and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 870**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

## PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 870.2380 to subpart C to read as follows:

**§ 870.2380 Cardiovascular machine learning-based notification software.**

(a) *Identification.* Cardiovascular machine learning-based notification software employs machine learning techniques to suggest the likelihood of a cardiovascular disease or condition for further referral or diagnostic follow-up. The software identifies a single condition based on one or more non-invasive physiological inputs as part of routine medical care. It is intended as the basis for further testing and is not intended to provide diagnostic quality output. It is not intended to identify or detect arrhythmias.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be met:

(i) Clinical validation must use a test dataset of real-world data acquired from a representative patient population. Data must be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment. The test dataset must be independent from data used in training/development and contain sufficient numbers of cases from important cohorts (*e.g.,* demographic populations, subsets defined by clinically relevant confounders, comorbidities, and subsets defined by hardware and acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and acquisition systems (*e.g.,* acquisition hardware or preprocessing software). Study protocols must include a description of the adjudication process(es) for determining ground truth of training and test datasets;

(ii) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output over the full range of inputs;

(iii) Performance goals used to determine success of clinical validation must be justified in the context of risks associated with follow-up testing;

(iv) Objective performance measures (*e.g.,* sensitivity, specificity, positive predictive value or negative predictive value) must be reported with relevant descriptive or developmental performance measures. Summary level demographic information and sub-group analyses must be provided for each study site, relevant demographic sub-groups, and acquisition systems; and

(v) The test dataset must include a minimum of three geographically diverse sites, separate from sites used in training of the model.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include:

(i) A description of the model/algorithm, algorithm inputs/outputs, and supported patient population;

(ii) Integration testing in the intended software system or software environment; and

(iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications, including:

(A) A description of input signal/data quality control measures; and

(B) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(3) Human factors assessment of the intended users in the intended use environment must evaluate the risk of misinterpretation of device output.

(4) Labeling must include:

(i) A summary of the performance testing methods, tested hardware, tested/supported patient population, results of the performance testing for tested performance measures/metrics, summary-level descriptions of patient demographics and associated subgroup analyses for training and test datasets, and the expected minimum performance of the device;

(ii) Device limitations or subpopulations for which the device may not perform as expected;

(iii) Warning that the user should not rely on the lack of a suspected finding to rule out follow-up;

(iv) A statement that the device output should not replace a full clinical evaluation of the patient and that the output may not be sufficient as the sole basis for further testing;

(v) Warnings identifying sensor acquisition factors that may impact measurement results;

(vi) Guidance for interpretation of the measurements and typical follow-up testing; and

(vii) The type(s) of hardware sensor data used, including specification of compatible sensors for data acquisition.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–18612 Filed 9–10–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF STATE

### 22 CFR Part 126

**[Public Notice: 13103]**

**RIN 1400–AG34**

### Amendment to the International Traffic in Arms Regulations: Prohibited Exports, Imports, and Sales to or From Certain Countries—Cyprus

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the International Traffic in Arms Regulations to reflect current defense trade policy toward Cyprus.

**DATES:** This rule is effective on October 1, 2026.

**FOR FURTHER INFORMATION CONTACT:** Mr. Damon Smith, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 596–3616; email: *DDTCCustomerService@state.gov.* ATTN: Regulatory Change, ITAR Section 126.1 Cyprus Country Policy Update.

**SUPPLEMENTARY INFORMATION:** The Department of State (the Department) amends section 126.1 of the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) to specify that the Republic of Cyprus' status as a proscribed destination is suspended from October 1, 2026, through September 30, 2027. This action continues the Department's current policy, which originally lifted the arms embargo to the Republic of Cyprus, under section 126.1 of the ITAR, on October 1, 2022.

Specifically, section 1250A(d) of the National Defense Authorization Act for

Fiscal Year 2020 (P.L. 116–92) (2020 NDAA) and section 205(d) of the Eastern Mediterranean Security and Energy Partnership Act of 2019 (P.L. 116–94, Div. J.) (EMSEPA) provide that the policy of denial for exports, reexports, and transfers of defense articles on the United States Munitions List to the Republic of Cyprus shall remain in place unless the President determines and certifies to the appropriate congressional committees not less than annually that: (A) the Government of the Republic of Cyprus is continuing to cooperate with the United States Government in efforts to implement reforms on anti-money laundering regulations and financial regulatory oversight; and (B) the Government of the Republic of Cyprus has made and is continuing to take the steps necessary to deny Russian military vessels access to ports for refueling and servicing.

