

Rule. They request a 60-day extension of the effective date of the Final Rule to October 14, 2005.

2. For good cause shown, the Commission will extend the effective date of the Final Rule 60 days from the current effective date (August 15, 2005) to October 14, 2005. Additionally, we will extend to November 15, 2005, the date by which all public utilities that own, control, or operate transmission facilities in interstate commerce are to adopt the Final Rule Appendix G as amendments to the Large Generator Interconnection Procedures and Large Generator Interconnection Agreements (LGIAs) in their Open Access Transmission Tariffs.<sup>2</sup> The transition period adopted in the Final Rule (which states that the low voltage ride-through, reactive power and supervisory control and data acquisition (SCADA) provisions apply only to LGIAs signed, filed with the Commission in executed form, or filed as non-conforming agreements, on or after January 1, 2006, or the date six months after publication of the Final Rule in the **Federal Register**) remains unchanged.

3. NERC and AWEA state that they will file a report with the Commission on or before September 14, 2005, describing the final results of their discussions and any recommended revisions to the low voltage ride-through provisions in the Final Rule. The Commission accepts this commitment, and will take any such recommended revisions submitted on or before September 14, 2005 into consideration as it considers the requests for rehearing filed in this proceeding. Additionally, the Commission will consider any supplemental comments related to the low voltage ride-through provisions of the Final Rule that are filed on or before September 14, 2005. However, the Commission will not consider comments that simply rehash prior arguments.

*The Commission orders:*

(A) The effective date of the Final Rule on Interconnection for Wind Energy is hereby extended to October 14, 2005, as discussed in the body of this order.

(B) The date by which all public utilities that own, control, or operate transmission facilities in interstate commerce are to adopt the Final Rule Appendix G as amendments to the Large Generator Interconnection Procedures and Large Generator Interconnection Agreements in their Open Access

Transmission Tariffs is hereby extended to November 14, 2005, as discussed in the body of this order.

(C) The Secretary shall promptly publish a copy of this order in the **Federal Register**.

By the Commission.

**Linda Mitry,**

*Deputy Secretary.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1301

[Docket No. DEA-196F]

RIN 1117-AA73

#### Reports by Registrants of Theft or Significant Loss of Controlled Substances

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final Rule.

**SUMMARY:** DEA is amending its regulations regarding reports by registrants of theft or significant loss of controlled substances. There had been some confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. In this final rule, DEA clarifies the regulations and provides guidance to registrants regarding the theft, significant loss, and unexplained loss of controlled substances.

**DATES:** This final rule is effective September 12, 2005.

**FOR FURTHER INFORMATION CONTACT:** Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307-7297.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### *DEA's Legal Authority*

DEA implements the Controlled Substances Act (21 U.S.C. 801-971) (CSA), as amended. DEA publishes the implementing regulations for this statute in Title 21 of the Code of Federal Regulations (CFR), Part 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of these substances for legitimate medical purposes and deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for

manufacturing, distribution, and dispensing of controlled substances. As part of these regulations, DEA requires that registrants have systems to maintain security for controlled substances and to report thefts or losses.

##### *Theft and Loss Reporting Requirements*

Section 1301.74(c), "Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs." states that "[t]he registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them."

Section 1301.76(b), "Other security controls for practitioners." requires that "[t]he registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA (or BND) Form 106 regarding such loss or theft."

##### *DEA's Proposed Rule*

On July 8, 2003, DEA published a notice of proposed rulemaking (NPRM) (68 FR 40576) to address confusion that exists within the regulated industry as to the exact meaning of the phrases "upon discovery" and "significant loss."

