

U.S.C. 6295(i)(6)(A)–(B)) For the first rulemaking cycle, EPCA directs DOE to initiate a rulemaking process prior to January 1, 2014, to determine whether: (1) To amend energy conservation standards for GSLs and (2) the exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C.

6295(i)(6)(A)(i)) The rulemaking is not limited to incandescent lamp technologies and must include a consideration of a minimum standard of 45 lm/W for GSLs. (42 U.S.C.

6295(i)(6)(A)(ii)) EPCA provides that if the Secretary determines that the standards in effect for GSILs should be amended, a final rule must be published by January 1, 2017, with a compliance date at least 3 years after the date on which the final rule is published. (42 U.S.C. 6295(i)(6)(A)(iii)) The Secretary must also consider phased-in effective dates after considering certain manufacturer and retailer impacts. (42 U.S.C. 6295(i)(6)(A)(iv)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), or if a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a “backstop” under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard. (42 U.S.C. 6295(i)(6)(A)(v)) As a result of DOE’s failure to complete a rulemaking in accordance with the statutory criteria in 42 U.S.C.

6295(i)(6)(A), DOE codified the backstop requirement in the May 2022 Backstop Final Rule. (87 FR 27439, 27442–27443)

As explained in the May 2022 Backstop Final Rule, DOE was delayed in certifying the backstop requirement for GSLs by two years due to its evolving position under the first cycle of GSL rulemaking under 42 U.S.C. 6295(i)(6)(A). This related to DOE’s changing interpretation of whether the statutory backstop had been triggered and, contrary to Soft Lights assertion, had no bearing on whether LEDs were properly classified as GSLs under EPCA. As previously stated, the inclusion of LEDs in the definition of GSL is a clear statutory requirement that is not subject to agency discretion. Further, the 45 lm/W backstop requirement is not technology specific, and DOE is not banning incandescent technology. Thus, while Soft Lights is correct that there are currently no GSILS on the market that can meet the 45 lm/W requirement, this does not foreclose an incandescent from being invented, and sold, in the future that could meet the 45 lm/W requirement. Lastly, even if the 45 lm/

W backstop had not been triggered, the rulemaking that DOE was required to undertake in 42 U.S.C. 6295(i)(6)(A)(i) was to consider standards for GSLs. Congress had already defined GSLs in EPCA as including LEDs and directed that the rulemaking “shall not be limited to incandescent lamp technologies.” (42 U.S.C. 6295(i)(6)(A)(ii)(I)) Thus, DOE had existing statutory authority, aside from the backstop requirement, to establish energy conservation standards for GSLs, which, by statute, include LEDs.

### C. Adverse Health Effects of LEDs

In its petition, Soft Lights asserts that DOE’s review of the health effects of LED lamps was inadequate and negligent. Further, Soft Lights contends that the FDA has sole authority to regulate visible radiation from electronic products and DOE was negligent in mandating the 45 lm/W backstop requirement for GSLs without ensuring that the FDA publishes comfort, health, and safety regulations for LED products. (Soft Lights Petition, No. 1 at p. 2–3, 13, 28) Soft Lights contends that LED lamps pose a danger to public health and LED visible radiation causes serious adverse health effects and creates discriminatory barriers. (Soft Lights Petition, No. 1 at p. 41)

DOE notes that the FDA has authority to regulate certain aspects of LED products as radiation-emitting devices and has issued performance standards for certain types of light-emitting products.<sup>3</sup> Currently, there is no FDA performance standard for LED products in part 1040. DOE acknowledges that Soft Lights expresses in its petition health concerns that Soft Lights associates with LEDs. However, such concerns are not for the consideration of DOE. DOE is not currently aware, nor was it at the time the May 2022 Definition and Backstop Final Rules were issued, of any prohibition on the use of LED lighting that would have impacted its rulemaking.

### III. Denial of Petition

Taking into account all of the factors discussed previously and consistent with the requirements under EPCA, DOE is hereby denying Soft Light’s petition for rulemaking.

### IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final denial of petition for repeal.

<sup>3</sup> See, the Federal Food, Drug and Cosmetic Act section 531 *et seq.*; 21 U.S.C. 360KK; and 21 CFR part 1040.

### Signing Authority

This document of the Department of Energy was signed on March 14, 2023, by Francisco Alejandro Moreno, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 15, 2023.

