(a)(2)(i) (proposed § 50.73(a)(4)) requires reporting of:

"(A) The completion of any nuclear plant shutdown required by the plant's Technical Specifications; or

"(B) Any operation prohibited by the plant's Technical Specifications; or

"(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 50.54(x) of this part."

This paragraph has been reworded to more clearly define the events that must be reported. In addition, the scope has been changed to require the reporting of events or conditions "prohibited by the plant's Technical Specifications" rather than events where "a plant Technical Specification Action Statement is not met." This change accommodates plants that do not have requirements that are specifically defined as Action Statements.

This paragraph now requires events to be reported where the licensee is required to shut down the plant because the requirements of the Technical Specifications were not met. For the purpose of this paragraph, "shutdown" is defined as the point in time where the Technical Specifications require that the plant be in the first shutdown condition required by a Limiting Condition for Operation (e.g., hot standby (Mode 3) for PWRs with the Standard Technical Specifications). If the condition is corrected before the time limit for being shut down (i.e., before completion of the shutdown), the event need not be reported.

In addition, if a condition that was prohibited by the Technical Specifications existed for a period of time longer than that permitted by the Technical Specifications, it must be reported even if the condition was not discovered until after the allowable time had elapsed and the condition was rectified immediately after discovery.

Section 50.73(a)(2)(ii) (proposed § 50.73(a)(5)) requires reporting of: "Any event or condition that resulted in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded, or that resulted in the nuclear power plant being:

"(A) In an unanalyzed condition that significantly compromised plant safety;

"(B) In a condition that was outside the design basis of the plant; or

"(C) In a condition not covered by the plant's operating and emergency procedures."

This paragraph requires events to be reported where the plant, including its principal safety barriers, was seriously degraded or in an unanalyzed condition.

For example, small voids in systems designed to remove heat from the reactor core which have been previously shown through analysis not to be safety significant need not be reported. However, the accumulation of voids that could inhibit the ability to adequately remove heat from the reactor core, particularly under natural circulation conditions, would constitute an unanalyzed condition and must be reported. In addition, voiding in instrument lines that results in an erroneous indication causing the operator to significantly misunderstand the true condition of the plant is also an unanalyzed condition and must be reported.

The Commission recognizes that the licensee may use engineering judgment and experience to determine whether an unanalyzed condition existed. It is not intended that this paragraph apply to minor variations in individual parameters, or to problems concerning single pieces of equipment. For example, at any time, one or more safety-related components may be out of service due to testing, maintenance, or a fault that has not yet been repaired. Any trivial single failure or minor error in performing surveillance tests could produce a situation in which two or more often unrelated, safety-related components are out-of-service. Technically, this is an unanalyzed condition. However, these events should be reported only if they involve functionally related components or if they significantly compromise plant safety.

Finally, this paragraph also includes material (e.g., metallurgical, chemical) problems that cause abnormal degradation of the principal safety barriers (i.e., the fuel cladding, reactor coolant system pressure boundary, or the containment).

Additional examples of situations included in this paragraph are:

(a) Fuel cladding failures in the reactor or in the storage pool, that exceed expected values, that are unique or widespread, or that resulted from unexpected factors.

(b) Reactor coolant radioactivity levels that exceeded Technical Specification limits for iodine spikes or,

radioactivity levels at a BWR air ejector monitor that exceeded the Technical Specification limits.

(c) Cracks and breaks in piping, the reactor vessel, or major components in the primary coolant circuit that have safety relevance (steam generators, reactor coolant pumps, valves, etc.)

(d) Significant welding or material defects in the primary coolant system.

(e) Serious temperature or pressure transients (e.g., transients that violate the plant's Technical Specifications).

(f) Loss of relief and/or safety valve operability during test or operation (such that the number of operable valves or man-way closures is less than required by the Technical Specifications).

(g) Loss of containment function or integrity (e.g., containment leakage rates exceeding the authorized limits).

Section 50.73(a)(2)(iii) (proposed § 50.73(a)(6)) requires reporting of: "Any natural phenomenon or other external condition that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant."

This paragraph has been reworded to make it clear that it applies only to acts of nature (e.g., tornadoes) and external hazards (e.g., railroad tank car explosion). References to acts of sabotage have been removed because they are covered by § 73.71. In addition, threats to personnel from internal hazards (e.g., radioactivity releases) are now covered by a separate paragraph (§ 50.73(a)(2)(x)).

This paragraph requires those events to be reported where there is an actual threat to the plant from an external condition or natural phenomenon, and where the threat or damage challenges the ability of the plant to continue to operate in a safe manner (including the orderly shutdown and maintenance of shutdown conditions).