DEA has always viewed "upon discovery" to mean that notification should occur immediately and without delay. The purpose of immediate notification is to provide an opportunity for DEA, state, or local participation in the investigative process when warranted and to create a record that the theft or significant loss was properly reported. It also alerts law enforcement personnel to more broadly based circumstances or patterns of which the individual registrant may be unaware. This notification is considered part of a good-faith effort on the part of the regulated industries to maintain effective controls against the diversion of controlled substances, as required by § 1301.71(a). Lack of prompt notification could prevent effective investigation

<sup>2</sup> This extension also satisfies the request for extension submitted by Midwest Independent Transmission System Operator, Inc. on August 4, 2005.

and prosecution of individuals involved in the diversion of controlled substances. DEA proposed to insert the word "immediately" before the phrase "upon discovery" to clarify this point.

Regarding "significant loss," there is no single objective standard that can be established and applied to all registrants to determine whether a loss is "significant." Any unexplained loss or discrepancy should be reviewed within the context of a registrant's business activity and environment. What constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. A manufacturer may experience continuous losses in the manufacturing process due to, for example, atmospheric changes or mixing procedures. Such losses may not be deemed by the registrant to be significant and may be recorded in batch records. Conversely, for registrants other than manufacturers, the repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem that must be reported to DEA, even though the individual quantity of each occurrence is not significant.

Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances. DEA proposed to amend the regulations by inserting a list of factors that registrants should consider when determining whether a loss of controlled substances is significant.

## II. Comments Received in Response to the NPRM Published July 8, 2003

DEA received eight comments in response to the NPRM. In general, the comments were supportive of DEA efforts to clarify current regulations and provide guidance regarding reporting of theft or significant loss of controlled substances. At the same time, commenters offered a number of suggestions that, in their view, would provide even greater clarity and certainty to the regulations. These comments are addressed below.

### *Timing of Reports*

Regarding the timing of initial theft or loss reports, DEA proposed to insert the word "immediately" before the phrase "upon discovery." DEA also suggested in the proposed rule preamble that

submission of the DEA Form 106 itself is not immediately necessary if the registrant needs time to investigate the facts surrounding the theft or significant loss, but that updates should be provided to DEA if the investigation takes more than two months. One commenter recommended that the regulations provide an objective standard regarding the time frame when reports must be made (while retaining the subjective standard for registrants to decide when a report is necessary). Specifically, the commenter suggested that initial reports be required within one business day and that DEA Form 106 must be filed within 30 days.

DEA agrees with the commenter that an objective standard for initial notification would be useful and believes the one-business-day suggestion is consistent with its proposed addition of the word "immediately." Regarding the 30-day requirement for submission of the Form 106, however, DEA believes that may be difficult to comply with in some cases, so prefers to retain the registrant flexibility provided by the approach outlined in the proposed rule preamble, *i.e.*, DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear, but updates should be provided to DEA if the investigation takes more than two months.

### *Clarification on "Discovery"*

Related to this change, several commenters requested clarification or proposed changes to what constitutes "discovery." They suggested this was more a source of confusion to the regulated community than was the timing issue. According to these commenters, DEA should explicitly recognize that "discovery" may well occur in increments, therefore, knowing when to make a report becomes complex. One commenter suggested that the addition of objective standards for submitting reports would resolve much of the confusion, while another suggested adding "and verification" after the phrase "upon discovery."

DEA does not disagree with these commenters and recognized the incremental nature of discovery in the preamble to the proposed rule when it suggested that an update be provided to DEA within 60 days of initial notification, if the investigation into the theft or significant loss is still ongoing, and that the Form 106 need not be filed at all if the registrant ultimately determines that no theft or significant loss occurred. DEA's overriding interest here is in obtaining immediate notification of suspected or actual theft

or significant loss and accepts the one-business-day suggestion as a clear standard for making that required initial notification.

### *Method of Initial Notification*

One commenter questioned the nature of the initial notification itself, seeking clarification on whether a telephone call would suffice. In the preamble to the proposed rule, DEA recommended that the initial notification be a short statement provided by fax, which would avoid delays that might be associated with using regular U.S. mail. Faxing is not the only option a registrant may use, but DEA does believe that the notification should be in writing. Not only does this eliminate any misunderstanding that could arise in an oral communication, but it also provides the registrant with a record of what was provided, when it was provided, and to whom it was provided.