**Treena V. Garrett,**

*Federal Register Liaison Officer, U.S. Department of Energy.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 91

[Docket No. FAA–2011–0246; Amdt. No. 91–321F]

RIN 2120–AL79

### Prohibition Against Certain Flights in the Territory and Airspace of Libya

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** This action amends, with modifications to reflect changed conditions in the Tripoli Flight Information Region (FIR) (HLLL) and the associated risks to U.S. civil aviation safety, the prohibition against certain flight operations in the Tripoli FIR (HLLL) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. Specifically, with this final rule, the FAA removes the prohibition against U.S. civil aviation operations at altitudes below Flight Level (FL) 300 in

those portions of the Tripoli FIR (HLLL) that are outside the territory and airspace of Libya. The FAA also republishes the approval process and exemption information for this SFAR consistent with other recently published flight prohibition SFARs. The FAA also modifies the title of the relevant section of the Code of Federal Regulations to reflect that the geographic scope of FAA's flight prohibition for U.S. civil aviation is now limited to the territory and airspace of Libya.

**DATES:** This final rule is effective on March 17, 2023.

**FOR FURTHER INFORMATION CONTACT:** Bill Petrak, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267-8166; email [bill.petrak@faa.gov](mailto:bill.petrak@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

This action amends SFAR No. 112, title 14 Code of Federal Regulations (CFR), 91.1603, which currently prohibits certain U.S. civil flight operations in the Tripoli FIR (HLLL)<sup>1</sup> by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. This final rule contains modifications to reflect changed conditions in the Tripoli FIR (HLLL) and the associated risks to U.S. civil aviation safety. Specifically, with this final rule, the FAA removes the prohibition against U.S. civil aviation operations at altitudes below Flight Level (FL) 300 in those portions of the Tripoli FIR (HLLL) that are outside the territory and airspace of Libya. However, the FAA continues to prohibit U.S. civil aviation operations at all altitudes in the territory and airspace of

Libya due to the significant, continuing unacceptable risks to the safety of such operations from various armed groups' access to advanced anti-aircraft weapon systems, airspace de-confliction challenges, and ongoing, intermittent violence in Libya.

The FAA also extends the expiration date of this Special Federal Aviation Regulation (SFAR) from March 20, 2023 until March 20, 2025. Consistent with other recently published flight prohibition SFARs, this action also republishes the approval process and exemption information for this flight prohibition SFAR.

**II. Authority and Good Cause**

*A. Authority*

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. Sections 106(f) and (g) of title 49, U.S. Code (U.S.C.), subtitle I, establish the FAA Administrator's authority to issue rules on aviation safety. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the agency's authority. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise this authority consistently with the obligations of the U.S. Government under international agreements.

The FAA is promulgating this rule under the authority described in 49 U.S.C. 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security.

This regulation is within the scope of the FAA's authority because it continues to prohibit the persons described in paragraph (a) of SFAR No. 112, 14 CFR 91.1603, from conducting flight operations in the territory and airspace of Libya due to the continuing hazards to the safety of U.S. civil flight operations, as described in the preamble to this final rule.

*B. Good Cause for Immediate Adoption*

Section 553(b)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for

rules when the agency for "good cause" finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Also, section 553(d) permits agencies, upon a finding of good cause, to issue rules with an effective date less than 30 days from the date of publication. In this instance, the FAA finds good cause to forgo notice and comment and the delayed effective date because they would be impracticable, unnecessary, and contrary to the public interest.

Providing notice and the opportunity for the public to comment here would be contrary to the public interest. The FAA's flight prohibitions, and any amendments thereto, need to include appropriate boundaries that reflect the agency's current understanding of the risk environment for U.S. civil aviation. This allows the FAA to protect the safety of U.S. operators' aircraft and the lives of their passengers and crews without over-restricting or under-restricting U.S. operators' routing options. However, the risk environment for U.S. civil aviation in airspace managed by other countries with respect to safety of flight is fluid in circumstances involving fighting, extremist and militant activity, or periods of heightened tensions, particularly where weapons capable of targeting or otherwise negatively affecting U.S. civil aviation are or may be present. This fluidity, and the potential for rapid changes in the risks to U.S. civil aviation, significantly limits how far in advance of a new or amended flight prohibition the FAA can usefully assess the risk environment. The delay that would be occasioned by providing an opportunity to comment on this action would significantly increase the risk that the resulting final action would not accurately reflect the current risks to U.S. civil aviation associated with the situation and thus would not establish boundaries for the flight prohibition commensurate with those risks.

