| Country | Entity | License requirement | License review policy | Federal Register citation |
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| * | * * * | * | * * | * |
| NETHERLANDS ..... | * * | * | * * | * |
| | Kapil Raj Arora, Breukelensestraat 44, 2574 RC, The Hague, Netherlands; *and* Knobbelswaansingel 19, 2496 LN, The Hague, Netherlands. | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial ..... | 81 FR 14958, 3/21/16. |
| | * * | * | * * | * |
| PAKISTAN ..... | * * | * | * * | * |
| | Orion Eleven Pvt. Ltd., Street 11 Valley Road, Westridge Rawalpindi, Pakistan. | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial ..... | 79 FR 56003, 9/18/14. |
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[FR Doc. 2024–21109 Filed 9–13–24; 8:45 am]

**BILLING CODE 0099–10–P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

### 15 CFR Parts 764 and 766

**[Docket No. 240911–0236]**

**RIN 0694–AJ84**

### Administrative and Enforcement Provisions

**AGENCY:** Bureau of Industry and Security, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** With this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by making certain revisions and clarifications. This final rule revises provisions related to the voluntary self-disclosure process for exporters who believe that they may have violated the EAR, or any order, license or authorization issued thereunder. This final rule also provides clarified guidance on charging and penalty determinations in settlement of administrative enforcement cases.

**DATES:** This rule is effective September 16, 2024.

**FOR FURTHER INFORMATION CONTACT:** For general questions, contact Tracy Martin, Office of Export Enforcement, Bureau of Industry and Security, U.S. Department of Commerce at (202) 482–1208 or by email: *Tracy.Martin@bis.doc.gov.*

**SUPPLEMENTARY INFORMATION:**

## A. Background

With this rule BIS revises § 764.5 of the EAR regarding the procedures for submitting voluntary self-disclosures (VSDs) and supplement No. 1 to part 766, which includes guidance on charging and penalty determinations in settlement of administrative enforcement cases. As discussed in more detail below, these revisions implement certain policies related to the VSD process that BIS has announced in policy memoranda since 2022, and also makes changes to how BIS calculates penalties in administrative cases.

*1. Relevant Statutory Authority and Regulatory Framework*

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). Section 1760(c) of ECRA (50 U.S.C. 4819(c)) authorizes the Secretary of Commerce (Secretary) to impose civil penalties for violations of ECRA, its implementing regulations, or any order or license issued thereunder. Specifically, ECRA authorizes the Secretary to impose the following civil penalties for each violation:

(A) A fine of not more than $300,000 or an amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed, whichever is greater.

(B) Revocation of a license issued under [ECRA] to the person.

(C) A prohibition on the person's ability to export, reexport, or in-country transfer any items controlled under [ECRA].

50 U.S.C. 4819(c)(1). The amount of the maximum civil penalty per violation under ECRA is subject to adjustment under the Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461) and is currently $364,992. See 15 CFR 6.3(c)(6). Within these limits, 50 U.S.C. 4819(c)(3) authorizes the Secretary to issue regulations to ''provide standards for establishing levels of civil penalty . . . based upon factors such as the seriousness of the violation, the culpability of the violator, and such mitigating factors as the violator's record of cooperation with the Government in disclosing the violation.'' The Secretary's authority under ECRA is delegated to BIS (see section 1781 of ECRA, 50 U.S.C. 4851) and is implemented through the EAR.

Consistent with these authorities, BIS has implemented regulations providing standards for establishing levels of civil penalties in supplement No. 1 to part 766, titled ''Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases'' (''BIS Penalty Guidelines''). Last revised in the rule entitled ''Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases'' published in the **Federal Register** on June 22, 2016 (81 FR 40506), the BIS Penalty Guidelines describe how BIS's Office of Export Enforcement (OEE), the organizational unit of BIS that is responsible for enforcing the provisions of the EAR, makes penalty determinations in administrative enforcement cases. The BIS Penalty Guidelines describe various factors—including aggravating, general, and mitigating factors—that OEE will consider in determining how to respond to apparent export violations in administrative cases. Specifically, the BIS Penalty Guidelines outline how OEE calculates monetary penalties for a particular violation, which includes determination of the relevant base penalty, and how the various aggravating, general, and mitigating factors justify an upward or downward departure from that base penalty. As discussed in the BIS Penalty Guidelines, the presence of significant aggravating factors may lead OEE to consider the conduct to be egregious, which may result in considerably higher monetary penalties. Conversely, the presence of significant mitigating factors may result in a lower monetary penalty.

One factor given significant weight in the BIS Penalty Guidelines is whether a party submitted a VSD regarding the violation. BIS encourages parties who

may have violated the EAR to submit a VSD and views VSDs as a strong indication of a party's commitment to U.S. export control compliance. Section 764.5 of the EAR establishes BIS's general policy and procedures for disclosing potential violations of ECRA and the EAR to BIS. Specifically, BIS encourages the submission of a VSD if a potential violation of the EAR is discovered.

*2. BIS Enforcement Policy Memoranda*

Beginning in 2022, BIS issued a series of publicly available memoranda describing policy changes to strengthen its administrative enforcement program and to encourage companies, universities, and individuals to submit VSDs. Such disclosures can provide BIS with helpful information from industry about export compliance practices, as well as information about other potential violations. These memoranda include the following: (1) ''Further Strengthening Our Administrative Enforcement Program,'' dated June 30, 2022 (*https://www.bis.gov/sites/default/files/files/Administrative%20Enforcement%20Memo.pdf*) (the ''2022 Policy Memorandum''); (2) ''Clarifying Our Policy Regarding Voluntary Self-Disclosures and Disclosures Concerning Others,'' dated April 18, 2023 (*https://www.bis.gov/sites/default/files/files/VSD%20Policy%20Memo%20%2804.18.2023%29.pdf*) (the ''2023 Policy Memorandum''); and (3) ''Further Enhancements to Our Voluntary Self-Disclosure Process,'' dated January 16, 2024 (*https://www.bis.gov/sites/default/files/files/VSD%20MEMO.pdf*) (the ''2024 Policy Memorandum'') (collectively, the ''Policy Memoranda''). The Policy Memoranda emphasize the importance of administrative enforcement measures to mitigate the threat that sensitive technologies will fall into adversarial hands and focus on the deterrent effect of imposing significantly higher penalties for egregious violations that affect national security. So that OEE can focus its limited resources on more serious cases, the Policy Memoranda also highlight OEE's desire to resolve less serious violations as quickly as possible—with lower penalties or no penalty where appropriate—and announce new policies making it easier to submit disclosures and expanding the beneficial effect of submitting a VSD.

Policy changes that were announced in the Policy Memoranda include: (1) the establishment of a ''fast track'' disclosure process for minor or technical violations and allowing for companies to submit an abbreviated narrative account in connection with such disclosures that contains less detail than required by § 764.5; (2) the availability of electronic submission of VSDs via email; (3) using non-monetary penalties to resolve cases that are not egregious and have not resulted in national security harm, but rise above the level of cases warranting a warning letter; (4) clarifying that OEE will consider it an aggravating factor for purposes of determining a potential penalty if a party identifies that it committed a possible violation and then chooses not to disclose it; and (5) clarifying and simplifying BIS's process for handling requests to take corrective action for unlawfully exported items at issue in a VSD that would otherwise be prohibited by § 764.2(e)

The substance of the Policy Memoranda and their codification into regulations are firmly within the statutory authority granted by section 1760(c) of ECRA (50 U.S.C. 4819(c)). The Policy Memoranda were developed in accordance with the legislative framework, which empowers the Secretary to implement and enforce policies in this area. By translating these memoranda into formal regulations, BIS can ensure that the directives are legally binding and consistent with the legislative intent, thereby enhancing their effectiveness and enforceability while adhering to the statutory requirements.

**B. Purpose of This Final Rule**

The primary purpose of this final rule is twofold: first, to incorporate into the EAR the various policies announced in the Policy Memoranda, which are designed to encourage industry and academia to submit VSDs and to provide for efficient resolution of cases involving less serious violations, and second, to revise the BIS Penalty Guidelines to change how OEE calculates the base penalty in administrative cases, and how it applies various factors to the base penalty to determine the final penalty.

With respect to the changes implementing the elements of the Policy Memoranda, BIS is revising § 764.5 (regarding voluntary self-disclosure) and the BIS Penalty Guidelines. BIS is incorporating into the EAR relevant elements from the Policy Memoranda so that the regulations contain all relevant policies and procedures for submitting VSDs. As a result, industry will not be required to look to multiple sources to understand OEE's procedures and expectations regarding the submission of VSDs. BIS is also making clear in the BIS Penalty Guidelines that for violations of a lower value and with minimal aggravating factors, OEE's preference is to impose non-monetary penalties to shore up a company's compliance program, which is more effective in these types of cases.

With respect to the changes to the way OEE calculates penalties, BIS is revising the BIS Penalty Guidelines so that potential penalties more appropriately reflect the seriousness of the offense by linking that determination directly to transaction value and other circumstances pertaining to a violation. These Penalty Guideline changes do so primarily for two reasons. First, BIS has identified scenarios in which the previous BIS Penalty Guidelines, which applied schedule amounts and caps well below the statutory limitations to penalties for non-egregious cases, produce a base penalty that is disproportionately low compared to the transaction value, and therefore is insufficient to serve as a deterrent or incentive for companies to invest properly in export compliance. For example, under the previous rule, the penalty for a non-egregious violation disclosed through a VSD for a transaction valued at $100 million would be capped at $125,000. In this rule, BIS is removing from the BIS Penalty Guidelines the caps that previously existed for non-egregious cases. BIS will continue to take mitigating factors into account, as described in the revised BIS Penalty Guidelines, and to apply an appropriate reduction to the base penalty if circumstances warrant it.