### *DEA Form 106*

A final area of comments on the notification process raised issues about the purpose of Form 106 and offered suggestions that the commenters believed would make it a more useful report. While DEA appreciates these comments and suggestions, DEA considers them beyond the scope of this rulemaking. DEA Form 106 is scheduled to be revised within the next year, and DEA will consider these comments during that process.

In reviewing the existing regulation and DEA Form 106, DEA noted that while the form itself specified that the form should be completed and submitted to DEA, the regulations merely required that the form be completed and did not contain a requirement that the form be submitted. Therefore, DEA is amending the regulations to explicitly acknowledge the requirement, currently contained only in the DEA Form 106 instructions, that the completed DEA Form 106 be submitted to DEA.

### *Factors To Be Considered in Determining Whether a Loss Is Significant*

In the proposed rulemaking, DEA included a change that would add a list of factors to be considered in determining whether a loss is "significant." DEA recognizes there is no single objective standard that can be applied to all registrants—what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. Any unexplained loss or discrepancy must be reviewed within the context of a registrant's business activity and

environment. Several commenters thought the list of factors is a helpful addition. One commenter disagreed, stating that “none of these factors or questions is particularly useful in determining whether initial notification should be provided to DEA to satisfy the requirement of reporting” and suggested that confusion over what constitutes a significant loss exists not only among DEA registrants, but also among DEA field offices, which results in differences in interpretation and enforcement.

DEA recognizes that there has been confusion within the regulated community regarding the application of this standard and for that very reason proposed the list of factors to clarify for all parties what registrants should be considering—at a minimum—when determining whether a loss is significant. As DEA noted in the proposed rule preamble, “individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.” DEA encourages registrants to use additional factors beyond what DEA suggests in the evaluation of whether a loss is significant. DEA believes, however, that it has provided as much direction on this matter as it reasonably can, given the case-by-case nature of this determination.

#### *In-Transit Loss*

One commenter also suggested the insertion of the word “significant” before the phrase “in-transit losses of controlled substances” in § 1301.74(c), unless DEA intends for all in-transit losses to be reported. DEA does, in fact, intend for all in-transit losses to be reported, not just significant losses. Therefore, to clarify this point, and based on the comment received, DEA is amending the regulatory text to reflect that “all” in-transit losses must be reported to DEA.

#### *DEA Form 41*

Several commenters requested additional clarification and guidance on reporting and recordkeeping, particularly with regard to breakage and spillage and the submission of Form 41.

In the preamble to the proposed rulemaking, DEA did provide guidance on this topic, both to distinguish it from reporting of thefts or significant losses

of controlled substances (and the use of DEA Form 106) and to restate the disposal and documentation obligations when breakage, spillage, or other damage to controlled substances occurs. DEA believes this guidance is adequate and sufficiently clear and does not wish to expand on the topic as a part of this rulemaking on theft and significant loss. Registrants should continue to employ common sense, good faith approaches to their reporting and recordkeeping obligations in the case of breakage and spillage.

#### *Reporting of Thefts and Losses to ARCOS*

Finally, DEA received a request for clarification of the reporting of thefts and losses to DEA’s Automation of Reports and Consolidated Orders System (ARCOS). DEA wishes to reiterate that thefts and losses are reported to ARCOS. Thefts are reported using transaction codes based on the type of theft, e.g., theft from premises, in-transit loss, etc. Losses are reported to ARCOS simply as losses. DEA did not propose any regulatory change regarding this reporting, nor is it making a regulatory change at this time.

#### *Regulatory Certifications*

##### *Regulatory Flexibility Act*

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation seeks to clarify existing DEA regulations regarding the reporting of thefts and significant losses of controlled substances. No new recordkeeping or reporting requirements are imposed by this rulemaking.

