control measures are implemented to address device system hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on assay performance.

(v) Final release criteria to be used for manufactured assay lots with appropriate evidence that lots released at the extremes of the specification will meet the identified analytical and clinical performance characteristics as well as stability.

(vi) Stability studies for reagents must include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.

(vii) All stability protocols, including acceptance criteria.

(viii) Detailed documentation of analytical performance studies conducted as appropriate to the technology, specimen types tested, and intended use of the device, including limit of detection (LoD), linearity, precision, endogenous and exogenous interferences, cross-reactivity, carryover, matrix equivalency, sample and reagents stability, and as applicable, upper and lower limits of quantitation (ULoQ and LLoQ, respectively). Samples selected for use must be from subjects with clinically relevant circulating genotypes in the United States. Cross-reactivity studies must include samples from HBV nucleic acid negative subjects with other viral or non-viral causes of liver disease, including autoimmune hepatitis, alcoholic liver disease, chronic hepatitis C virus (HCV), primary biliary cirrhosis, and nonalcoholic steatohepatitis, when applicable. The effect of each identified nucleic-acid isolation and purification procedure on detection must be evaluated.

(ix) For devices with associated software or instrumentation, documentation must include a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, and hazard analysis and risk assessment activities, including an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(x) Detailed documentation of performance from a clinical study with a design and number of clinical samples (appropriately statistically powered) that is appropriate for the intended use of the device as well as conducted in the appropriate settings by the intended users. The samples must include prospective (sequential) samples for each claimed specimen type and, as appropriate, additional characterized clinical samples. Samples must be sourced from geographically diverse areas.

Dated: September 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21932 Filed 9–24–24; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 120 and 121

[Public Notice: 12552; DOS–2024–0023]

RIN 1400–AF29

International Traffic in Arms Regulations: Revisions to Definition and Controls Related to Defense Services; Extension of Comment Period

AGENCY: Department of State.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Department of State is extending the comment period for a proposed rule published July 29, 2024. The original comment period required submission of comments on or before September 27, 2024. In response to requests from the public, the Department extends the comment period through October 15, 2024.

DATES: The comment period for the proposed rule published July 29, 2024, at 89 FR 60980, is extended. Comments should be received on or before October 15, 2024.

ADDRESSES: Interested parties may submit comments by one of the following methods:

- *Email: DDTCPublicComments@state.gov* with the subject line: ''Regulatory Change: Defense Service Definition''.
- *Internet:* At *www.regulations.gov,* search for this notice, by docket number DOS–2024–0023. Additional instructions regarding submission of comments can be found in the document published at 89 FR 60980, July 29, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah Heidema, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–1282; email *DDTCCustomerService@state.gov.* ATTN: Revisions to Definition and Controls Related to Defense Services.

SUPPLEMENTARY INFORMATION: On July 29, 2024, the Department of State published a proposed rule proposing revisions to the definition of defense service at 22 CFR 120.32 of the International Traffic in Arms Regulations (22 CFR parts 120 through 130) and to the United States Munitions List at 22 CFR 121.1 (89 FR 60980). On the same day, the Department of Commerce published a complementary proposed rule proposing changes to existing restrictions under the Export Administration Regulations (15 CFR parts 730 through 744) on military and intelligence end uses and end users and related controls on certain activities of U.S. persons, as well as the proposed addition of a military-support end-user control (89 FR 60985). In response to requests from the public received by the Department of Commerce, and due to their plan to extend the comment period for their complementary proposed rule for 15 more days, as published via separate notice, the Department of State is similarly extending the comment period for its proposed rule for 15 days.

Stanley L. Brown,

Acting Assistant Secretary, Bureau of Political-Military Affairs, Department of State.

[FR Doc. 2024–22041 Filed 9–23–24; 4:15 pm]

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