While the FAA sought and responded to public comments, the boundaries of the area in which unacceptable risks to the safety of U.S. civil aviation existed might change due to: evolving military or political circumstances; extremist and militant group activity; the introduction, removal, or repositioning of more advanced anti-aircraft weapon systems; or other factors. As a result, if the situation improved while the FAA sought and responded to public comments, the rule the FAA finalized might be over-restrictive, unnecessarily limiting U.S. operators' routing options and potentially causing them to incur unnecessary additional fuel and operations-related costs, as well as

<sup>1</sup> Articles 1 and 2 of the Convention on International Civil Aviation (the "Chicago Convention"), done at Chicago, December 7, 1944, and to which nearly all countries around the world are parties, recognize that every country has complete and exclusive sovereignty of the airspace above its territory, and defines the term "territory," for purposes of the Convention, as "the land areas and territorial waters adjacent thereto under the sovereignty, suzerainty, protection or mandate of such [country]." While there are many potential nuances depending upon local geographic factors, in most cases, the territorial sea of a country extends 12 nautical miles from the coastal baselines of that country drawn in accordance with international law. The Tripoli FIR (HLLL) includes the entire territory and airspace of Libya, and extends north into international airspace above the Gulf of Sidra. It also extends south into a portion of the territory and airspace of Chad.

potentially causing passengers to incur unnecessarily some costs attributed to their time. Conversely, if the situation deteriorated while the FAA sought and responded to public comments, the rule the FAA finalized might be under-restrictive, allowing U.S. civil aviation to continue operating in areas where unacceptable risks to their safety had developed. Such an outcome would endanger the safety of these aircraft, as well as their passengers and crews, exposing them to unacceptable risks of death, injury, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the territory and airspace of Libya.

Alternatively, if the FAA made changes to the area in which U.S. civil aviation operations would be prohibited between a notice of proposed rulemaking and a final rule due to changed conditions, the version of the rule the public commented on would no longer reflect the FAA's current assessment of the risk environment for U.S. civil aviation. In addition, some or all of the rationale for such changes during the course of the rulemaking might be based upon classified information or controlled unclassified information not authorized for public release. The FAA's ability to notify the public of its reasoning and respond to comments would necessarily be limited—thus rendering such proceedings impracticable, unnecessary, and contrary to the public interest.

Therefore, providing notice and the opportunity for comment would be contrary to the public interest, as it would hinder FAA's ability to maintain appropriate flight prohibitions based on up-to-date risk assessments of the risks to the safety of U.S. civil aviation operations in airspace managed by other countries.

For the same reasons discussed above, the potential safety impacts and the need for prompt action on up-to-date information that is not public would make delaying the effective date impracticable and contrary to the public interest. For altitudes at or below FL300 in those portions of the Tripoli FIR (HLLL) that are outside the territory and airspace of Libya, any delay in the effective date of the rule would continue a prohibition on U.S. civil aviation operations at those altitudes that the FAA has determined is no longer needed for the safety of U.S. civil aviation and would thus unnecessarily restrict U.S. operators' routing options at those altitudes.

Accordingly, the FAA finds good cause exists to forgo notice and

comment and any delay in the effective date for this rule.

### III. Background

On July 27, 2020, the FAA published a final rule in the **Federal Register** prohibiting U.S. civil flight operations in the entirety of the territory and airspace of Libya. That rule also prohibited U.S. civil flight operations in those portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya at altitudes below FL300.<sup>2</sup> The FAA assessed the area of unacceptable inadvertent risk to U.S. civil aviation operations at all altitudes had spread to the entire territory and airspace of Libya. This spread was due to the geographic expansion of the ongoing conflict between the Tripoli-based Government of National Accord (GNA) and the Tobruk-based Libyan National Army (LNA) for control over Libya's government, territory, and resources.

Foreign state actors continued to provide material and technical assistance to both the GNA and the LNA. This support involved third party forces, as well as the deployment of advanced weapons, including advanced fighter aircraft, weaponized unmanned aircraft systems (UAS), surface-to-air missile (SAM) systems, and, likely, jammers. Both sides had conducted air strikes, utilizing tactical combat aircraft and long-range, armed UAS, to target airport infrastructure and aircraft on the ground at airports. In May 2020, Russia deployed multiple fighter aircraft to Libya to provide close air support to its private military contractors and the LNA and protect their operations from attacks by manned aircraft and weaponized UAS. The foreign states supporting the LNA and GNA also deployed anti-aircraft weapons and self-protection jamming systems to mitigate the air threat. The combination of these activities posed airspace de-confliction concerns and an inadvertent risk of in-flight engagement of civil aircraft as a result of possible misidentification or miscalculation.

More advanced, higher-altitude air defense systems had also been deployed to Libya. In addition to an SA-22 SAM system, a foreign sponsor associated with the GNA had reportedly deployed multiple variants of anti-aircraft weapons to provide a layered air defense in Tripoli. This deployment included a medium range I-Hawk SAM and a Korkut 35mm air defense gun.