The licensee is to decide if a phenomenon or condition actually threatened the plant. For example, a minor brush fire in a remote area of the site that was quickly controlled by fire fighting personnel and, as a result, did not present a threat to the plant need not be reported. However, a major forest fire, large-scale flood, or major earthquake that presents a clear threat to the plant must be reported. Industrial or transportation accidents that occurred near the site and created a plant safety concern must also be reported.

Section 50.73(a)(2)(x) (proposed § 50.73(a)(7)) requires reporting of: "Any event that posed an actual threat to the

safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant including fires, toxic gas releases, or radioactive releases."

This paragraph has been reworded to include physical hazards (internal to the plant) to personnel (e.g., electrical fires). In addition, in response to numerous comments, the scope has been narrowed so that the hazard must hamper the ability of site personnel to perform safety-related activities affecting plant safety.

In-plant releases must be reported if they require evacuation of rooms or buildings containing systems important to safety and, as a result, the ability of the operators to perform necessary safety functions is significantly hampered. Precautionary evacuations of rooms and buildings that subsequent evaluation determines were not required need not be reported.

Proposed § 50.73(a)(8) was intended to capture an event that involved a controlled release of a significant amount of radioactive material to offsite areas. In addition, "significant" was based on the plant's Technical Specification limits for the release of radioactive material. However, this section has been deleted because the reporting of these events is already required by § 50.73(a)(2)(i) and § 20.405.

Section 50.73(a)(2) (viii) and (ix) (proposed § 50.73(a)(9)) require reporting of:

• • • • •
(viii)(A) Any airborne radioactivity release that exceeded 2 times the applicable concentrations of the limits specified in Table II of Appendix B to Part 20 of this chapter in unrestricted areas, when averaged over a time period of one hour.

(B) Any liquid effluent release that exceeded 2 times the limiting combined Maximum Permissible Concentration (MPC) (see Note 1 of Appendix B to Part 20 of this chapter) at the point of entry into the receiving water (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases, when averaged over a time period of one hour.

(ix) Reports submitted to the Commission in accordance with paragraph (a)(2)(viii) of this section also meet the effluent release reporting requirements of paragraph 20.405(a)(5) of Part 20 of this chapter.

• • • • •
Paragraph (viii) has been changed to clarify the requirements to report releases of radioactive material. The paragraph is similar to § 20.405 but places a lower threshold for reporting events at commercial power reactors. The lower threshold is based on the significance of the breakdown of the

licensee's program necessary to have a release of this size, rather than on the significance of the impact of the actual release.

Reports of events covered by § 50.73(a)(2)(viii) are to be made in lieu of reporting noble gas releases that exceed 10 times the instantaneous release rate, without averaging over a time period, as implied by the requirement of § 20.405(a)(5).

Paragraph 50.73(b) describes the format and content of the LER. It requires that the licensee prepare the LER in sufficient depth so that knowledgeable readers conversant with the design of commercial nuclear power plants, but not familiar with the details of a particular plant, can understand the complete event (i.e., the cause of the event, the plant status before the event, and the sequence of occurrences during the event).

Paragraph 50.73(b)(1) requires that the licensee provide a brief abstract describing the major occurrences during the event, including all actual component or system failures that contributed to the event, all relevant operator errors or violations of procedures, and any significant corrective action taken or planned as a result of the event. This paragraph is needed to give LER data base users a brief description of the event in order to identify events of interest.

Paragraph 50.73(b)(2) requires that the licensee include in the LER a clear, specific narrative statement of exactly what happened during the entire event so that readers not familiar with the details of a particular plant can understand the event. The licensee should emphasize how systems, components, and operating personnel performed. Specific hardware problems should not be covered in excessive detail. Characteristics of a plant that are unique and that influenced the event (favorably or unfavorably) must be described. The narrative must also describe the event from the perspective of the operator (e.g., what the operator saw, did, perceived, understood, or misunderstood).

Paragraph 50.73(b)(3) requires that the LER include a summary assessment of the actual and potential safety consequences and implications of the event. This assessment may be based on the conditions existing at the time of the event. The evaluation must be carried out to the extent necessary to fully assess the safety consequences and safety margins associated with the event. An assessment of the event under alternative conditions must be included if the incident would have been more severe (e.g., the plant would have been

in a condition not analyzed in the Safety Analysis Report) under reasonable and credible alternative conditions, such as power level or operating mode. For example, if an event occurred while the plant was at 15% power and the same event could have occurred while the plant was at 100% power, and, as a result, the consequences would have been considerably more serious, the licensee must assess and report those consequences.