Second, the previous BIS Penalty Guidelines provided specific percentage ranges for reductions associated with certain mitigating factors (but not all mitigating factors), while it provided no such ranges for aggravating or general factors. The inclusion of specific percentage ranges for some mitigating factors and not for other factors led parties to incorrect assumptions about the range of reduction to which they were entitled. For example, the previous BIS Penalty Guidelines provided for a reduction of the base penalty amount of up to 25% for first time violations; however, a party's first offense might occur together with aggravating factors or with other mitigating factors that, when taken into account, indicate that a penalty based on a smaller or larger reduction to the base penalty is appropriate. Since it is impossible to associate potential ranges for reductions or increases with all mitigating and aggravating factors that would appropriately capture every potential combination of facts and circumstances associated with a violation, in this rule BIS is removing from the BIS Penalty Guidelines all specific ranges for

potential reduction. With these revisions, OEE is making clear that the civil monetary penalty will be adjusted (up or down) to reflect the applicable factors for administrative action set forth in the BIS Penalty Guidelines. The factors may result in a penalty amount that is lower or higher than the base penalty amount, depending upon whether they are aggravating or mitigating and how they, in the discretion of OEE, apply in totality in a particular case. As before, aggravating factors will not be used to increase the base penalty beyond the limits established in ECRA.

**C. Revisions to § 764.5 (Voluntary Self-Disclosures)**

*1. Addition of Non-Disclosure as an Aggravating Factor*

Section 764.5 did not previously include as an aggravating factor, the failure of a party to submit a voluntary disclosure. In this final rule, and consistent with the policy outlined in the 2023 Policy Memorandum, BIS revises paragraph (a) of § 764.5 to state that OEE will consider a deliberate decision by a firm (as that term is defined in § 772.1 of the EAR) not to disclose a significant apparent violation to be an aggravating factor when determining what administrative sanctions, if any, will be sought. A deliberate decision not to disclose occurs when a firm uncovers a significant apparent violation that it has committed but then chooses not to file a VSD. This new rule effectively enhances the mitigating effect of voluntary disclosure, particularly in serious cases. For example, under the previous guidelines, if a firm identified a significant apparent violation and chose not to disclose it to OEE, the company was only choosing to forgo the mitigation credit offered under the guidelines. Now, because a deliberate decision not to disclose is an aggravating factor, if a firm chooses not to disclose, it not only forgoes the mitigation credit, but also faces the possibility that BIS will further increase the penalty.

This change also reflects the importance of a firm's deliberate decision not to disclose a significant apparent violation to OEE's assessment of the strength of the company's commitment to compliance. This revision makes clear that OEE will include in its consideration of a firm's commitment to compliance whether the company made a decision not to disclose significant apparent violations. It also reflects that the deliberate non-disclosure of a significant apparent violation may compound the harm to U.S. national security or foreign policy interests by preventing the government from taking steps to mitigate the national security consequences of the violation in a manner that a firm could not. This revision allows OEE to impose penalties—or to charge certain conduct that may have otherwise been treated with a warning letter—in such cases that are appropriate to deter future noncompliance and encourage voluntary disclosure.

*2. Addition of Dual Track Process for Processing VSDs*

Section 764.5 previously had only one process for handling all VSDs, regardless of whether the violation at issue in the VSD was significant, or minor. This final rule revises § 764.5 by adding a new paragraph (c) regarding disclosures involving minor or technical violations. The previous paragraph (c), now paragraph (d), is revised to focus on the portion of the dual-track system that relates to significant violations. Former paragraphs (d) through (f) are redesignated as paragraphs (e) through (g) and are also revised to reflect the dual-track system. The redesignation and changes to these paragraphs are explained below.

New paragraph (c) of § 764.5, titled ''Voluntary Self-Disclosures involving minor or technical violations,'' explains the process for submitting VSDs involving minor or technical violations. Paragraph (c)(1) explains that a minor or technical violation is one that does not include any aggravating factors, as defined in the BIS Penalty Guidelines, and includes several examples. Paragraph (c)(2) provides guidance on submitting an abbreviated narrative for a VSD involving minor or technical violations, including where to submit the abbreviated narrative report and what information to include, and provides that the Director of OEE may require a full narrative report pursuant to new paragraph (d)(3) if OEE suspects that aggravating factors are present. Paragraph (c)(3) authorizes parties to bundle the submission of multiple minor or technical violations into one overarching submission if the violations occurred within the preceding quarter. This change allows for disclosures of minor or technical violations to be bundled into a single VSD submission on a quarterly basis using the abbreviated narrative account process as described elsewhere in this rule. This revision will significantly reduce the workload of companies submitting minor or technical violations.

New paragraph (d), which is now titled ''Voluntary Self-Disclosures involving significant violations,'' explains the process for voluntarily disclosing a significant violation. This paragraph largely retains the language of former paragraph (c) regarding how to submit the disclosure, what to include in the narrative, the types of supporting documentation to include, deadlines regarding submitting information, and the related extension request process. BIS has added the instruction that a significant violation is one that involves one or more of the aggravating factors in the BIS Penalty Guidelines, and that parties who are unsure whether their disclosure involves a minor or technical violation or a significant violation should follow the procedures for disclosing a significant violation.

Former paragraph (d), now paragraph (e) of § 764.5, has been renamed from ''Action by the Office of Export Enforcement'' to ''Dual-track processing of Voluntary Self-Disclosures by the Office of Export Enforcement'' for consistency with the dual-track approach to VSDs. In paragraph (e)(1), BIS explains that OEE will generally resolve VSDs involving minor or technical violations within 60 days, either by informing the submitter that it intends to take no action or by issuing a warning letter. In paragraph (e)(2), BIS explains that for VSDs that indicate significant violations, BIS will conduct an investigation and, as quickly as the facts and circumstances permit, take one of five possible actions. The five potential actions correspond to the possible actions BIS could take under the former paragraph (d).

BIS has made conforming changes throughout these paragraphs to reflect the updated paragraph numbering, as well as minor revisions for clarity. These include consistently using the term ''full narrative'' instead of ''narrative account'' to describe the detailed submission that follows an initial notification when using the process in paragraph (d)(2), adding packing lists to the examples of supporting documentation that may be appropriate to include with a full narrative, and adding contact information for email submissions.

*3. Revisions to Paragraph Regarding Treatment of Unlawfully Exported Items*

Former paragraph (f) is now moved to paragraph (g) to accommodate the addition of new paragraph (c). Consistent with announcements in the 2024 Policy Memorandum, this paragraph has been revised to add a clause explaining that any person (not just the party submitting a VSD) may notify the Director of OEE that a violation has occurred and then request

permission from the Office of Exporter Services to engage in activities described in § 764.2(e) that would otherwise be prohibited. Previously, this paragraph limited such requests for permission to parties who submitted a VSD. This change allows parties in possession of or with an interest in an item involved in a VSD that would otherwise be subject to the prohibitions in § 764.2(e) to submit a request to OEE even if they did not submit a VSD.

BIS also added paragraph (g)(1)(iii), which explains that in order to return to the United States an item that has been unlawfully exported and disclosed under § 764.5, a person is only required to notify the Director of OEE. BIS adds this language to clarify that OEE authorizes the return of any unlawfully exported item to the United States and to reduce the burden on industry and BIS by removing the need for companies to submit and OEE to review such requests for authorization.

This section also adds a new paragraph detailing how to submit requests for authorization and that explains what information is required to process requests, which includes: the nature of the violation including when and how the violations occurred; description, quantity, value in U.S. dollars and Export Control Classification Number (ECCN) or other classification of the items involved; license reference numbers, if applicable; identities and addresses of all individuals and organizations subject to the request; the scope of the request specifying the § 764.2(e) activities, including end-use; and point of contact.

Paragraph (g)(4) regarding authorization for reexports of items subject to a VSD is revised to clarify that such authorization is required for transfers as well. Paragraph (4) is revised to include reference to the notifications provided for in the revisions to the note to paragraph (g)(1)(ii) discussed above. BIS also adds language to this paragraph instructing applicants to include with any request for authorization under this paragraph a copy of the relevant VSD or notification. A new note to paragraph (g)(4) clarifies that a party may submit a request under this section to obtain permission to use a license exception or No License Required (NLR) designation so long as the reexport or transfer at issue otherwise meets the terms and conditions of the relevant license exception or the NLR designation. Finally, this additional paragraph (g) clarifies that Automated Export System (AES) filing errors, where there is no other violation of the EAR, only require notification to OEE under paragraphs (g)(1)(i) and (ii) and do not require additional authorization under this paragraph (g). Paragraph (g) also clarifies that in such cases, a party must correct the AES filing with the Census Bureau before proceeding with activities subject to the EAR, provided the activities meet any EAR requirements. Removing authorization requests related to AES filing errors will save exporter and government resources. If a report includes any other violation, such as failure to obtain a required license, authorization under section 764 is required.