On April 14, 2020, the President delegated to the Secretary of State the functions and authorities vested by the 2020 NDAA and the EMSEPA (85 FR 35797, June 12, 2020). On July 10, 2026, utilizing these authorities, the Secretary of State certified to the appropriate congressional committees that the Republic of Cyprus meets the statutory requirements to remove the policy of denial for exports, reexports, and transfers of defense articles to the Republic of Cyprus for fiscal year 2027. The Secretary of State further approved the suspension of the policy of denial for exports, reexports, and transfers of defense articles and defense services to the Republic of Cyprus for fiscal year 2027. In conjunction with this action, the Secretary of State also suspended the policy of denial for retransfers and temporary imports destined for or originating in the Republic of Cyprus and brokering activities involving the Republic of Cyprus for fiscal year 2027.

As a result of this certification, certain exemptions to licensing requirements continue to be available for exports, reexports, retransfers, and temporary imports destined for or originating in the Republic of Cyprus and brokering activities involving the Republic of Cyprus, provided the conditions for use of those exemptions are met. Applications for licenses and other authorizations submitted to the Directorate of Defense Trade Controls involving the Republic of Cyprus and nationals of the Republic of Cyprus are subject to case-by-case review.

**Regulatory Analysis and Notices**

*Administrative Procedure Act*

This rulemaking involves a military or foreign affairs function of the United States under 5 U.S.C. 553(a). As the provisions of section 553 do not apply to this rulemaking, the Department is publishing this rule with a specified effective date and without a request for public comment.

*Regulatory Flexibility Act*

This rule is exempt from the notice-and-comment rulemaking provisions of 5 U.S.C. 553, so it does not require analysis under the Regulatory Flexibility Act.

*Unfunded Mandates Reform Act of 1995*

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*Congressional Review Act*

The Office of Information and Regulatory Affairs has determined that this rulemaking is not a major rule under the criteria of 5 U.S.C. 804. This rule will not increase costs or prices and should have no adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. The Department does not expect this rule to have an annual effect on the economy of $100 million or more.

*Executive Orders 12372 and 13132*

This rulemaking will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

*Executive Orders 12866 and 13563*

Executive Orders 12866 and 13563 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, distributed impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Because this rule merely extends a governmental policy that has already been in place for four years and does not impose additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has been designated as a significant regulatory action by the Office of Information and Regulatory Affairs under Executive Order 12866, as amended.

*Executive Order 14192*

This rule is exempt from the requirements of Executive Order 14192 because it relates to a military, national security, or foreign affairs function of the United States.

*Executive Order 12988*

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

*Executive Order 13175*

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

*Paperwork Reduction Act*

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

**List of Subjects in 22 CFR Part 126**

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, title 22, chapter I, subchapter M, part 126 is amended as follows:

## PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for part 126 continues to read as follows:

**Authority:** 22 U.S.C. 287c, 2651a, 2752, 2753, 2776, 2778, 2779, 2779a, 2780, 2791, 2797; sec. 1225, Pub. L. 108–375, 118 Stat. 2091; sec. 7045, Pub. L. 112–74, 125 Stat. 1232; sec. 1250A, Pub. L 116–92, 133 Stat. 1665; sec. 205, Pub. L. 116–94, 133 Stat. 3052; E.O. 13637, 78 FR 16129, 3 CFR, 2013 Comp., p. 223.

■ 2. Amend § 126.1 by revising paragraph (r)(2) to read as follows:

**§ 126.1 Prohibited exports, imports, and sales to or from certain countries.**

* * * * *

(r) * * *

(2) From October 1, 2026, through September 30, 2027, the policy of denial and the status of Cyprus as a proscribed destination is suspended.

* * * * *

**Thomas G. DiNanno,**

*Under Secretary, Arms Control and International Security, Department of State.*

[FR Doc. 2026–18630 Filed 9–10–26; 8:45 am]

**BILLING CODE 4710–25–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### 23 CFR Part 658

**[Docket No. FHWA–2026–0498]**

**RIN 2125–AG31**

## Route Designations—Vehicle Length, Width, and Weight Limitations

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT or Department).

**ACTION:** Final rule.

**SUMMARY:** This final rule makes the following changes to the National Network (NN) in Syracuse, New York: the de-designation of the segment of the NN from Interstate 81 (I–81) between the New York, Susquehanna, and Western Railway bridge and the I–81/I–690 interchange (I–81 Viaduct); and the addition to the NN of the signalized surface urban arterial roadway system (Community Grid) that replaces the I–81 Viaduct and is designated as part of Business Loop 81 (BL 81). The remainder of I–81 between the I–81/I–690 interchange and the I–81/I–481 interchange (Exit 29) will be reclassified as BL 81 and remain on the NN. Interstate 481 (I–481) will be reclassified as I–81 and will remain on the NN. This rule will become effective immediately.