Paragraph 50.73(b)(4) requires that the licensee describe in the LER any corrective actions planned as a result of the event that are known at the time the LER is submitted, including actions to reduce the probability of similar events occurring in the future. After the initial LER is submitted only substantial changes in the corrective action need be reported as a supplemental LER.

Paragraph 50.73(c) authorizes the NRC staff to require the licensee to submit specific supplemental information beyond that required by § 50.73(b). Such information may be required if the staff finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. Such requests for supplemental information must be made in writing, and the licensee must submit the requested information as a supplement to the initial LER within a time period mutually agreed upon by the NRC staff and the licensee.

Paragraph 50.73(f) gives the NRC's Executive Director for Operations the authority to grant case-by-case exemptions to the reporting requirements contained in the LER system. This exemption could be used to limit the collection of certain data in those cases where full participation would be unduly difficult because of a plant's unique design or circumstances.

Paragraph 50.73(g) states that the reporting requirements contained in § 50.73 replace the reporting requirements in all nuclear power plant Technical Specifications that are typically associated with Reportable Occurrences.

The reporting requirements superseded by § 50.73 are those contained in the Technical Specification sections that are usually titled "Prompt Notification with Written Followup" (Section 6.9.1.8) and "Thirty Day Written Reports" (Section 6.9.1.9). The reporting requirements that have been superseded are also described in Regulatory Guide 1.16, Revision 4, "Reporting of Operating Information—Appendix A Technical Specification," Paragraph 2, "Reportable Occurrences." The special report typically described in Section 6.9.2

"Special Reports" of the Technical Specifications are still required.

V. Regulatory Analysis

The Commission has prepared a regulatory analysis for this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. A copy of the regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 1717 H Street, N.W., Washington, D.C. Single copies of the analysis may be obtained from Frederick J. Hebon, Chief, Program Technology Branch, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone (301) 492-4480.

VI. Paperwork Reduction Act Statement

The Nuclear Regulatory Commission has submitted this rule to the Office of Management and Budget for such review as may be appropriate under the Paperwork Reduction Act, Pub. L. 96-511. The date on which the reporting requirements of this rule become effective reflects inclusion of the 60-day period which the Act allows for such review.

VII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule affects electric utilities that are dominant in their respective service areas and that own and operate nuclear utilization facilities licensed under sections 103 and 104b of the Atomic Energy Act of 1954, as amended. The amendments clarify and modify presently existing notification requirements.

Accordingly, there is no new, significant economic impact on these licensees, nor do these licensees fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

List of Subjects

10 CFR Part 20

Licensed material, Nuclear power plants and reactors, Penalty, Reporting and recordkeeping requirements.

10 CFR PARTS 50

Incorporation by reference, Antitrust, Classified information, Fire protection,

Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 20 and 50 are published as a document subject to codification.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2262); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.58, 50.91 and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 956, as amended (42 U.S.C. 2273), §§ 50.10 (a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10 (b) and (c) and 50.54 are issued under sec. 181i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. A new § 50.73 is added to read as follows:

§ 50.73 Licensee event report system.

(a) *Reportable events.* (1) The holder of an operating license for a nuclear power plant (licensee) shall submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 30 days after the discovery of the event. Unless otherwise specified in this section, the licensee shall report an event regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee shall report:

(i)(A) The completion of any nuclear plant shutdown required by the plant's Technical Specifications; or

(B) Any operation or condition prohibited by the plant's Technical Specifications; or

(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 50.54(x) of this part.

(ii) Any event or condition that resulted in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded, or that resulted in the nuclear power plant being:

(A) In an unanalyzed condition that significantly compromised plant safety;

(B) In a condition that was outside the design basis of the plant; or

(C) In a condition not covered by the plant's operating and emergency procedures.

(iii) Any natural phenomenon or other external condition that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant.

(iv) Any event or condition that resulted in manual or automatic actuation of any Engineered Safety Feature (ESF), including the Reactor Protection System (RPS). However, actuation of an ESF, including the RPS, that resulted from and was part of the preplanned sequence during testing or reactor operation need not be reported.

(v) Any event or condition that alone could have prevented the fulfillment of the safety function of structures or systems that are needed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

(vii) Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition;

(B) Remove residual heat;

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident.

(viii)(A) Any airborne radioactivity release that exceeded 2 times the applicable concentrations of the limits specified in Appendix B, Table II of Part 20 of this chapter in unrestricted areas, when averaged over a time period of one hour.

(B) Any liquid effluent release that exceeded 2 times the limiting combined Maximum Permissible Concentration (MPC) (see Note 1 of Appendix B to Part 20 of this chapter) at the point of entry into the receiving water (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases, when averaged over a time period of one hour.