**D. Revisions to the BIS Penalty Guidelines (Supplement No. 1 to Part 766)**

This rule makes several changes to the BIS Penalty Guidelines in supplement no. 1 to part 766 of the EAR, described in greater detail below. These include updates to the statutory references, changes to the penalty calculations and to certain mitigating or aggravating factors, the addition of non-monetary settlements as an action that BIS may take, and the removal of language relating to the application of penalty amounts toward compliance program enhancements.

*1. Updates to Statutory References*

This rule revises the BIS Penalty Guidelines to replace references to outdated statutes. References to the Export Administration Act of 1979 (EAA) are replaced by references to ECRA; additionally, references to the ''Federal Civil Penalties Inflation Adjustment Act of 1990'' (FPIAA 1990) are replaced by the ''Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015'' (FCPIAAIA 2015). These changes are made to reflect BIS's current statutory authorities.

*2. Removal of Applicable Schedule Amounts From the BIS Penalty Guidelines*

Under section I ''Definitions,'' BIS is removing the definition of ''applicable schedule amount'' completely. BIS is also removing the corresponding references in the base penalty matrix and in the explanation of the base penalty calculation in non-egregious cases in section IV.B. This change will make administrative penalties more straightforward and in line with the overall value of the transaction at issue. Previously, these schedule amounts limited the amount of the penalty in situations where they applied. For example, penalties for a transaction valued at $170,000 or more were capped at $250,000. OEE is removing this limitation so that it can impose penalties with sufficient deterrent effect in situations where transaction values are high.

*3. Changes to Section II To Clarify and Expand the Range of Possible OEE Responses to Apparent Violations of the EAR*

a. Addition of Paragraph (II)(C) for the Provision of Non-Monetary Penalties

In the 2022 Policy Memorandum, BIS introduced non-monetary resolutions as a new type of penalty response to resolve enforcement cases that involve non-egregious conduct and that have not resulted in serious national security harm, but remain serious enough to warrant more than a warning letter or no-action letter. Such resolutions require remediation through the imposition of a suspended denial order with certain conditions, such as training and compliance requirements, as appropriate, to mitigate harm from past violations and prevent future ones. Non-monetary resolutions give OEE the flexibility to impose sanctions that require a company to improve its compliance program even when a monetary penalty would not be appropriate or the value of such a penalty would be too low to have a deterrent effect. In this rule, BIS formalizes non-monetary resolutions as an enforcement response by listing it under paragraph (II)(D) of the BIS Penalty Guidelines. The subsequent subparagraphs under section II to supplement no. 1 are renumbered paragraph (II)(E) through new paragraph (II)(H).

b. Removal of Application of Penalty Toward Compliance Enhancements in OEE Consideration of Suspended or Deferred Penalties.

Paragraphs (II)(G) and (II)(H), formerly paragraphs (II)(F) and (II)(G), are revised to remove reference to the practice of allowing a Respondent to apply a portion of a suspended or deferred penalty toward compliance program enhancements. This change reflects BIS's view that companies should independently make appropriate investments in their compliance program sufficient to identify and prevent potential violations, and generally should not expect to receive credit for the cost of making such investments against administrative penalties for past misconduct.

*4. Changes to Section III, ''Factors Affecting Administrative Sanctions''*

BIS also makes several changes to section III regarding aggravating, general, and mitigating factors affecting

administrative sanctions. These changes include revising the foreign policy considerations in paragraph (III)(C)(2) and adding a paragraph (N) under section III. Paragraphs (III)(D) through the new paragraph (III)(N) and their headings and content are changed accordingly and redesignated to accommodate this additional paragraph (N). The revisions, redesignation, and changes to these paragraphs are explained below.

a. Amending Factor C To Include OEE's Consideration of Conduct Enabling Human Rights Abuses

ECRA authorizes BIS to implement export controls ''to carry out the foreign policy of the United States, including the protection of human rights and the promotion of democracy,'' 50 U.S.C. 4811(2)(D). Consistent with this authority, and in line with U.S. foreign policy objectives, BIS is amending Aggravating Factor C, Harm to Regulatory Program Objectives, at Paragraph (III)(C)(2) to include the enabling of human rights abuses as a specific consideration when BIS assesses the potential impact of an apparent violation on U.S. foreign policy objectives.

b. Addition of New Aggravating Factor for Deliberate Failure To Disclose a Significant Apparent Violation

This rule adds a new aggravating factor at paragraph (III)(D), titled ''Failure to disclose a significant apparent violation,'' This new paragraph (III)(D) is added to clarify that OEE will consider a deliberate decision by a firm (as that term is defined in § 772.1 of the EAR) not to disclose a significant apparent violation to be an aggravating factor when determining what administrative sanctions, if any, will be sought. This is consistent with the corresponding change to § 764.5 discussed above. As discussed above, this revision is intended to encourage disclosure by industry when significant apparent violations are uncovered. The text previously found in paragraph (III)(D) is relocated to paragraph (III)(E), and all of the subsequent factors in section III are renumbered through new factor N at paragraph (III)(N).

BIS has made two additional changes for consistency with the addition of this aggravating factor. First, BIS has also deleted the note under ''Concealment'' in Aggravating Factor A, which previously stated that failure to file a VSD does not constitute concealment. Second, BIS has added a sentence under ''Compliance Program'' in new paragraph (F), previously paragraph (E), stating that OEE will consider whether a firm has made a deliberate decision not to voluntarily disclose a significant apparent violation uncovered by its compliance program as part of its consideration of the compliance program under General Factors.

c. Clarifying ''Regulatory History'' and ''Criminal Convictions'' Subfactors Under General Factors

BIS has changed two subfactors to Factor E (previously D), titled ''Individual Characteristics,'' to clarify how it considers the respondent's prior history. First, in subfactor 4, which relates to the respondent's regulatory history, BIS has removed language that previously excluded a respondent's history relating to antiboycott matters from consideration, as well as language that limited BIS's review of prior history to five years preceding the date of the transaction giving rise to the apparent violation. This change was made to focus OEE penalty decisions on the most relevant prior conduct. BIS has also made clarifying revisions, including bringing the information that OEE will consider previous penalties, warning letters, or administrative actions (including settlements)—which was already reflected in the header for this subfactor—into the explanatory text.

Second, subfactor 6 at paragraph (III)(E)(6), ''Criminal Convictions,'' is revised to clarify that, in addition to considering whether a respondent has been convicted or entered a guilty plea as part of a resolution with the Department of Justice, OEE also may consider whether a respondent has entered into any other type of resolution with the Department of Justice or other prosecutorial authorities related to a criminal violation. This change clarifies that OEE will consider resolutions other than a criminal conviction, such as Deferred Prosecution Agreements or Non-Prosecution Agreements, as part of the respondent's criminal history.

d. Clarifying What Constitutes Exceptional Cooperation Under Mitigating Factors

The mitigating factor ''Exceptional Cooperation with OEE,'' previously Factor G, is now renumbered under Factor H at paragraph (III)(H), and continues to list illustrative examples of how OEE evaluates exceptional cooperation. Paragraph (III)(H)(4) under this factor is revised to list an additional consideration regarding whether the Respondent has previously disclosed information regarding the conduct of others that led to an enforcement action by OEE. This change is made to provide an incentive for companies to disclose the wrongful conduct of others.

*5. Changes to Section IV, ''Civil Penalties''*

a. Revisions to Paragraph (IV)(B)(1) To Identify Decision Maker for Egregiousness Determination

The previous paragraph (IV)(B)(1) said simply that ''OEE'' will determine whether a case is considered ''egregious'' under the BIS Penalty Guidelines. BIS has revised this paragraph to specify that the OEE Director will make determinations as to whether a case is deemed egregious for purposes of the base penalty calculation. This determination no longer requires the Assistant Secretary of Commerce for Export Enforcement to give concurrence. The Assistant Secretary is already the signature authority on final orders implementing settlement agreements, so the Assistant Secretary's additional concurrence is unnecessary.

b. Revisions to Paragraph (IV)(B)(2)

The ''Base Penalty Matrix'' under paragraph (IV)(B)(2)(a) and paragraph (IV)(B)(2)(b) are edited as follows: paragraph (IV)(B)(2)(a)(i) provides that in non-egregious VSD cases, the base penalty amount is no longer capped at a maximum of $125,000, but is instead capped at one-half of the transaction value. Paragraph (IV)(B)(2)(a)(ii) provides that, in a non-egregious case not initiated by a VSD, the base penalty amount is no longer based on the applicable schedule amount or capped at $250,000, but is instead capped at the full transaction value. BIS is removing from the base penalty matrix and related text the previously established schedule amounts and penalty caps for non-egregious cases to allow penalties to be calculated based on transactional value instead of progressive brackets that round up. For example, a transaction valued at $100,000 would have a schedule amount of $170,000 under existing guidelines. The penalty cap is removed to recognize that certain transactions are of such high value, that any potential penalty under the cap would not serve as an effective deterrent.

Additionally, in paragraph (IV)(B)(2)(b) ''Adjustment for Applicable Relevant Factors,'' this rule removes references to percentages and reductions that may correspond to certain factors affecting administrative sanctions in a specific case and replaces them with an explanation that the application of the factors, as they apply in combination to a particular case, may result in a penalty

amount that is higher or lower than the base penalty amount. As discussed in the background section above, this change is necessary because the previous guidelines, which assigned percentages to certain factors but not to other factors, reduced OEE's flexibility to impose appropriate penalties that serve as a deterrent and created a misperception that those percentages could not be offset by aggravating factors.

c. Addition of Paragraph (IV)(B)(2)(a)(v) To Clarify Annual Adjustments to Statutory Maximum Penalty

BIS is adding paragraph (IV)(B)(2)(a)(v). This new paragraph describes the applicable statutory maximum civil penalty per violation as established by ECRA, and which is adjusted annually under FCPIAAIA 2015.