The activities of the GNA and the LNA also presented risks to U.S. civil

aviation in the territory and airspace of Libya. Both the GNA and the LNA possessed anti-aircraft artillery and MANPADS, some of which have a maximum altitude of up to 25,000 feet (7,620 meters). As a result of weapons activity posing a risk to civil aviation, the GNA closed Mitiga International Airport (HLLM) on multiple occasions during January and February 2020. LNA leader General Haftar announced on January 23, 2020, that LNA forces would engage any military or civil aircraft operating from Mitiga International Airport (HLLM). The FAA was also concerned the GNA and the LNA might augment their air defense operations with increased Global Positioning System (GPS) and radio frequency jamming.

Collectively, the FAA assessed that the escalating fighting, increased foreign intervention, and deployment of additional air defense capabilities presented an increasing risk to U.S. civil aviation operations in the territory and airspace of Libya at all altitudes. For these reasons, the July 27, 2020 final rule incorporated the flight prohibition on U.S. civil aviation operations in the territory and airspace of Libya at all altitudes, previously contained in NOTAM KICZ A0026/19, into SFAR No. 112, § 91.1603.

In addition, the FAA assessed that the hazards to the safety of U.S. civil aviation operations at altitudes below FL 300 described in the preamble to the March 2019 final rule remained of concern in those portions of the Tripoli FIR (HLLL) that are outside the territory and airspace of Libya.<sup>3</sup> The FAA noted that foreign military manned and unmanned tactical aircraft might operate or approach targets from off the northern coast, presenting airspace de-confliction challenges at altitudes below FL300. Additionally, there was the potential for GPS interference bleed over that might impact flights operating over the southern Mediterranean Sea in the Tripoli FIR (HLLL). For these reasons, the July 27, 2020 final rule also continued the prohibition against all flights by U.S. civil operators and airmen at altitudes below FL300 in those portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya.<sup>4</sup>

<sup>3</sup> *Amendment of the Prohibition Against Certain Flights in the Tripoli Flight Information Region (FIR) (HLLL) final rule*, 84 FR at 9952–9953 (Mar. 19, 2019).

<sup>4</sup> For all of the reasons described in the preamble to the July 27, 2020 final rule, the FAA also extended the expiration date of SFAR No. 112, § 91.1603, until March 20, 2023. See *Prohibition Against Certain Flights in the Tripoli Flight*

<sup>2</sup> *Prohibition Against Certain Flights in the Tripoli Flight Information Region (FIR) (HLLL) final rule*, 85 FR 45084 (Jul. 27, 2020).

#### IV. Discussion of the Final Rule

The FAA continues to assess the situation in the territory and airspace of Libya as hazardous for U.S. civil aviation. Representatives of the Libyan Army of the GNA and the LNA General Command of the Armed Forces signed a United Nations-backed ceasefire agreement on October 23, 2020. Among other things, the October 23, 2020 ceasefire provided for: an immediate ceasefire, effective upon signature of the agreement; the departure of all mercenaries and foreign fighters from Libya, including its land, air, and sea territory, within three months; and the suspension of all military training agreements and departure of all training crews until a new unified government assumed its functions.

Since the October 23, 2020 ceasefire agreement, combat operations in Libya have significantly decreased, with only intermittent ground clashes between opposing factions. In addition, Russian-backed Wagner Group (also referred to as private military company (PMC) Wagner) has reduced the number of its air defense systems and forces deployed in Libya, with more than 1,300 Wagner personnel having departed the country. However, protests and intermittent clashes between the various armed factions in Libya continue. Unrest in the capital, in particular, has been driven by militia infighting and multiple failed attempts by the Government of National Stability (GNS) to enter Tripoli, and has contributed to the lack of progress on key milestones set forth in the ceasefire agreement. In particular, the provisions of the ceasefire agreement relating to departure of all mercenaries and foreign fighters from Libya and the suspension of all military training agreements and departure of all training crews until the Government of National Unity (GNU) assumed its functions have not been fully implemented. In June and August 2022, the GNS attempted to enter Tripoli to seize control of government offices and were met with protests and violence, including armed clashes that resulted in the temporary suspension of flight operations at Mitiga International Airport (HLLM).

Airspace de-confliction challenges also remain a safety-of-flight concern in the territory and airspace of Libya. Various armed groups operating in Libya continue to have access to advanced anti-aircraft weapons systems. These groups likely lack comprehensive airspace awareness sufficient to enable effective aircraft identification and de-confliction of civil and military flights.

These circumstances create the potential for localized operational control and use of anti-aircraft systems, rather than a coordinated air defense command and control structure, posing an enduring inadvertent risk to civil aviation operations in the territory and airspace of Libya. Forces aligned with GNA and LNA can quickly increase force protection measures, such as GPS jamming, air strikes, and the deployment of SAM systems capable of reaching as high as 49,000 feet. In addition to foreign-operated air defense capabilities, both GNA and LNA forces have access to anti-aircraft artillery and advanced MANPADS, some of which have a maximum altitude of 25,000 feet.