(ix) Reports submitted to the Commission in accordance with paragraph (a)(2)(viii) of this section also meet the effluent release reporting requirements of paragraph 20.405(a)(5) of Part 20 of this chapter.

(x) Any event that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant including fires, toxic gas releases, or radioactive releases.

(b) *Contents.* The Licensee Event Report shall contain:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific, narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear power plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of structures, components, or systems that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate times of occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

(F) The Energy Industry Identification System component function identifier

and system name of each component or system referred to in the LER.

(1) The Energy Industry Identification System is defined in: IEEE Std 803-1983 (May 16, 1983) Recommended Practices for Unique Identification Plants and Related Facilities—Principles and Definitions.

(2) IEEE Std 803-1983 has been approved for incorporation by reference by the Director of the Federal Register. A notice of any changes made to the material incorporated by reference will be published in the *Federal Register*. Copies may be obtained from the Institute of Electrical and Electronics Engineers, 345 East 47th Street, New York, NY 10017. A copy is available for inspection and copying for a fee at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. and at the Office of the Federal Register, 1100 L St. NW., Washington, D.C.

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a train of a safety system inoperable, an estimate of the elapsed time from the discovery of the failure until the train was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J)(1) Operator actions that affected the course of the event, including operator errors, procedural deficiencies, or both, that contributed to the event.

(2) For each personnel error, the licensee shall discuss:

(i) Whether the error was a cognitive error (e.g., failure to recognize the actual plant condition, failure to realize which systems should be functioning, failure to recognize the true nature of the event) or a procedural error;

(ii) Whether the error was contrary to an approved procedure, was a direct result of an error in an approved procedure, or was associated with an activity or task that was not covered by an approved procedure;

(iii) Any unusual characteristics of the work location (e.g., heat, noise) that directly contributed to the error; and

(iv) The type of personnel involved (i.e., contractor personnel, utility-licensed operator, utility nonlicensed operator, other utility personnel).

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or

components that could have performed the same function as the components and systems that failed during the event.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental information.* The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee shall submit the requested information as a supplement to the initial LER.

(d) *Submission of reports.* Licensee Event Reports must be prepared on Form NRC 366 and submitted within 30 days of discovery of a reportable event or situation to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555. The licensee shall also submit an additional copy to the appropriate NRC Regional Office listed in Appendix A to Part 73 of this chapter.

(e) *Report legibility.* The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

(f) *Exemptions.* Upon written request from a licensee including adequate justification or at the initiation of the NRC staff, the NRC Executive Director for Operations may, by a letter to the licensee, grant exemptions to the reporting requirements under this section.

(g) *Reportable occurrences.* The requirements contained in this section replace all existing requirements for licensees to report "Reportable Occurrences" as defined in individual Plant Technical Specifications.

The following additional amendments are also made to Parts 20 and 50 of the regulations in this chapter.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

3. In § 20.402, paragraph (a) is revised; the introductory text of paragraph (b) is revised; and a new paragraph (e) is added to read as follows:

§ 20.402 Reports of theft or loss of licensed material.

(a)(1) Each licensee shall report to the Commission, by telephone, immediately after it determines that a loss or theft of licensed material has occurred in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter.

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

(b) Each licensee who makes a report under paragraph (a) of this section shall, within 30 days after learning of the loss or theft, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part. The report shall include the following information:

(e) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73 (b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b) of this section. Events reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (b) of this section.

4. In § 20.403, the introductory text of paragraphs (a) and (b) is revised, and paragraph (d) is revised to read as follows:

§ 20.403 Notifications of incidents.

(a) *Immediate notification.* Each licensee shall immediately report any events involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause:

(b) *Twenty-four hour notification.* Each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed

by the licensee that may have caused or threatens to cause:

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees that have an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with § 50.72 of this chapter.

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

5. In § 20.405, paragraphs (a) and (c) are revised, and new paragraphs (d) and (e) are added to read as follows:

§ 20.405 Reports of overexposures and excessive levels and concentrations.

(a)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing concerning any one of the following types of incidents within 30 days of its occurrence:

(i) Each exposure of an individual to radiation in excess of the applicable limits in §§ 20.101 or 20.104(a) of this part, or the license;

(ii) Each exposure of an individual to radioactive material in excess of the applicable limits in §§ 20.103(a)(1), 20.103(a)(2), or 20.104(b) of this part, or in the license;

(iii) Levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(iv) Any incident for which notification is required by § 20.403 of this part; or

(v) Levels of radiation or concentrations of radioactive material (whether or not involving excessive exposure of any individual) in an unrestricted area in excess of ten times any applicable limit set forth in this part or in the license.