**Export Control Reform Act of 2018**

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act (ECRA), 50 U.S.C. 4801–4852. ECRA, as amended, provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

**Rulemaking Requirements**

1. Executive Orders 12866, 13563, and 14094 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects and distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility.

Pursuant to E.O. 12866, this final rule has been determined to not be a significant regulatory action. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. BIS believes that the regulation will reduce the overall burden hours and costs associated with the following information collections. However, the minimal reduction of burden hours falls within the existing estimates currently associated with these control numbers.

- 0694–0088, ''Simplified Network Application Processing System,'' which carries a burden-hour estimate of 29.7 minutes for a manual or electronic submission;
- 0694–0137 ''License Exceptions and Exclusions,'' which carries a burden-hour estimate of 1.5 hours per submission (*Note:* submissions for License Exceptions are rarely required);
- 0694–0096 ''Five Year Records Retention Period,'' which carries a burden-hour estimate of less than 1 minute; and
- 0607–0152 ''Automated Export System (AES) Program,'' which carries a burden-hour estimate of 3 minutes per electronic submission.

Additional information regarding these collections of information—including all background materials—can be found at *https://www.reginfo.gov/public/do/PRAMain* and using the search function to enter either the title of the collection or the OMB Control Number.

3. Pursuant to section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

**List of Subjects in 15 CFR Parts 764 and 766**

Administrative practice and procedure, Confidential business information, Exports, Law enforcement, Penalties.

Accordingly, parts 764 and 766 of the Export Administration Regulations (15 CFR parts 730 to 774) are amended as follows:

## PART 764—ENFORCEMENT AND PROTECTIVE MEASURES

■ 1. The authority citation for part 764 continues to read as follows:

**Authority:** 50 U.S.C. 4801–4852; 50 U.S.C. 4611–4613; 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Section 764.5 is amended by revising paragraphs (a) and (b) through (f) and adding paragraph (g) to read as follows:

**§ 764.5 Voluntary self-disclosure.**

(a) *General policy.* BIS strongly encourages disclosure to the Office of Export Enforcement (OEE) if you believe that you may have violated the EAR, or any order, license or authorization issued thereunder. As described in supplement no. 1 to part 766, voluntary self-disclosure is a mitigating factor, and a firm's deliberate decision not to disclose significant apparent violations is an aggravating factor in determining what administrative sanctions, if any, will be sought by OEE. A deliberate decision not to disclose occurs when a firm uncovers a significant apparent violation that it has committed but then chooses not to file a VSD.

* * * * *

(c) *Voluntary self-disclosures involving minor or technical violations*—(1) *General.* Any person wanting to voluntarily disclose a minor or technical violation should submit an abbreviated narrative report, as described in paragraph (c)(2) of this section. A minor or technical violation is one that does not contain any aggravating factors present as defined in section III(A) of supplement no. 1 to part 766. Examples of minor or technical violations include, but are not limited to, immaterial Electronic Export Information (EEI) filing errors, inadvertent record keeping violations resulting from failed file retrieval or retention mechanisms (*e.g.,* physical damage caused by flood or fire and/or electronic corruption due to malware, virus, or outage), incorrect use of one license exception where other license exceptions were available, etc.

(2) *Abbreviated narrative report.* The abbreviated narrative report should be submitted by email to *bis_vsd_intake@bis.doc.gov* or in writing to the address in paragraph (d)(7) of this section. The email subject line should include the word ''abbreviated'' if it is an abbreviated VSD.:

(i) The notification should include:

(A) The name of the person making the disclosure and should designate a contact person regarding the abbreviated narrative report and provide that contact person's current business street address, email address, and telephone number; and

(B) A description of the general nature and extent of the violations (including, but not limited to, the destination and

parties involved in any transaction, and the number, classification, and value of any items involved). Parties may itemize the various minor or technical violations in list or spreadsheet form.

(ii) The Director of OEE at their discretion may request a full narrative report pursuant to paragraph (d)(3) of this section if OEE suspects the presence of aggravating factors which will be due in 180 days from the date of the OEE Director's request.

(3) *Bundling of minor/technical violations.* Parties may bundle multiple minor or technical violations into one overarching submission, if the violations occurred within the preceding quarter. Parties may submit such minor or technical violations into a single VSD submission on a quarterly basis using the abbreviated narrative account process identified in paragraph (c)(2) of this section.

(d) *Voluntary self-disclosures involving significant violations*—(1) *General.* Any person wanting to voluntarily disclose a significant violation should, in the manner outlined in paragraph (c)(2) of this section, initially notify OEE as soon as possible after violations are discovered, and then conduct a thorough review of all export-related transactions where violations are suspected. A significant violation is one that involves one or more aggravating factors as defined in section III(A) of supplement no. 1 to part 766. Those unsure of whether their possible disclosure relates to a minor or technical violation, or a significant violation, should follow the procedure in paragraph (d)(2) of this section for a significant violation.

(2) *Initial notification*—(i) *Manner and content of initial notification.* The initial notification should be submitted by email to *bis_vsd_intake@bis.doc.gov* or in writing to the address in paragraph (d)(7) of this section. The notification should include the name of the person making the disclosure and a brief description of the suspected violations and should designate a contact person regarding the initial notification and provide that contact person's current business street address, email address, and telephone number. The notification should describe the general nature and extent of the violations. OEE recognizes that there may be situations where it will not be practical to make an initial notification in writing. For example, written notification may not be practical if a shipment leaves the United States without the required license, yet there is still an opportunity to prevent acquisition of the items by unauthorized persons. In such situations, OEE should be contacted promptly at the office listed in paragraph (d)(7) of this section.

(ii) *Initial notification date.* For purposes of calculating when a complete narrative account must be submitted under paragraph (d)(2)(iii) of this section, the initial notification date is the date the notification is received by OEE. OEE will notify the disclosing party in writing of the date that it receives the initial notification. At OEE's discretion, such writing from OEE may be on paper, or in an email message or facsimile transmission from OEE, or by any other method for the transmission of written communications. Where it is not practical to make an initial notification in writing, the person making the notification should confirm the oral notification in writing as soon as possible.

(iii) *Timely completion of narrative accounts.* The full narrative account required by paragraph (d)(3) of this section must be received by OEE within 180 days of the initial notification date for purposes of paragraph (b)(3) of this section, absent an extension from the Director of OEE. If the person making the initial notification subsequently completes and submits to OEE the narrative account required by paragraph (d)(3) of this section such that OEE receives it within 180 days of the initial notification date, or within the additional time, if any, granted by the Director of OEE pursuant to paragraph (d)(2)(iv) of this section, the disclosure, including violations disclosed in the narrative account that were not expressly mentioned in the initial notification, will be deemed to have been made on the initial notification date for purposes of paragraph (b)(3) of this section if the initial notification was made in compliance with paragraphs (d)(1) and (2) of this section. Failure to meet the deadline (either the initial 180-day deadline or an extended deadline granted by the Director of OEE) would not be an additional violation of the EAR, but such failure may reduce or eliminate the mitigating impact of the voluntary disclosure under supplement no. 1 to this part. For purposes of determining whether the deadline has been met under this paragraph, a complete narrative account must contain all of the pertinent information called for in paragraphs (d)(3) through (5) of this section, and the voluntary self-disclosure must otherwise meet the requirements of this section.

(iv) *Deadline extensions.* The Director of OEE may extend the 180-day deadline upon a determination in his or her discretion that U.S. Government interests would be served by an extension or that the person making the initial notification has shown that more than 180 days is reasonably needed to complete the narrative account.

(A) *Conditions for extension.* The Director of OEE in his or her discretion may place conditions on the approval of an extension. For example, the Director of OEE may require that the disclosing person agree to toll the statute of limitations with respect to violations disclosed in the initial notification or discovered during the review for or preparation of the narrative account, and/or require the disclosing person to undertake specified interim remedial compliance measures.

(B) *Contents of request.* (*1*) In most instances 180 days should be adequate to complete the narrative account. Requests to extend the 180-day deadline set forth in paragraph (d)(2)(iii) of this section will be determined by the Director of OEE pursuant to his or her authority under this paragraph (d)(2)(iv) based upon his consideration and evaluation of U.S. Government interests and the facts and circumstances surrounding the request and any related investigations. Such requests should show specifically that the person making the request:

(*i*) Began its review promptly after discovery of the violations;

(*ii*) Has been conducting its review and preparation of the narrative account as expeditiously as can be expected, consistent with the need for completeness and accuracy;

(*iii*) Reasonably needs the requested extension despite having begun its review promptly after discovery of the violations and having conducted its review and preparation of the narrative account as expeditiously as can be expected consistent with the need for completeness and accuracy; and

(*iv*) Has considered whether interim compliance or other corrective measures may be needed and has undertaken such measures as appropriate to prevent recurring or additional violations.

(*2*) Such requests also should set out a proposed timeline for completion and submission of the narrative account that is reasonable under the applicable facts and circumstances and should also designate a contact person regarding the request and provide that contact person's current business street address, email address, and telephone number. Requests may also include additional information that the person making the request reasonably believes is pertinent to the request under the applicable facts and circumstances.