On August 22, 2022, LNA air defense forces claimed to have shot down a U.S. MQ-9 UAS operating in the vicinity of Benghazi during a period of increased tensions and threats of renewed violence between competing militias vying for control of Tripoli. The MQ-9 was operating in support of diplomatic engagements, and the operator had conducted pre-mission coordination with Libyan authorities. While this incident involved a military UAS, it is illustrative of the potential for inadequate aircraft identification and de-confliction procedures leading to an inadvertent shoot down, resulting in significant casualties, and loss of an aircraft, if a civil aircraft carrying passengers were mistakenly engaged.

In addition, despite a reduction in foreign presence, tensions in Libya remain elevated, and warring factions in Libya and their affiliated foreign sponsors maintain access to advanced weapons. Tensions over the implementation of a unity government spiked violently in March, June, and August 2022 in conjunction with GNU attempts to enter Tripoli and assume control of national government functions. The ensuing clashes between Libya's various armed factions included small arms and indirect fire exchanges, causing temporary disruptions to airport operations in the capital region. Within their respective strongholds in various areas of the country, Libya's armed factions have either gained access to, or have foreign sponsors equipped with, tactical aircraft, long-range weaponized UAS, air defense systems, and GPS jammers. Given the current tenuous security environment in Libya, the FAA remains concerned about the continued risk of rapid escalation involving these systems during spikes in tensions, which would pose safety-of-flight risks to U.S. civil aviation outside the capital region.

As a result of the significant, continuing unacceptable risks to the

safety of U.S. civil aviation operations at all altitudes in the territory and airspace of Libya, the FAA maintains the prohibition on U.S. civil aviation operations at all altitudes in the territory and airspace of Libya and extends the expiration date of SFAR No. 112, 14 CFR 91.1603, from March 20, 2023, until March 20, 2025. Further amendments to SFAR No. 112, 14 CFR 91.1603, might be appropriate if the risk to U.S. civil aviation safety and security changes. In this regard, the FAA will continue to monitor the situation and evaluate the extent to which persons described in paragraph (a) of this rule might be able to operate safely in the territory and airspace of Libya.

The FAA assesses the risk to U.S. civil aviation operations in the portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya at altitudes below FL300 has diminished and the situation has stabilized sufficiently to permit U.S. civil aviation operations to resume in that airspace. Since the October 2020 ceasefire agreement, foreign actors have significantly reduced weapons shipments and military activities off the coast of Libya. Previously, these activities included targeting suspected weapons shipments destined for the opposing side or their foreign sponsors. As a result, the risk of either side or their foreign sponsors misidentifying civil aircraft operations in the overwater portion of the Tripoli FIR as carrying weapons shipments destined for the other side or their foreign sponsors and mistakenly targeting them has diminished. The reduction of widespread conflict has also reduced the risk to U.S. civil aviation operations in the small portion of the Tripoli FIR (HLLL) that extends into Chad's territorial airspace. Therefore, due to the diminished risks to the safety of U.S. civil aviation operations and stabilized situation in those portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya, the FAA amends SFAR No. 112, 14 CFR 91.1603, to remove the prohibition on U.S. civil aviation operations in those areas.

The FAA republishes the details concerning the approval and exemption processes in Sections V and VI of this preamble, consistent with other recently published flight prohibition SFARs to enable interested persons to refer to this final rule for comprehensive information about requesting relief from the FAA from the provisions of SFAR No. 112, § 91.1603. The FAA also modifies the heading of SFAR No. 112, 14 CFR 91.1603, in the CFR, to reflect the change in the geographic scope of the FAA's flight prohibition for U.S.

civil aviation, which is now limited to the territory and airspace of Libya.

#### V. Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

##### A. Approval Process Based on an Authorization Request From a Department, Agency, or Instrumentality of the United States Government

In some instances, U.S. Government departments, agencies, or instrumentalities may need to engage U.S. civil aviation to support their activities in the territory and airspace of Libya. If a department, agency, or instrumentality of the U.S. Government determines that it has a critical need to engage any person described in paragraph (a) of SFAR No. 112, 14 CFR 91.1603, including a U.S. air carrier or commercial operator, to transport civilian or military passengers or cargo or conduct other operations in the territory and airspace of Libya, that department, agency, or instrumentality may request the FAA to approve persons described in paragraph (a) of SFAR No. 112, 14 CFR 91.1603, to conduct such operations.