(2) Each report required under paragraph (a)(1) of this section must describe the extent of exposure of individuals to radiation or to radioactive material, including:

(i) Estimates of each individual's exposure as required by paragraph (b) of this section;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels or concentrations; and

(iv) Corrective steps taken or planned to prevent a recurrence.

(c)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing of levels of radiation or releases of radioactive material in excess of limits specified by 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," or in excess of license conditions related to compliance with 40 CFR Part 190.

(2) Each report submitted under paragraph (c)(1) of this section must describe:

(i) The extent of exposure of individuals to radiation or to radioactive material;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels, or concentrations; and

(iv) Corrective steps taken or planned to assure against a recurrence, including the schedule for achieving conformance with 40 CFR Part 190 and with associated license conditions.

(d) For holders of an operating license for a nuclear power plant, the incidents included in paragraphs (a) or (c) of this section must be reported in accordance with the procedures described in paragraphs 50.73 (b), (c), (d), (e), and (g) of this chapter and must also include the information required by paragraphs (a) and (c) of this section. Incidents reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraphs (a) or (c) of this section.

(e) All other licensees who make reports under paragraphs (a) or (c) of this section shall, within 30 days after learning of the overexposure or excessive level or concentration, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

6. In § 50.36, new paragraphs (c)(6) and (7) are added to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) * * *

(6) *Initial Notification.* Reports made to the Commission by licensees in response to the requirements of this section must be made as follows:

(i) Licensees that have an installed Emergency Notification System shall make the initial notification to the NRC Operations Center in accordance with § 50.72 of this part.

(ii) All other licensees shall make the initial notification by telephone to the Administrator of the appropriate NRC Regional Office listed in Appendix D, Part 20, of this chapter.

(7) *Written reports.* Holders of an operating license for a nuclear power plant shall submit a written report to the Commission concerning the incidents included in paragraphs (c) (1) and (2) of this section in accordance with the procedures described in § 50.73 (b), (c), (d), (e), and (g) of this part. Incidents reported in accordance with § 50.73 of this part need not also be reported under paragraphs (c) (1) or (2) of this section.

Dated at Washington, D.C. this 20th day of July 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 83-20168 Filed 7-25-83; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

[T.D. 83-155]

Customs Regulations Amendments Relating to Country of Origin Marking

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to establish certification requirements for importers with respect to the country of origin marking of certain articles repacked in the United States after release from Customs custody. This change requires importers to certify to the district director having custody of the articles that: (a) If the importer does the repacking, the new container must be marked in accordance with applicable law and regulations; or (b) if the article is sold or transferred, the importer must notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking of the article must conform to the marking requirements. The purpose of this change is to ensure that an ultimate purchaser in the United States is aware of the country of origin of the imported article.

EFFECTIVE DATE: October 24, 1983.

FOR FURTHER INFORMATION CONTACT:

Anthony L. Piazza, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-8468).

SUPPLEMENTARY INFORMATION:**Background**

Section 304, Tariff Act of 1930, as amended (19 U.S.C. 1304), provides that, unless expressly excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the article or container will permit, in such manner as to indicate to an ultimate purchaser, the English name of the country of origin of the article.

Part 134, Customs Regulations (19 CFR Part 134), sets forth the country of origin marking requirements and the exceptions of 19 U.S.C. 1304. The general exceptions to marking are contained in 19 U.S.C. 1304(a)(3) and § 134.32, Customs Regulations.

Among the exceptions to the country of origin marking requirements are: (1) Articles which the Secretary of the Treasury, pursuant to public notice published in the Treasury Decisions before July 1, 1937, determined "were imported in substantial quantities during the 5-year period immediately preceding January 1, 1937, and were not required during such period to be marked to indicate their origin" * * * (19 U.S.C. 1304(a)(3)(j)). The full list of articles excepted from the marking requirements under 19 U.S.C. 1304(a)(3)(j) is set forth in section 134.33, Customs Regulations, referred to as the "J-list"; and (2) articles which are incapable of being marked (19 CFR 134.32(a)).

Generally, whenever an article is excepted from the marking requirements, the container or holder in which the article reaches the ultimate purchaser is required to be marked to indicate the country of origin of the article whether or not the article itself is marked (19 U.S.C. 1304(b)).

The "ultimate purchaser", as defined in § 134.1, Customs Regulations, is generally the last person in the United States who will receive the article in the form in which it was imported. It is not feasible to state who will be the ultimate purchaser in every circumstance. However, the following examples may be helpful:

(1) If an imported article will be used in manufacture, the manufacturer may be the ultimate purchaser if he subjects the imported article to a process which results in a substantial transformation of the article, even though the process may not result in a new or different article.