*(C) Timing of requests.* Requests for an extension should be made before the 180-day deadline and as soon as

possible once a disclosing person determines that it will be unable to meet the deadline or the extended deadline where an extension previously has been granted, and possesses the information needed to prepare an extension request in accordance with paragraph (d)(2)(iv)(B) of this section. Requests for extension that are not received before the deadline for completing the narrative account has passed will not be considered. Parties who request an extension shortly before the deadline incur the risk that the Director of OEE will be unable to consider the request, determine whether or not to grant the extension, and communicate his or her decision before the deadline, and that any subsequently submitted narrative account will be considered untimely under paragraph (d)(2)(iii) of this section.

(3) *Full narrative.* After the initial notification, a thorough review should be conducted of export-related transactions where violations with potentially aggravating factors are suspected (as defined in section III(A) of supplement no. 1 to part 766). OEE recommends that the review cover a period of five years prior to the date of the initial notification. If your review goes back less than five years, you risk failing to discover violations that may later become the subject of an investigation. Any violations not voluntarily disclosed do not receive consideration under this section. However, the failure to make such disclosures will not be treated as a separate violation unless some other section of the EAR or other provision of law requires disclosure. Upon completion of the review, OEE should be furnished with a narrative account that sufficiently describes the suspected violations so that their nature and gravity can be assessed. The narrative account should also describe the nature of the review conducted and measures that may have been taken to minimize the likelihood that violations will occur in the future. The narrative account should include:

(i) The kind of violation involved, for example, a shipment without the required license or dealing with a party denied export privileges;

(ii) An explanation of when and how the violations occurred;

(iii) The complete identities and addresses of all individuals and organizations, whether foreign or domestic, involved in the activities giving rise to the violations;

(iv) License numbers;

(v) The description, quantity, value in U.S. dollars and ECCN or other classification of the items involved; and

(vi) A description of any mitigating circumstances.

(4) *Supporting documentation.* (i) The narrative account should be accompanied by copies of documents that explain and support it, including:

(A) Licensing documents such as licenses, license applications, import certificates and end-user statements;

(B) Shipping documents such as Shipper's Export Declarations, air waybills, bills of lading and packing lists; and

(C) Other documents such as letters, facsimiles, telexes and other evidence of written or oral communications, internal memoranda, purchase orders, invoices, letters of credit and brochures.

(ii) Any relevant documents not attached to the narrative account must be retained by the person making the disclosure until OEE requests them, or until a final decision on the disclosed information has been made. After a final decision, the documents should be maintained in accordance with the recordkeeping rules in part 762 of the EAR (15 CFR part 762).

(5) *Certification.* A certification must be submitted stating that all of the representations made in connection with the voluntary self-disclosure are true and correct to the best of that person's knowledge and belief. Certifications made by a corporation or other organization should be signed by an official of the corporation or other organization with the authority to do so. § 764.2(g), relating to false or misleading representations, applies in connection with the disclosure of information under this section.

(6) *Oral presentations.* OEE believes that oral presentations are generally not necessary to augment the written narrative account and supporting documentation. If the person making the disclosure believes otherwise, a request for a meeting should be included with the disclosure.

(7) *Where to make voluntary self-disclosures.* The information constituting a voluntary self-disclosure or any other correspondence pertaining to a voluntary self-disclosure may be submitted by email to *bis_vsd_intake@bis.doc.gov* or mailed to: Director, Office of Export Enforcement, 1401 Constitution Ave., Room H4514, Washington, DC 20230, Tel: (202) 482–5036.

(e) *Dual-track processing of Voluntary Self-Disclosures by the Office of Export Enforcement.* (1) For VSDs that involve minor or technical infractions, including abbreviated VSDs, OEE will generally resolve the VSD within 60 days of a final VSD submission with one of the actions in paragraphs (e)(1)(i) and (ii) of this section.

(i) Inform the person making the disclosure that, based on the facts disclosed, it plans to take no action; or

(ii) Issue a warning letter.

(2) For VSDs that indicate significant violations, OEE will conduct an investigation, and as quickly as the facts and circumstances of a given case permit, OEE may take any of the following actions:

(i) Inform the person making the disclosure that, based on the facts disclosed, it plans to take no action;

(ii) Issue a warning letter;

(iii) Issue a proposed charging letter pursuant to § 766.18 of the EAR and attempt to settle the matter;

(iv) Issue a charging letter pursuant to § 766.3 of the EAR if a settlement is not reached; and/or

(v) Refer the matter to the Department of Justice for criminal prosecution.

(f) *Criteria.* Supplement no. 1 to part 766 describes how BIS typically exercises its discretion regarding whether to pursue an administrative enforcement case under part 766 and what administrative sanctions to seek in settling such a case.

(g) *Treatment of unlawfully exported items.* (1) Any person taking certain actions with knowledge that a violation of ECRA or the EAR has occurred has violated § 764.2(e).

(i) Any person who has made a voluntary self-disclosure knows that a violation may have occurred. Therefore, at the time that a voluntary self-disclosure is made, the person making the disclosure may request permission from BIS to engage in the activities described in § 764.2(e) that would otherwise be prohibited.

(ii) Any person may also notify the Director of OEE that a violation has occurred and request permission from BIS to engage in the activities described in § 764.2(e) that would otherwise be prohibited.

(iii) Actions to return to the United States an item that has been unlawfully exported and disclosed under this section only require notification to the Director of OEE. Items subject to a violation that have been returned to the United States do not require further authorization under this paragraph (g) for future activities, provided that those future activities comply with any applicable EAR requirements.

(2) How to submit a request under paragraphs (g)(1)(i) through (iii) of this section: A request should be submitted on letterhead, signed, and sent to the Director of the Office of Exporter

Services at *emcd@bis.doc.gov* with a copy sent to *bis_vsd_intake@bis.doc.gov.* The request should be specific and detail the following information: nature of the violation including when and how the violations occurred; description, quantity, value in U.S. dollars and ECCN or other classification of the items involved; license numbers, if applicable; identities and addresses of all individuals and organizations subject to the request, the scope of the request specifying the § 764.2(e) activities, including end-use, and point of contact. A copy of the initial or final VSD or notification made to the Director of OEE should be attached to the request.

(3) If a request submitted pursuant to paragraph (g)(1)(i) or (ii) of this section is granted by the Office of Exporter Services in consultation with OEE, future activities with respect to those items that would otherwise violate § 764.2(e) will not constitute violations.

**Note 1 to paragraph (g)(3):** Even if permission is granted, the person making a voluntary self-disclosure pursuant to paragraph (g)(1)(i) of this section is not absolved from liability for any violations disclosed nor relieved of the obligation to obtain any required reexport authorizations.

(4) *Reexports and transfers (in-country).* To reexport or transfer (in-country) items that are the subject of a voluntary self-disclosure or notification, and that have been exported contrary to the provisions of ECRA or the EAR, authorization may be requested from BIS in accordance with the provisions of part 748 of the EAR (15 CFR part 748). If the applicant who submitted the reexport or transfer authorization knows that the items are the subject of a voluntary self-disclosure or notification, the request should state that a voluntary self-disclosure or notification was made in connection with the export of the items for which authorization is sought and a copy of the voluntary self-disclosure or notification should be included with the license application.

**Note 2 to paragraph (g)(4):** If the items are otherwise eligible for reexport or transfer under a license exception or the No License Required (NLR) designation, a request under this paragraph (g) may be submitted to obtain permission for the use of the license exception or NLR designation for such reexport or transfer, provided the transaction otherwise meets the terms and conditions of the license exception or NLR designation.

(5) *Automated Export System (AES) filing errors.* Disclosures and notifications of AES filing errors reported to OEE under paragraphs (g)(1)(i) and (ii) of this section, where no other violation of the EAR only require notification to OEE and do not require authorization under this paragraph (g) to engage in activities subject to the EAR. The AES filing must be corrected with the Census Bureau before proceeding with such activities provided the activities meet any applicable EAR requirements. If another violation, such as failure to obtain a required license, has occurred in addition to the AES filing error, authorization under this paragraph (g) is required.

## PART 766—ADMINISTRATIVE ENFORCEMENT PROCEEDINGS

■ 3. The authority citation for part 766 continues to read as follows:

**Authority:** 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. Supplement no. 1 to part 766 is revised to read as follows:

### Supplement No. 1 to Part 766—Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases

#### Introduction

This supplement describes how the Office of Export Enforcement (OEE) at the Bureau of Industry and Security (BIS) responds to apparent violations of the Export Administration Regulations (EAR) and, specifically, how OEE makes penalty determinations in the settlement of civil administrative enforcement cases under part 764 of the EAR. This guidance does not apply to enforcement cases for violations under part 760 of the EAR—Restrictive Trade Practices or Boycotts. Supplement no. 2 to part 766 continues to apply to civil administrative enforcement cases involving part 760 violations.

Because many administrative enforcement cases are resolved through settlement, the process of settling such cases is integral to the enforcement program. OEE carefully considers each settlement offer in light of the facts and circumstances of the case, relevant precedent, and OEE's objective to achieve in each case an appropriate penalty and deterrent effect. In settlement negotiations, OEE encourages parties to provide, and will give serious consideration to, information and evidence that parties believe are relevant to the application of this guidance to their cases, to whether a violation has in fact occurred, or to whether they have an affirmative defense to potential charges.

This guidance does not confer any right or impose any obligation regarding what penalties OEE may seek in litigating a case or what posture OEE may take toward settling a case. Parties do not have a right to a settlement offer or particular settlement terms from OEE, regardless of settlement positions OEE has taken in other cases.