The requesting U.S. Government department, agency, or instrumentality must submit the request for approval to the FAA's Associate Administrator for Aviation Safety in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality.<sup>5</sup> The FAA will not accept or consider requests for approval from anyone other than the requesting U.S. Government department, agency, or instrumentality. In addition, the senior official signing the letter requesting FAA approval must be sufficiently positioned within the requesting department, agency, or instrumentality to demonstrate that the organization's senior leadership supports the request for approval and is committed to taking all necessary steps to minimize aviation safety and security risks to the proposed flights. The senior official must also be in a position to: (1) attest to the accuracy of all representations made to the FAA in the request for approval, and (2) ensure that any support from the requesting U.S. Government department, agency, or instrumentality

<sup>5</sup> This approval procedure applies to U.S. Government departments, agencies, or instrumentalities; it does not apply to the public. The FAA describes this procedure in the interest of providing transparency with respect to the FAA's process for interacting with U.S. Government departments, agencies, or instrumentalities that seek to engage U.S. civil aviation to operate in the area in which this SFAR would prohibit their operations in the absence of specific FAA approval.

described in the request for approval is in fact brought to bear and is maintained over time. Unless justified by exigent circumstances, requesting U.S. Government departments, agencies, or instrumentalities must submit requests for approval to the FAA no less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the operator(s) to commence the proposed operation(s).

The requestor must send the request to the Associate Administrator for Aviation Safety, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Electronic submissions are acceptable, and the requesting entity may request that the FAA notify it electronically as to whether the FAA grants the request for approval. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Air Transportation Division, Flight Standards Service, at (202) 267-8166, to obtain the appropriate email address. A single letter may request approval from the FAA for multiple persons described in SFAR No. 112, 14 CFR 91.1603, or for multiple flight operations. To the extent known, the letter must identify the person(s) the requestor expects the SFAR to cover on whose behalf the U.S. Government department, agency, or instrumentality seeks FAA approval, and it must describe—

- The proposed operation(s), including the nature of the mission being supported;
- The service the person(s) covered by the SFAR will provide;
- To the extent known, the specific locations in the territory and airspace of Libya where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the territory and airspace of Libya and the airports, airfields, or landing zones at which the aircraft will take off and land; and
- The method by which the requesting department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of the proposed operations (*i.e.*, the pre-mission planning and briefing, in-flight, and post-flight phases).

The request for approval must also include a list of operators with whom the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or its prime contractor has a subcontract(s)) for specific flight

operations in the territory and airspace of Libya. The requestor may identify additional operators to the FAA at any time after the FAA issues its approval. Neither the operators listed in the original request, nor any operators the requestor subsequently seeks to add to the approval, may commence operations under the approval until the FAA issues them an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, for operations in the territory and airspace of Libya. The approval conditions discussed below apply to all operators. Requestors should send updated lists to the email address they obtained from the Air Transportation Division by calling (202) 267-8166.

If an approval request includes classified information or controlled unclassified material not authorized for public release, requestors may contact Aviation Safety Inspector Bill Petrak for instructions on submitting it to the FAA. His contact information appears in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

FAA approval of an operation under SFAR No. 112, 14 CFR 91.1603, does not relieve persons subject to this SFAR of the responsibility to comply with all other applicable FAA rules and regulations. Operators of civil aircraft must comply with the conditions of their certificates, OpSpecs, and LOAs, as applicable. Operators must also comply with all rules and regulations of other U.S. Government departments, agencies, or instrumentalities that may apply to the proposed operation(s), including, but not limited to, regulations issued by the Transportation Security Administration.

##### B. Approval Conditions

If the FAA approves the request, the FAA's Aviation Safety organization will send an approval letter to the requesting U.S. Government department, agency, or instrumentality informing it that the FAA's approval is subject to all of the following conditions:

(1) The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator, while still allowing the operator to achieve its operational objectives.

(2) Before any approval takes effect, the operator must submit to the FAA:

(a) A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the territory and airspace of Libya; and

(b) The operator's written agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the territory and airspace of Libya.

(3) Other conditions the FAA may specify, including those the FAA might impose in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy the FAA issues under chapter 443 of title 49, U.S. Code.

If the FAA approves the proposed operation(s), the FAA will issue an OpSpec or LOA, as applicable, to the operator(s) identified in the original request and any operators the requestor subsequently adds to the approval, authorizing them to conduct the approved operation(s). In addition, as stated in paragraph (3) of this section V.B., the FAA notes that it may include additional conditions beyond those contained in the approval letter in any OpSpec or LOA associated with a particular operator operating under this approval, as necessary in the interests of aviation safety. U.S. Government departments, agencies, and instrumentalities requesting FAA approval on behalf of entities with which they have a contract or subcontract, grant, or cooperative agreement should request a copy of the relevant OpSpec or LOA directly from the entity with which they have any of the foregoing types of arrangements, if desired.