(2) If the manufacturing process is merely a minor one which leaves the identity of the imported article intact, the consumer or user of the article, who obtains it after the processing, will be regarded as the ultimate purchaser.

(3) If an article is to be sold at retail in its imported form, the purchaser at retail is the ultimate purchaser.

When an article is imported in the container in which it will reach the ultimate purchaser it is relatively simple for Customs to determine the sufficiency of the country of origin marking. However, a problem exists with J-list articles, and articles incapable of being marked, which are imported in bulk and repacked in the United States by the importer or a subsequent purchaser after release from Customs custody. In these cases, while the container in which the article is imported is usually marked, the container in which the article is repacked for sale to an ultimate purchaser is frequently not. Although the problem appears to be greatest involving steel wire rope, it also involves numerous other articles whose containers are required to be marked.

To minimize the practice of not disclosing country of origin information on the new containers, by notice published in the Federal Register on September 10, 1982 (47 FR 39866), Customs proposed a procedure to require importers of repacked J-list articles, and articles incapable of being marked, to certify to the district director having custody of the articles that: (a) If the importer repacks the article, he shall do so in accordance with the marking requirements; or (b) if the article is sold or transferred, the importer shall notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking must conform to these requirements.

At present, repacked articles do not come under Customs scrutiny because Customs and the Treasury Department have taken the position (based on a restrictive interpretation of 19 U.S.C. 1304) that the statute applies only to articles or their containers at the time of importation. However, this position, and Customs lack of enforcement of the marking requirements after articles are released from Customs custody, has resulted in many articles reaching the ultimate purchaser in unmarked containers, which otherwise should have been marked. Rather than permitting the repacking rationale to serve to frustrate the clear intent of the statute (i.e., to notify an ultimate purchaser of an article's foreign origin), Customs seeks to enforce the statute with respect to repacked articles by applying the rationale in *U.S. Wolfson*

Bros. Corp. v. United States, 52 CCPA 46, C.A.D. 856 (1965). In that case the court held that if the article will not reach the ultimate purchaser in the container in which it is imported, then Customs cannot find the marking of the imported container to satisfy the requirement of the statute.

Discussion of Comments

Over twelve hundred and fifty (1250) comments were received in response to the notice of September 10, 1982. Approximately twelve hundred (1200) commenters favored the proposal; fifty (50) or so opposed it on various grounds. Several commenters made suggestions that Customs believes would increase the effectiveness of the proposal and reduce the administrative burden for Customs and importers.

The commenters favoring the proposal argued that the present regulations fail to implement effectively the purpose of 19 U.S.C. 1304. They commented that if the change is adopted it will be of paramount importance in providing country of origin information to ultimate purchasers, and will reduce the incidences of fraudulent and deceptive practices which have led to unfair competition in many cases.

A commenter representing the Hand Tools Institute, an association consisting of domestic producers of hand tools, suggested that the proposal not be limited to overcoming difficulties which have attended the repacking of unmarked articles, but should also resolve marking problems with respect to the packing and repacking of marked articles, especially where the marking on the article is concealed. For example, various foreign-made tools are entering the United States in bulk, properly marked with the country of origin marking. Once in the United States however, these tools are repacked in such a way to conceal the country of origin marking by placing the items face down in sealed, unmarked blister packs. To correct this problem, the commenter suggested that the certification include language that "any packing or repacking must not obscure or conceal the country of origin information appearing on the articles, or else the outermost container must be marked in accordance with the applicable law or regulation."

Customs believes that this suggestion constitutes a major change to the proposal, which is limited to unmarked articles. Such a change would require additional notice to the public and an opportunity to comment before being adopted. Accordingly, a separate notice will be published in the Federal Register soliciting public comment on the

concealment of marking problem as it relates to the repacking of marked articles.

A second commenter suggested allowing the importer to file with the district director at each port where the article is entered a blanket certification to cover all importations of that article for a given period (e.g., calendar year), rather than requiring a certification for each entry filed.

Customs has adopted this modification because it will greatly reduce the paperwork burden for importers.

A third commenter argued that to require a certification broadly for every repacked article would sweep in many products not intended to be covered by the law and regulations. Therefore, it was suggested that the words "and not subject to an exemption under the act or regulations" be inserted after the word "possession" in the first sentence of the proposed certification, to minimize this situation.

Customs also agrees with this suggestion and has modified the certification to include similar exempting language.

Certain opposing commenters apparently misinterpreted the proposal. They stated that it requires the importer "to ensure that repackers correctly mark each individual package."

The only obligation that an importer has with respect to repackers is to notify them that the country of origin information is required on the new package.

Other opposing commenters claimed that the proposal involves the establishment of a non-tariff trade barrier.