#### I. Definitions

**Note:** See also: Definitions contained in § 766.2 of the EAR.

*Apparent Violation* means conduct that constitutes an actual or possible violation of the Export Control Reform Act of 2018, the EAR, other statutes administered or enforced by BIS, as well as executive orders, regulations, orders, directives, or licenses issued pursuant thereto.

*Transaction value* means the U.S. dollar value of a subject transaction, as demonstrated by commercial invoices, bills of lading, signed Customs declarations, AES filings or similar documents. Where the transaction value is not otherwise ascertainable, OEE may consider the market value of the items that were the subject of the transaction and/or the economic benefit derived by the Respondent from the transaction, in determining transaction value. In situations involving a lease of U.S.-origin items, the transaction value will generally be the value of the lease. For purposes of these guidelines, ''transaction value'' will not necessarily have the same meaning, nor be applied in the same manner, as that term is used for import valuation purposes at 19 CFR 152.103.

*Voluntary self-disclosure* means the self-initiated notification to OEE of an apparent violation as described in and satisfying the requirements of § 764.5 of the EAR.

#### II. Types of Responses to Apparent Violations

OEE, among other responsibilities, investigates apparent violations of the EAR, or any order, license or authorization issued thereunder. When it appears that such a violation may have occurred, OEE investigations may lead to no action, a warning letter or an administrative enforcement proceeding. A violation may also be referred to the Department of Justice for criminal prosecution. The type of enforcement action initiated by OEE will depend primarily on the nature of the violation. Depending on the facts and circumstances of a particular case, an OEE investigation may lead to one or more of the following actions:

*A. No Action.* If OEE determines that there is insufficient evidence to conclude that a violation has occurred, determines that a violation did not occur and/or, based on an analysis of the Factors outlined in section III of these guidelines, concludes that the conduct does not rise to a level warranting an administrative response, then no action will be taken. In such circumstances, if the investigation was initiated by a voluntary self-disclosure (VSD), OEE will issue a letter (a no-action letter) indicating that the investigation is being closed with no administrative action being taken. OEE may issue a no-action letter in non-voluntarily disclosed cases at its discretion. A no-action determination by OEE represents OEE's disposition of the apparent violation, unless OEE later learns of additional information regarding the same or similar transactions or other relevant facts. A no-action letter is not a final agency action with respect to whether a violation occurred.

*B. Warning Letter.* If OEE determines that a violation may have occurred but a civil penalty is not warranted under the circumstances, and believes that the

underlying conduct could lead to a violation in other circumstances and/or that a Respondent does not appear to be exercising due diligence in assuring compliance with the statutes, executive orders, and regulations that OEE enforces, OEE may issue a warning letter. A warning letter may convey OEE's concerns about the underlying conduct and/or the Respondent's compliance policies, practices, and/or procedures. It may also address an apparent violation of a minor or technical nature, where good faith efforts to comply with the law and cooperate with the investigation are present, or where the investigation commenced as a result of a voluntary self-disclosure satisfying the requirements of § 764.5 of the EAR, provided that no aggravating factors exist. In the exercise of its discretion, OEE may determine in certain instances that issuing a warning letter, instead of bringing an administrative enforcement proceeding, will achieve the appropriate enforcement result. A warning letter will describe the apparent violation and urge compliance. A warning letter represents OEE's enforcement response to and disposition of the apparent violation, unless OEE later learns of additional information concerning the same or similar apparent violations. A warning letter does not constitute a final agency action with respect to whether a violation has occurred.

*C. Administrative enforcement case.* If OEE determines that a violation has occurred and, based on an analysis of the Factors outlined in section III of these guidelines, concludes that the Respondent's conduct warrants a civil monetary penalty or other administrative sanctions, OEE may initiate an administrative enforcement case. The issuance of a charging letter under § 766.3 of the EAR initiates an administrative enforcement proceeding. Charging letters may be issued when there is reason to believe that a violation has occurred. Cases may be settled before or after the issuance of a charging letter. *See* § 766.18 of the EAR. OEE may prepare a proposed charging letter which could result in a case being settled before issuance of an actual charging letter. *See* § 766.18(a) of the EAR. If a case does not settle before issuance of a charging letter and the case proceeds to adjudication, the resulting charging letter may include more violations than alleged in the proposed charging letter, and the civil monetary penalty amounts assessed may be greater that those provided for in section IV of these guidelines. Civil monetary penalty amounts for cases settled before the issuance of a charging letter will be determined as discussed in section IV of these guidelines. A civil monetary penalty may be assessed for each violation. The maximum amount of such a penalty per violation is stated in § 764.3(a)(1), subject to adjustments under Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74, sec. 701), which are codified at 15 CFR 6.4. OEE will afford the Respondent an opportunity to respond to a proposed charging letter. Responses to charging letters following the institution of an enforcement proceeding under part 766 of the EAR are governed by § 766.3 of the EAR.

*D. Non-Monetary Penalty.* OEE may seek a non-monetary penalty if OEE determines the violations are not egregious and have not resulted in serious national security harm, but rise above the level of cases warranting a warning letter or no-action letter. Instead of requiring monetary penalties, such agreements will require remediation through the imposition of a suspended denial order with certain conditions, such as training and compliance requirements, as appropriate, to mitigate harm from past violations and prevent future ones.

*E. Civil Monetary Penalty.* OEE may seek a civil monetary penalty if OEE determines that a violation has occurred and, based on the Factors outlined in section III of these guidelines, concludes that the Respondent's conduct warrants a monetary penalty. Section IV of these guidelines will guide the agency's exercise of its discretion in determining civil monetary penalty amounts.

*F. Criminal Referral.* In appropriate circumstances, OEE may refer the matter to the Department of Justice for criminal prosecution. Apparent violations referred for criminal prosecution also may be subject to a civil monetary penalty and/or other administrative sanctions or action by BIS.

*G. Other Administrative Sanctions or Actions.* In addition to or in lieu of other administrative actions, OEE may seek sanctions listed in § 764.3 of the EAR. BIS may also take the following administrative actions, among other actions, in response to an apparent violation:

*License Revision, Suspension or Revocation.* BIS authorizations to engage in a transaction pursuant to a license or license exception may be revised, suspended or revoked in response to an apparent violation as provided in §§ 740.2(b) and 750.8 of the EAR.

*Denial of Export Privileges.* An order denying a Respondent's export privileges may be issued, as described in § 764.3(a)(2) of the EAR. Such a denial may extend to all export privileges, as set out in the standard terms for denial orders in supplement no. 1 to part 764 of the EAR, or may be narrower in scope (*e.g.,* limited to exports of specified items or to specified destinations or customers). A denial order may also be suspended in whole or in part in accordance with § 766.18(c).

*Exclusion from practice.* Under § 764.3(a)(3) of the EAR, any person acting as an attorney, accountant, consultant, freight forwarder or other person who acts in a representative capacity in any matter before BIS may be excluded from practicing before BIS.

*Training and Audit Requirements.* In appropriate cases, OEE may require as part of a settlement agreement that the Respondent provide training to employees as part of its compliance program, adopt other compliance measures, and/or be subject to internal or independent audits by a qualified outside person.

*H. Suspension or Deferral.* In appropriate cases, payment of a civil monetary penalty may be suspended or deferred during a probationary period under a settlement agreement and order. If the terms of the settlement agreement or order are not adhered to by the Respondent, then suspension or deferral may be revoked and the full amount of the penalty imposed. *See* § 764.3(a)(1)(iii) of the EAR. In determining whether suspension or deferral is appropriate, OEE may consider, for example, whether the Respondent has demonstrated a limited ability to pay a penalty that would be appropriate for such violations, so that suspended or deferred payment can be expected to have sufficient deterrent value, and whether, in light of all of the circumstances, such suspension or deferral is necessary to make the financial impact of the penalty consistent with the impact of penalties on other parties who committed similar violations.

**III. Factors Affecting Administrative Sanctions**

Many apparent violations are isolated occurrences, the result of a good-faith misinterpretation, or involve no more than simple negligence or carelessness. In such instances, absent the presence of aggravating factors, the matter frequently may be addressed with a no action determination letter or, if deemed necessary, a warning letter. In other cases, where the imposition of an administrative penalty is deemed appropriate, OEE will consider some or all of the following Factors in determining the appropriate sanctions in administrative cases, including the appropriate amount of a civil monetary penalty where such a penalty is sought and is imposed as part of a settlement agreement and order. These factors describe circumstances that, in OEE's experience, are commonly relevant to penalty determinations in settled cases. Factors that are considered exclusively aggravating, such as willfulness, or exclusively mitigating, such as situations where remedial measures were taken, are set forth paragraphs II(A) through (D) and (G) through (I). This guidance also identifies General Factors—which can be either mitigating or aggravating—such as the presence or absence of an internal compliance program at the time the apparent violations occurred. Other relevant Factors may also be considered at OEE's discretion.

While some violations of the EAR have a degree of knowledge or intent as an element of the offense, OEE may regard a violation of any provision of the EAR as knowing or willful if the facts and circumstances of the case support that conclusion. For example, evidence that a corporate entity had knowledge at a senior management level may mean that a higher penalty may be appropriate. OEE will also consider, in accordance with supplement no. 3 to part 732 of the EAR (15 CFR part 732), the presence of any red flags that should have alerted the Respondent that a violation was likely to occur. The aggravating factors identified in the Guidelines do not alter or amend § 764.2(e) or the definition of ''knowledge'' in § 772.1, or other provisions of parts 764 and 772 of the EAR (15 CFR parts 764 and 772). If the violations are of such a nature and extent that a monetary fine alone represents an insufficient penalty, a denial or exclusion order may also be imposed to prevent future violations of the EAR.