## VI. Information Regarding Petitions for Exemption

Any operations not conducted under an approval the FAA issues through the approval process set forth previously may only occur in accordance with an exemption from SFAR No. 112, 14 CFR 91.1603. A petition for exemption must comply with 14 CFR part 11. The FAA will consider whether exceptional circumstances exist beyond those described in the approval process in the previous section. To determine whether a petition for exemption from the prohibition this SFAR establishes fulfills the standards described in 14 CFR 11.81, the FAA consistently finds necessary the following information:

- The proposed operation(s), including the nature of the operation;
- The service the person(s) covered by the SFAR will provide;

- The specific locations in the territory and airspace of Libya where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the territory and airspace of Libya and the airports, airfields, or landing zones at which the aircraft will take off and land;

- The method by which the operator will obtain current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*i.e.*, the pre-mission planning and briefing, in-flight, and post-flight phases); and
- The plans and procedures the operator will use to minimize the risks identified in this preamble to the proposed operations, to support the relief sought and demonstrate that granting such relief would not adversely affect safety or would provide a level of safety at least equal to that provided by this SFAR. The FAA has found comprehensive, organized plans and procedures of this nature to be helpful in facilitating the agency's safety evaluation of petitions for exemption from flight prohibition SFARs.

The FAA includes, as a condition of each such exemption it issues, a release and agreement to indemnify, as described previously.

The FAA recognizes that, with the support of the U.S. Government, the governments of other countries could plan operations that may be affected by SFAR No. 112, 14 CFR 91.1603. While the FAA will not permit these operations through the approval process, the FAA will consider exemption requests for such operations on an expedited basis and in accordance with the order of preference set forth in paragraph (c) of SFAR No. 112, 14 CFR 91.1603.

If a petition for exemption includes information that is sensitive for security reasons or proprietary information, requestors may contact Aviation Safety Inspector Bill Petrak for instructions on submitting it to the FAA. His contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

## VII. Severability

Congress authorized the FAA by statute to promote safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce and national security. 49 U.S.C. 44701. Consistent with that mandate, the FAA is prohibiting certain persons from conducting flight

operations in the territory and airspace of Libya due to the continuing hazards to the safety of U.S. civil flight operations. The purpose of this rule is to operate holistically in addressing a range of hazards and needs in the territory and airspace of Libya. However, the FAA recognizes that certain provisions focus on unique factors. Therefore, the FAA finds that the various provisions of this final rule are severable and able to operate functionally if severed from each other. In the event a court were to invalidate one or more of this final rule's unique provisions, the remaining provisions should stand, thus allowing the FAA to continue to fulfill its Congressionally authorized role of promoting safe flight of civil aircraft in air commerce.

## VIII. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354), as codified in 5 U.S.C. 603 *et seq.*, requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96-39), as codified in 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined this final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive order. As 5 U.S.C. 553 does

not require notice and comment for this final rule, 5 U.S.C. 603 and 604 do not require regulatory flexibility analyses regarding impacts on small entities. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

#### A. Regulatory Evaluation

This action amends, with modifications to reflect changed conditions in the Tripoli FIR (HLLL) and the associated risks to U.S. civil aviation safety, the SFAR prohibiting certain U.S. civil flight operations in the Tripoli FIR (HLLL). This action also extends the expiration date of the SFAR for an additional two years. As a result of this rule, U.S. civil operators and airmen may operate in those portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya at all altitudes, instead of being limited to conducting flight operations in those portions of the Tripoli FIR (HLLL) outside the territory and airspace of Libya at altitudes at or above FL300. U.S. civil aviation operations in the territory and airspace of Libya remain prohibited at all altitudes.

The alternative flight routes result in some additional fuel and operations costs to the operators, as well as some costs attributed to passenger time. Accordingly, the incremental costs of the amendment of this flight prohibition SFAR are minimal. By prohibiting unsafe flights, the benefits of this rule will exceed the minimal flight deviation costs. Therefore, the FAA finds that the incremental costs of amending and extending SFAR No. 112, 14 CFR 91.1603, will be minimal and are exceeded by the benefits of avoided risks of deaths, injuries, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the territory and airspace of Libya.

#### B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever 5 U.S.C. 553 or any other law requires an agency to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after that section or any other law requires publication of a general notice of proposed rulemaking.

The FAA concludes good cause exists to forgo notice and comment and to not delay the effective date for this rule. As 5 U.S.C. 553 does not require notice and comment in this situation, 5 U.S.C. 603 and 604 similarly do not require regulatory flexibility analyses.