The mere certification that an importer will abide by the marking law, which binds the importer in any event, does not prevent or otherwise restrict importations. It merely ensures an importer's compliance with a rule that now imposes sanctions for its violation.

One commenter opposed the proposal upon grounds that similar requirements are not imposed on domestic industry and its products. The Congress in its wisdom saw fit to require country of origin marking only on articles that are produced in foreign countries. The fundamental objective of country of origin marking legislation, since the first enactment appeared as section 6 of the Tariff Act of 1890, has been to notify an ultimate purchaser of an article's foreign origin before determining whether to buy the article or its domestic counterpart. This choice was provided in large part because Congress recognized that if given a choice, consumers prefer domestic goods. The

failure to provide country of origin information on foreign articles or their containers prevents consumers from exercising this right.

Many domestic food processors objected that labeling requirements would be prohibitive. Customs believes that most of the products concerned will be substantially transformed and therefore will not be subject to the rule. The regulation is intended to apply to articles which are repacked after importation but not to articles substantially changed by manufacture or processing which results in an article having a name, character, or use differing from that to the imported article. For example, meat imported in 60-pound boxes would have to carry country of origin labeling as long as it remained physically in the form in which it is imported, even if repacked in smaller size containers. However, if such meat is further processed or combined with other products to make ground beef or other consumer meat products, the processor, as the ultimate purchaser of the meat in the form in which it was imported, would not be responsible for continued country of origin labeling.

Another commenter opposed the certification requirement upon grounds that the Federal Trade Commission (FTC) has the authority to compel marking after articles are imported.

Customs does not believe the rule impinges upon the authority of the FTC. Nothing in the law or regulations should be construed as excepting any particle (or its container) from the particular requirements of marking provided for in any other provision of law, such as those of the FTC, Food and Drug Administration, and other such agencies. The certification merely attaches sanctions to obligations which already exist under 19 U.S.C. 1304 and Part 134, Customs Regulations. The case cited by the commenter, *L. Heller & Son v. Federal Trade Commission*, 191 F. 2d 954 (7th Cir. 1951), is inapposite for the proposition that seeks to bar Customs from promulgating the rule. The court recognized that the two statutes, 19 U.S.C. 1304 and section 5 of the Federal Trade Commission Act, are not repugnant. The court stated that 19 U.S.C. 1304 was "concerned solely with the extent to which the Treasury Department, incidentally to its collection of Customs duties, should regulate the labeling of imported goods."

A commenter for the steel importing community challenged the measure as beyond the jurisdiction of Customs. The point is made that articles entering the domestic commerce after clearing

Customs are not susceptible to continuing regulation by Customs.

Clearly, the Secretary of the Treasury has power to attach conditions to any exemption in order to carry out Congressional intent and prevent subversion of the marking statute. As such, the Secretary has announced the certification process as a framework for obtaining compliance with the statute.

A commenter representing a foreign meat producer claimed that the proposed rule is inconsistent with the General Agreement on Tariffs and Trade (GATT).

This is incorrect as the marking statutes antedated the GATT and were not repealed thereby.

Section 134.34, Customs Regulations, provides that an exception from marking under section 134.32(d), Customs Regulations, may be authorized in the discretion of the district director for articles which are repacked after leaving Customs custody and the containers will be marked. One commenter believed that the proposal, if adopted, should supersede the discretionary exemption in § 134.34.

Customs agrees. Since, unless expressly excepted, the marking of the new containers will be mandatory, § 134.34 will be removed.

Customs recognizes that the change will not eliminate all marking problems. However, we are convinced that it is a proper response to an increasing administrative burden. We are hopeful that it will strike a balance between administrative concern for compliance with the marking statute and the desire of interested parties to understand the parameters of their responsibility for satisfying country of origin marking requirements.

Many commenters stated their views on the rule's applicability to specific articles. However, Customs obviously cannot in this document answer all of the questions raised in this context. Such questions should be submitted to the Director, Entry, Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229, in accordance with the ruling procedures set forth in Part 177, Customs Regulations (19 CFR Part 177).

After consideration of the comments and further review of the matter, it has been determined to adopt the proposal, with the changes noted above. However, rather than amending § 134.22 as proposed, a new § 134.25 is being added to Part 134 to deal more specifically with the marking of containers of repacked articles which are the subject of this rule.

Executive Order 12291

It has been determined that this document does not contain a "major rule" requiring preparation of a regulatory impact analysis under Executive Order 12291.

Regulatory Flexibility Act

It is certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this rule will not have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was Jesse V. Vitello, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service (202-566-8237). However, personnel from other Customs offices participated in its development.