*Aggravating Factors*

*A. Willful or Reckless Violation of Law.* OEE will consider a Respondent's apparent willfulness or recklessness in violating, attempting to violate, conspiring to violate, or causing a violation of the law. Generally, to the extent the conduct at issue appears to be the result of willful conduct—a deliberate intent to violate, attempt to violate, conspire to violate, or cause a violation of the law—the OEE enforcement response will be stronger. Among the factors OEE may consider in evaluating apparent willfulness or recklessness are:

*1. Willfulness.* Was the conduct at issue the result of a decision to take action with the knowledge that such action would constitute a violation of U.S. law? Did the Respondent know that the underlying conduct constituted, or likely constituted, a violation of U.S. law at the time of the conduct?

*2. Recklessness/gross negligence.* Did the Respondent demonstrate reckless disregard or gross negligence with respect to compliance with U.S. regulatory requirements or otherwise fail to exercise a minimal degree of caution or care in avoiding conduct that led to the apparent violation? Were there warning signs that should have alerted the Respondent that an action or failure to act would lead to an apparent violation?

*3. Concealment.* Was there a deliberate effort by the Respondent to hide or purposely obfuscate its conduct in order to mislead OEE, Federal, State, or foreign regulators, or other parties involved in the conduct, about an apparent violation?

*4. Pattern of Conduct.* Did the apparent violation constitute or result from a pattern or practice of conduct or was it relatively isolated and atypical in nature? In determining both whether to bring charges and, once charges are brought, whether to treat the case as egregious, OEE will be mindful of certain situations where multiple recurring violations resulted from a single inadvertent error, such as misclassification. However, for cases that settle before filing of a charging letter with an Administrative Law Judge, OEE will generally charge only the most serious violation per transaction. If OEE issues a proposed charging letter and subsequently files a charging letter with an Administrative Law Judge because a mutually agreeable settlement cannot be reached, OEE will continue to reserve its authority to proceed with all available charges in the charging letter based on the facts presented. When determining a penalty, each violation is potentially chargeable.

*5. Prior Notice.* Was the Respondent on notice, or should it reasonably have been on notice, that the conduct at issue, or similar conduct, constituted a violation of U.S. law?

*6. Management Involvement.* In cases of entities, at what level within the organization did the willful or reckless conduct occur? Were supervisory or managerial level staff aware, or should they reasonably have been aware, of the willful or reckless conduct?

*B. Awareness of Conduct at Issue: The Respondent's awareness of the conduct giving rise to the apparent violation.* Generally, the greater a Respondent's actual knowledge of, or reason to know about, the conduct constituting an apparent violation, the stronger the OEE enforcement response will be. In the case of a corporation, awareness will focus on supervisory or managerial level staff in the business unit at issue, as well as other senior officers and managers. Among the factors OEE may consider in evaluating the Respondent's awareness of the conduct at issue are:

*1. Actual Knowledge.* Did the Respondent have actual knowledge that the conduct giving rise to an apparent violation took place, and remain willfully blind to such conduct, and fail to take remedial measures to address it? Was the conduct part of a business process, structure or arrangement that was designed or implemented with the intent to prevent or shield the Respondent from having such actual knowledge, or was the conduct part of a business process, structure or arrangement implemented for other legitimate reasons that consequently made it difficult or impossible for the Respondent to have actual knowledge?

*2. Reason to Know.* If the Respondent did not have actual knowledge that the conduct took place, did the Respondent have reason to know, or should the Respondent reasonably have known, based on all readily available information and with the exercise of reasonable due diligence, that the conduct would or might take place?

*3. Management Involvement.* In the case of an entity, was the conduct undertaken with the explicit or implicit knowledge of senior management, or was the conduct undertaken by personnel outside the knowledge of senior management? If the apparent violation was undertaken without the knowledge of senior management, was there oversight intended to detect and prevent violations, or did the lack of knowledge by senior management result from disregard for its responsibility to comply with applicable regulations and laws?

*C. Harm to Regulatory Program Objectives: The actual or potential harm to regulatory program objectives caused by the conduct giving rise to the apparent violation.* This factor is present where the conduct in question, in purpose or effect, substantially implicates national security, foreign policy or other essential interests protected by the U.S. export control system. Among other things, OEE may consider such factors as the reason for controlling the item to the destination in question; the sensitivity of the item; the prohibitions or restrictions against the recipient of the item; and the licensing policy concerning the transaction (such as presumption of approval or denial). OEE, in its discretion, may consult with other U.S. agencies or with licensing and enforcement authorities of other countries in making its determination. Among the factors OEE may consider in evaluating the harm to regulatory program objectives are:

*1. Implications for U.S. National Security: The impact that the apparent violation had or could potentially have on the national security of the United States.* For example, if a particular export could undermine U.S. military superiority or endanger U.S. or friendly military forces or be used in a military application contrary to U.S. interests, OEE would consider the implications of the apparent violation to be significant.

*2. Implications for U.S. Foreign Policy: The effect that the apparent violation had or could potentially have on U.S. foreign policy objectives.* For example, if a particular export is, or is likely to be, used by a foreign regime to monitor communications of its population in order to suppress free speech and persecute dissidents, or otherwise used to enable human rights abuses, OEE would consider the implications of the apparent violation to be significant.

*D. Failure to disclose a significant apparent violation.* If a firm (as that term is defined in § 772.1 of the EAR) deliberately chooses not to disclose a significant apparent violation that it has identified, OEE will consider that non-disclosure to be an aggravating factor when assessing what administrative sanctions, if any, will be sought. A deliberate decision not to disclose occurs when a firm uncovers a significant apparent violation that they have committed but then chooses not to file a VSD.

*General Factors*

*E. Individual Characteristics: The particular circumstances and characteristics of a Respondent.* Among the factors OEE may consider in evaluating individual characteristics are:

*1. Commercial Sophistication: The commercial sophistication and experience of the Respondent.* Is the Respondent an individual or an entity? If an individual, was the conduct constituting the apparent violation for personal or business reasons?

*2. Size and Sophistication of Operations: The size of a Respondent's business operations, where such information is available and relevant.* At the time of the violation, did the Respondent have any previous export experience and was the Respondent familiar with export practices and requirements? Qualification of the Respondent as a small business or organization for the purposes of the Small Business Regulatory Enforcement Fairness Act, as determined by reference to the applicable standards of the Small Business Administration, may also be considered.

*3. Volume and Value of Transactions: The total volume and value of transactions undertaken by the Respondent on an annual basis, with attention given to the volume and value of the apparent violations as compared with the total volume and value of all transactions.* Was the quantity and/or value of the exports high, such that a greater penalty may be necessary to serve as an adequate penalty for the violation or deterrence of future violations, or to make the penalty proportionate to those for otherwise comparable violations involving exports of lower quantity or value?

*4. Regulatory History: The Respondent's regulatory history, including OEE's issuance of prior penalties, warning letters, or other administrative actions (including settlements).* OEE will consider a Respondent's past regulatory history, including OEE's issuance of prior penalties, warning letters, or other administrative actions (including settlements). When an acquiring firm takes reasonable steps to

uncover, correct, and voluntarily disclose or cause the voluntary self-disclosure to OEE of conduct that gave rise to violations by an acquired business before the acquisition, OEE typically will not take such violations into account in applying these factors in settling other violations by the acquiring firm.

*5. Other illegal conduct in connection with the export.* Was the transaction in support of other illegal conduct, for example the export of firearms as part of a drug smuggling operation, or illegal exports in support of intellectual property theft, economic espionage or money laundering?

*6. Criminal Convictions.* Has the Respondent previously been convicted of a criminal violation or otherwise entered into a resolution with the Department of Justice or other prosecutorial authority related to a criminal violation?

**Note:** Where necessary to effective enforcement, the prior involvement in export violation(s) of a Respondent's owners, directors, officers, partners, or other related persons may be imputed to a Respondent in determining whether these criteria are satisfied.

*F. Compliance Program: The existence, nature and adequacy of a Respondent's risk-based BIS compliance program at the time of the apparent violation.* OEE will take account of the extent to which a Respondent complies with the principles set forth in BIS's Export Compliance Guidelines. Information about the Export Compliance Guidelines can be accessed through the BIS website at *http://www.bis.gov/.* OEE will also consider whether a Respondent's export compliance program uncovered a problem, thereby preventing further violations, and whether the Respondent has taken steps to address compliance concerns raised by the violation, to include the submission of a VSD and steps to prevent reoccurrence of the violation that are reasonably calculated to be effective. Conversely, OEE will also consider whether a firm has deliberately failed to voluntarily disclose a significant apparent violation uncovered by a company's export compliance program.

*Mitigating Factors*

*G. Remedial Response.* The Respondent's corrective action taken in response to the apparent violation. Among the factors OEE may consider in evaluating the remedial response are:

1. The steps taken by the Respondent upon learning of the apparent violation. Did the Respondent immediately stop the conduct at issue? Did the Respondent undertake to file a VSD?

2. In the case of an entity, the processes followed to resolve issues related to the apparent violation. Did the Respondent discover necessary information to ascertain the causes and extent of the apparent violation, fully and expeditiously? Was senior management fully informed? If so, when?