#### C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from risks to their operations in the territory and airspace of Libya, a location outside the U.S. Therefore, the rule complies with the Trade Agreements Act of 1979.

#### D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of \$155 million in lieu of \$100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

#### E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA to consider the impact of paperwork and other information collection burdens it imposes on the public. The FAA has determined no new requirement for information collection is associated with this final rule.

#### F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, the FAA's policy is to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined no ICAO Standards and Recommended Practices correspond to this regulation. The FAA finds this action is fully consistent with the obligations under 49 U.S.C. 40105(b)(1)(A) to ensure the FAA exercises its duties consistently with the obligations of the United States under international agreements.

While the FAA's flight prohibition does not apply to foreign air carriers, DOT codeshare authorizations prohibit foreign air carriers from carrying a U.S. codeshare partner's code on a flight segment that operates in airspace for which the FAA has issued a flight prohibition for U.S. civil aviation. In addition, foreign air carriers and other foreign operators may choose to avoid, or be advised or directed by their civil aviation authorities to avoid, airspace for which the FAA has issued a flight prohibition for U.S. civil aviation.

#### G. Environmental Analysis

The FAA has analyzed this action under Executive Order 12114, Environmental Effects Abroad of Major Federal Actions, and DOT Order 5610.1C, Paragraph 16. Executive Order 12114 requires the FAA to be informed of environmental considerations and take those considerations into account when making decisions on major Federal actions that could have environmental impacts anywhere beyond the borders of the United States. The FAA has determined this action is exempt pursuant to Section 2–5(a)(i) of Executive Order 12114 because it does not have the potential for a significant effect on the environment outside the United States.

The FAA has determined that this action will not have a significant environmental effect abroad. In accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 8–6(c), the FAA has prepared a memorandum for the record stating the reason(s) for this determination and has placed it in the docket for this rulemaking.

### IX. Executive Order Determinations

#### A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132. The agency has

determined this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

*B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use*

The FAA analyzed this rule under Executive Order 13211. The agency has determined it is not a “significant energy action” under the executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

*C. Executive Order 13609, Promoting International Regulatory Cooperation*

Executive Order 13609 promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

**X. Additional Information**

*A. Electronic Access*

Except for classified and controlled unclassified material not authorized for public release, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

Those documents may be viewed online at <https://www.regulations.gov> using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s website at <https://www.federalregister.gov> and the Government Publishing Office’s website at <https://www.govinfo.gov>. A copy may also be found at the FAA’s Regulations and Policies website at [https://www.faa.gov/regulations\\_policies](https://www.faa.gov/regulations_policies).

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence

Avenue SW, Washington, DC 20591, or by calling (202) 267-9677. Commenters must identify the docket or notice number of this rulemaking.

*B. Small Business Regulatory Enforcement Fairness Act*

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the persons listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

**List of Subjects in 14 CFR Part 91**

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Libya.

**The Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

**PART 91—GENERAL OPERATING AND FLIGHT RULES**

■ 1. The authority citation for part 91 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506-46507, 47122, 47508, 47528-47531, 47534, Pub. L. 114-190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1603 by revising the section heading and paragraphs (b), (c), and (e) to read as follows:

**§ 91.1603 Special Federal Aviation Regulation No. 112—Prohibition Against Certain Flights in the Territory and Airspace of Libya.**

\* \* \* \* \*

(b) *Flight prohibition.* Except as provided in paragraphs (c) and (d) of this section, no person described in paragraph (a) of this section may conduct flight operations in the territory and airspace of Libya.

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in the territory and airspace of Libya, provided that such flight operations occur under a contract, grant, or cooperative

agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the department, agency, or instrumentality and the person described in paragraph (a) of this section), with the approval of the FAA, or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: First, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

\* \* \* \* \*

(e) *Expiration.* This SFAR will remain in effect until March 20, 2025. The FAA may amend, rescind, or extend this SFAR, as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5), on or about March 13, 2023.

**Billy Nolen,**

*Acting Administrator.*

[FR Doc. 2023-05390 Filed 3-17-23; 11:15 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 10, 803, 812, and 822**

[Docket No. FDA-2021-N-0246]

**Medical Devices; Technical Amendments**

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Final rule; technical amendments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to update mailing address and docket number and conform the regulatory provisions to the Federal Food, Drug, and Cosmetics Act (FD&C Act). The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature to correct errors and to ensure accuracy and clarity in the Agency’s regulations.

**DATES:** This rule is effective March 21, 2023.

**FOR FURTHER INFORMATION CONTACT:** Madhusoodana Nambiar, Office of Policy, Center for Devices and