Lists of Subjects in 19 CFR Part 134

Customs duties and inspection, Imports, Importers, Labeling, Packaging, and Containers.

Amendments to the regulations

Part 134, Customs Regulations (19 CFR Part 134), is amended as set forth below.

Alfred R. De Angelus,

Acting Commissioner of Customs

Approved:

Robert E. Powis,

Acting Assistant Secretary of the Treasury.
July 18, 1983.

PART 134—COUNTRY OF ORIGIN MARKING

1. Part 134, Customs Regulations (19 CFR Part 134), is amended by adding a new § 134.25 to read as follows:

§ 134.25 Containers or holders for repacked J-list articles and articles incapable of being marked.

(a) *Certification requirements.* If an article subject to these requirements is intended to be repacked in new containers for sale to an ultimate purchaser after its release from Customs custody, or if the district director having custody of the article, has reason to believe such article will be repacked after its release, the importer shall certify to the district director that: (1) If the importer does the repacking, the new container shall be marked to indicate the country of origin of the article in accordance with the requirements of this Part; or (2) if the article is intended to be sold or transferred to a subsequent purchaser or repacker, the importer shall notify such purchaser or transferee, in writing, at the time of sale or transfer, that any repacking of the article must

conform to these requirements. The importer, or his authorized agent, shall sign the following statement.

Certificate of Marking—Repacked J-List Articles and Articles Incapable of Being Marked

(Port of entry) _____
I, _____ of _____, certify that if the article(s) covered by this entry (entry no.(s) dated _____), is (are) repacked in a new container(s), while still in my possession, the new containers, unless excepted, shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the container(s) will permit, in such manner as to indicate the country of origin of the article(s) to the ultimate purchaser(s) in accordance with the requirements of 19 U.S.C. 1304 and 19 CFR Part 134. I further certify that if the article(s) is (are) intended to be sold or transferred by me to a subsequent purchaser or repacker, I will notify such purchaser or transferee, in writing, at the time of sale or transfer, of the marking requirements.

Date _____
Importer—_____

The certification statement may appear as a typed or stamped statement on an appropriate entry document or commercial invoice, or on a preprinted attachment to such entry or invoice; or it may be submitted in blanket form to cover all importations of a particular product for a given period (e.g., calendar year). If the blanket procedure is used, a certification must be filed at each port where the article is entered.

(b) *Facsimile signatures.* The certification statement may be signed by means of an authorized facsimile signature.

(c) *Time of filing.* The certification statement shall be filed with the district director at the time of entry summary. If the certification is not available at that time, a bond shall be given for its production in accordance with § 141.66, Customs Regulations (19 CFR 141.66). In case of repeated failure to timely file the certification required under this section, the district director may decline to accept a bond for the missing document and demand redelivery of the merchandise under § 134.51, Customs Regulations (19 CFR 134.51).

(d) *Notice to subsequent purchaser or repacker.* If the article is sold or transferred to a subsequent purchaser or repacker the following notice shall be given to the purchaser or repacker:

Notice to Subsequent Purchaser or Repacker

These articles are imported. The requirements of 19 U.S.C. 1304 and 19 CFR Part 134 provide that the articles or their containers must be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit, in such a manner as to indicate to an ultimate purchaser in the United States, the

English name of the country of origin of the article.

(e) *Duties and Penalties.* Failure to comply with the certification requirements in paragraph (a) may subject the importer to a demand for liquidated damages under section 134.54(a) and for the additional duty under 19 U.S.C. 1304. Fraud or negligence by any person in furnishing the required certification may also result in a penalty under 19 U.S.C. 1592.

§ 134.34 [Removed]

2. Part 134 is further amended by removing § 134.34.

(R.S. 251, as amended (19 U.S.C. 66), section 304, 624, 46 Stat. 731 as amended, 759, (19 U.S.C. 1304, 1624), 77A Stat. 14 (19 U.S.C. 1202))

(FR Doc. 83-30136 Filed 7-25-83; 8:45 am)

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 73**

[Docket No. 83C-0041]

2-[[2,5-Diethoxy-4-[(4-Methylphenyl)Thio]Phenyl]AZO]-1,3,5-Benzenetriol; Listing as a Color Additive For Use in Soft (Hydrophilic) Contact Lenses; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 21, 1983, for a regulation that provides for the safe use of 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol as a color additive in marking soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes. The agency is taking this action in response to a petition filed by Precision-Cosmet Co., Inc.

DATE: Effective date confirmed: June 21, 1983.

FOR FURTHER INFORMATION CONTACT: George C. Murray, National Center for Devices and Radiological Health (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: In a final rule published in the Federal Register of May 20, 1983 (48 FR 22705), FDA amended the color additive regulations