**DATES:** Effective on September 11, 2026.

**FOR FURTHER INFORMATION CONTACT:** For technical questions, contact Mike Latuszek, FHWA Office of Freight Management and Operations, (573) 638–2612, or by email at *Michael.Latuszek@dot.gov.* For legal questions, please contact William Winne, FHWA Office of the Chief Counsel, (202) 366–1397, or by email at *William.Winne@dot.gov.* Business hours for FHWA are from 8:00 a.m. to 4:30 p.m. ET Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

### Electronic Access and Filing

This document may be viewed online through the Federal eRulemaking portal at *www.regulations.gov.* The website is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's website at: *www.federalregister.gov* and the Government Publishing Office's website at: *www.GovInfo.gov.*

### Background

Title 23 of the Code of Federal Regulations (CFR) under § 658.11 provides for changes to the National Network (NN), a network of highways from each State on which certain authorized commercial vehicles are allowed to operate. The New York State Department of Transportation (NYSDOT) has requested FHWA modify the NN in Syracuse, New York.

### National Network

This final rule makes changes to the NN. The NN consists of Interstate System routes (except exempted routes) and those non-Interstate System routes added through the rulemaking process. See 49 United States Code (U.S.C.) 31111(e)–(f) and 31113(e); 23 CFR 658 Appendix A; see also 49 FR 23302 (June 5, 1984). To ensure the NN remains substantially intact, FHWA retains the authority to rule upon all requests for additions to, and deletions from, the NN as well as requests for the imposition of certain restrictions. Pursuant to 23 CFR part 658, specifically § 658.11, requests for modifications to the NN, including justification, must be submitted in writing to the appropriate FHWA Division Office and endorsed by the Governor or the Governor's authorized representative. Proposals for the addition of routes to the NN must also be accompanied by an analysis of suitability based on the criteria in § 658.9. Once a non-Interstate System route is added to the NN, it is included in Appendix A of 23 CFR part 658—National Network-Federally Designated Routes.

On July 6, 2021, FHWA received a request from NYSDOT that proposes a modification to NN. The request proposes the de-designation of the segment of I–81 called the I–81 Viaduct from the NN and the addition of the signalized surface urban arterial roadway system called the Community Grid, which replaces the I–81 Viaduct, to the NN. The segment of I–81 between the I–81/I–481 interchange (Exit 16A) and the I–81/I–481 interchange (Exit 29) and the Community Grid would be reclassified as Business Loop 81 (BL 81) and be on the NN. I–481 would be reclassified as I–81, improved as needed to accommodate traffic demand, and would remain on the NN. In the northbound direction, BL 81 would include the Community Grid, which connects the reconstructed Almond Street to Erie Boulevard, to Pearl Street, and then to an on-ramp for the freeway section continuing to the I–81/I–481 interchange. In the southbound direction, BL 81 begins at the I–81/I–481 interchange and transitions from the freeway section to the Community Grid via an off-ramp to Oswego Boulevard, connects to Erie Boulevard and onto reconstructed Almond Street. I–81 northbound and southbound between the I–81/I–690 interchange and the I–81/I–481 interchange would remain as a freeway on the NN and would be reclassified as part of BL 81.

FHWA is acting on this request pursuant to its regulatory authority over revisions to the Interstate System (23 CFR 470.115(a) and 23 CFR 658.11(d)) and guidance on Interstate System de-designations.[1]

The NYSDOT requests to keep BL 81 on the NN. Pursuant to regulation, because the route would no longer be in the Interstate System, it must be added to NN as a non-Interstate System route and be listed in 23 CFR 658 Appendix A. The NYSDOT proposal also provided the required analysis of suitability based on the criteria in § 658.9, which includes a crash analysis and safety study, and documents the effects on interstate commerce, effects on alternate routes, effects on traffic operations, and consultation with local governments.

FHWA reviewed the NYSDOT's proposal and affirms the request to add BL 81 to the NN is consistent with the 23 U.S.C. 658.9 and 658.11, with respect to the criteria for the NN and the procedures for additions to the NN. FHWA approves the addition of BL 81 to the NN and revises existing regulations (23 CFR 658 Appendix A) to reflect the addition.

As the I–81 Viaduct is already part of the NN due to its Interstate designation,

[1] *https://www.fhwa.dot.gov/planning/national_highway_system/interstate_highway_system/withdrawalqa.cfm.*