##### *Executive Order 12866*

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. This rulemaking merely seeks to clarify existing DEA regulations, policies and procedures.

##### *Executive Order 12988*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

#### *Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$115 million or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### **List of Subjects in 21 CFR Part 1301**

Administrative practice and procedure, Drug traffic control, Security measures.

■ For the reasons set out above, 21 CFR part 1301 is amended as follows:

#### **PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES**

■ 1. The authority citation for part 1301 continues to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 951, 952, 953, 956, 957.

■ 2. Section 1301.74 is amended by revising paragraph (c) to read as follows:

#### **§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.**

\* \* \* \* \*

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any

controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

\* \* \* \* \*

■ 3. Section 1301.76 is amended by revising paragraph (b) to read as follows:

**§ 1301.76 Other security controls for practitioners.**

\* \* \* \* \*

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

\* \* \* \* \*

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control.*

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**BILLING CODE 4410-09-P**

## NATIONAL INDIAN GAMING COMMISSION

### 25 CFR Part 542

RIN 3141-AA27

#### Minimum Internal Control Standards

**AGENCY:** National Indian Gaming Commission.

**ACTION:** Final rule.

**SUMMARY:** In response to the inherent risks of gaming enterprises and the resulting need for effective internal controls in Tribal gaming operations, the National Indian Gaming Commission (Commission or NIGC) first developed Minimum Internal Control Standards (MICS) for Indian gaming in 1999, and then later revised them in 2002. The Commission recognized from the outset that periodic technical adjustments and revisions would be necessary in order to keep the MICS effective in protecting Tribal gaming assets and the interests of Tribal stakeholders and the gaming public. To that end, the following final rule revisions contain certain corrections and revisions to the Commission's existing MICS, which are necessary to clarify, improve, and update other existing MICS provisions. The purpose of these MICS revisions is to address apparent shortcomings in the MICS and various changes in Tribal gaming technology and methods. Public comment on these final MICS revisions was received by the Commission for a period of 48 days after the date of their

publication in the **Federal Register** as a proposed rule on March 10, 2005.

After consideration of all received comments, the Commission has made whatever changes to the proposed revisions that it deemed appropriate and is now promulgating and publishing the final revisions to the Commission's MICS Rule, 25 CFR part 542.

**DATES:** *Effective Date:* August 12, 2005.

*Compliance Date:* Except for the final revisions to subsection 542.3(f), on or before October 11, 2005, the Tribal gaming regulatory authority shall: (1) In accordance with the Tribal gaming ordinance, establish and implement Tribal internal control standards that shall provide a level of control that equals or exceeds the revised standards set forth herein; and (2) establish a deadline no later than December 12, 2005, by which a gaming operation must come into compliance with the Tribal internal control standards. However, the Tribal gaming regulatory authority may extend the deadline by an additional 60 days if written notice is provided to the Commission no later than December 12, 2005. Such notification must cite the specific revisions to which the extension pertains.

With regard to the final revisions to subsection 542.3(f), on or before October 11, 2005, the Tribal gaming regulatory authority shall: (1) In accordance with the Tribal gaming ordinance, establish and implement Tribal internal control standards that shall provide a level of control that equals or exceeds the revised standards set forth in subsection 542.3(f); and (2) establish a deadline no later than August 14, 2006, by which a gaming operation must come into compliance with the Tribal internal control standards. To further clarify the referenced deadline, the final revisions to subsection 542.3(f) are applicable to fiscal years of the gaming operation ending after August 14, 2006. No extension of the compliance period is allowed for the final revisions to subsection 542.3(f).

**FOR FURTHER INFORMATION CONTACT:** Vice-Chairman Nelson Westrin, (202) 632-7003 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

On January 5, 1999, the Commission first published its Minimum Internal Control Standards (MICS) as a Final Rule. As gaming Tribes and the Commission gained practical experience applying the MICS, it became apparent that some of the standards required clarification or modification to operate as the Commission had intended and to accommodate changes and advances