3. In the case of an entity, whether it adopted new and more effective internal controls and procedures to prevent the occurrence of similar apparent violations. If the entity did not have a BIS compliance program in place at the time of the apparent violation, did it implement one upon discovery of the apparent violation? If it did have a BIS compliance program, did it take appropriate steps to enhance the program to prevent the recurrence of similar violations? Did the entity provide the individual(s) and/or managers responsible for the apparent violation with additional training, and/or take other appropriate action, to ensure that similar violations do not occur in the future?

4. Where applicable, whether the Respondent undertook a thorough review to identify other apparent violations.

*H. Exceptional Cooperation with OEE: The nature and extent of the Respondent's cooperation with OEE, beyond those actions set forth in Factor F.* Among the factors OEE may consider in evaluating exceptional cooperation are:

1. Did the Respondent provide OEE with all relevant information regarding the apparent violation at issue in a timely, comprehensive and responsive manner (whether or not voluntarily self-disclosed), including, if applicable, overseas records?

2. Did the Respondent research and disclose to OEE relevant information regarding any other apparent violations caused by the same course of conduct?

3. Did the Respondent provide substantial assistance in another OEE investigation of another person who may have violated the EAR?

4. Has the Respondent previously made substantial voluntary efforts to provide information (such as providing tips that led to enforcement actions against other parties) to Federal law enforcement authorities in support of the enforcement of U.S. export control regulations? Has the Respondent previously disclosed information regarding the conduct of others that led to enforcement action by OEE?

5. Did the Respondent enter into a statute of limitations tolling agreement, if requested by OEE (particularly in situations where the apparent violations were not immediately disclosed or discovered by OEE, in particularly complex cases, and in cases in which the Respondent has requested and received additional time to respond to a request for information from OEE)? If so, the Respondent's entering into a tolling agreement may be deemed a mitigating factor.

**Note:** A Respondent's refusal to enter into a tolling agreement will not be considered by OEE as an aggravating factor in assessing a Respondent's cooperation or otherwise under the Guidelines.

*I. License Was Likely To Be Approved.* Would an export license application have likely been approved for the transaction had one been sought? Would the export have qualified for a License Exception? Some license requirements sections in the EAR also set forth a licensing policy (*i.e.,* a statement of the policy under which license applications will be evaluated), such as a general presumption of denial or case by case review. OEE may also consider the licensing history of the specific item to that destination and if the item or end-user has a history of export denials.

*Other Relevant Factors Considered on a Case-by-Case Basis*

*J. Related Violations.* Frequently, a single export transaction can give rise to multiple violations. For example, an exporter who inadvertently misclassifies an item on the Commerce Control List may, as a result of that error, export the item without the required export license and file Electronic Export Information (EEI) to the Automated Export System (AES) that both misstates the applicable Export Control Classification Number (ECCN) and erroneously identifies the export as qualifying for the designation ''NLR'' (no license required) or cites a license exception that is not applicable. In so doing, the exporter commits three violations: one violation of § 764.2(a) of the EAR for the unauthorized export and two violations of § 764.2(g) of the EAR for the two false statements on the EEI filing to the AES. OEE will consider whether the violations stemmed from the same underlying error or omission, and whether they resulted in distinguished or separate harm. OEE generally does not charge multiple violations on a single export, and would not consider the existence of such multiple violations as an aggravating factor in and of itself. It is within OEE's discretion to charge separate violations and settle the case for a penalty that is less than would be appropriate for unrelated violations under otherwise similar circumstances, or to charge fewer violations and pursue settlement in accordance with that charging decision. OEE generally will consider inadvertent, compounded clerical errors as related and not separate infractions when deciding whether to bring charges and in determining if a case is egregious.

*K. Multiple Unrelated Violations.* In cases involving multiple unrelated violations, OEE is more likely to seek a denial of export privileges and/or a greater monetary penalty than OEE would otherwise typically seek. For example, repeated unauthorized exports could warrant a denial order, even if a single export of the same item to the same destination under similar circumstances might warrant just a civil monetary penalty. OEE takes this approach because multiple violations may indicate serious compliance problems and a resulting greater risk of future violations. OEE may consider whether a Respondent has taken effective steps to address compliance concerns in determining whether multiple violations warrant a denial order in a particular case.

*L. Other Enforcement Action.* Other enforcement actions taken by Federal, State, or local agencies against a Respondent for the apparent violation or similar apparent violations, including whether the settlement of alleged violations of BIS regulations is part of a comprehensive settlement with other Federal, State, or local agencies. Where an administrative enforcement matter under the EAR involves conduct giving rise to related criminal or civil charges, OEE may take into account the related violations, and their resolution, in determining what administrative sanctions are appropriate under part 766 of the EAR (15 CFR part 766). A criminal conviction indicates serious, willful misconduct and an accordingly high risk of future violations, absent effective

administrative sanctions. However, entry of a guilty plea can be a sign that a Respondent accepts responsibility for complying with the EAR and will take greater care to do so in the future. In appropriate cases where a Respondent is receiving substantial criminal penalties, OEE may find that sufficient deterrence may be achieved by lesser administrative sanctions than would be appropriate in the absence of criminal penalties. Conversely, OEE might seek greater administrative sanctions in an otherwise similar case where a Respondent is not subjected to criminal penalties. The presence of a related criminal or civil disposition may distinguish settlements among civil penalty cases that appear otherwise to be similar. As a result, the factors set forth for consideration in civil penalty settlements will often be applied differently in the context of a ''global settlement'' of both civil and criminal cases, or multiple civil cases, and may therefore be of limited utility as precedent for future cases, particularly those not involving a global settlement.

*M. Future Compliance/Deterrence Effect.* The impact an administrative enforcement action may have on promoting future compliance with the regulations by a Respondent and similar parties, particularly those in the same industry sector.

*N. Other Factors That OEE Deems Relevant.* On a case-by-case basis, in determining the appropriate enforcement response and/or the amount of any civil monetary penalty, OEE will consider the totality of the circumstances to ensure that its enforcement response is proportionate to the nature of the violation.

## IV. Civil Penalties

*A. Determining What Sanctions Are Appropriate in a Settlement*

OEE will review the facts and circumstances surrounding an apparent violation and apply the Factors Affecting Administrative Sanctions in section III of this supplement in determining the appropriate sanction or sanctions in an administrative case, including the appropriate amount of a civil monetary penalty where such a penalty is sought and imposed. Penalties for settlements reached after the initiation of litigation will usually be higher than those described by these guidelines.

*B. Amount of Civil Penalty*

*1. Determining Whether a Case is Egregious.* In those cases in which a civil monetary penalty is considered appropriate, the OEE Director will make a determination as to whether a case is deemed ''egregious'' for purposes of the base penalty calculation. If a case is determined to be egregious, the OEE Director also will also determine the appropriate base penalty amount within the range of base penalty amounts prescribed in paragraphs IV.B.2.a.iii and iv of this supplement. These determinations will be based on an analysis of the applicable factors. In making these determinations, substantial weight will generally be given to Factors A (''willful or reckless violation of law''), B (''awareness of conduct at issue''), C (''harm to regulatory program objectives''), and D (''individual characteristics''), with particular emphasis on Factors A, B, and C.

A case will be considered an ''egregious case'' where the analysis of the applicable factors, with a focus on Factors A, B, and C, indicates that the case represents a particularly serious violation of the law calling for a strong enforcement response.

*2. Monetary Penalties in Egregious Cases and Non-Egregious Cases.* The civil monetary penalty amount shall generally be calculated as follows, except that neither the base penalty amount nor the penalty amount will exceed the applicable statutory maximum:

*a. Base Category Calculation and Voluntary Self-Disclosures.*

i. In a non-egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base penalty amount shall be up to one-half of the transaction value.

ii. In a non-egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base penalty amount shall be up to the transaction value.

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure, the base penalty amount shall be an amount up to one-half of the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OEE's attention by means other than a voluntary self-disclosure, the base penalty amount shall be an amount up to the statutory maximum penalty applicable to the violation.

v. The applicable statutory maximum civil penalty per violation of the Export Control Reform Act (ECRA) of 2018 is a fine defined in ECRA and adjusted in accordance with U.S. law, *e.g.,* the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74, sec. 701), which in 2024 was $364,992, or an amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed, whichever is greater.

The following matrix represents the base penalty amount of the civil monetary penalty for each category of violation:

BASE PENALTY MATRIX

| Voluntary self-disclosure? | Egregious case? | |
|---|---|---|
| | NO | YES |
| YES | (1) Up to One-Half of the Transaction Value | (3) Up to One-Half of the Applicable Statutory Maximum. |
| NO | (2) Up to the Transaction Value | (4) Up to the Applicable Statutory Maximum. |

*b. Adjustment for Applicable Relevant Factors.* The base penalty amount of the civil monetary penalty will be adjusted to reflect applicable Factors for Administrative Action set forth in section III of these guidelines. The Factors may result in a penalty amount that is lower or higher than the base penalty amount depending upon whether they are aggravating or mitigating and how they, in the discretion of OEE, apply in combination in a particular case.

*C. Settlement Procedures*

The procedures relating to the settlement of administrative enforcement cases are set forth in § 766.18 of the EAR.

**Thea D. Rozman Kendler,**

*Assistant Secretary for Export Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 862

**[Docket No. FDA–2024–N–4058]**

## Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Clozapine Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is