(i) European Union Aviation Safety Agency (EASA) AD 2021–0181, dated July 30, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0181, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 17, 2022.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2022–04147 Filed 2–25–22; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2020–0345; Product Identifier 2019–NM–154–AD; Amendment 39–21951; AD 2022–04–09]**

**RIN 2120–AA64**

## Airworthiness Directives; AVOX System Inc. (Formerly Scott Aviation) Oxygen Cylinder and Valve Assemblies and Oxygen Valve Assemblies

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

**ACTION:** Final rule.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for certain AVOX System Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on but not limited to various transport airplanes. This AD was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. This AD requires an inspection of the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. For assemblies and parts with certain serial numbers, this AD requires a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, and replacement of assemblies having unacceptable gaps. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 4, 2022.

**ADDRESSES:** For service information identified in this final rule, contact AVOX Systems Inc., 225 Erie Street, Lancaster, NY 14086; telephone 716–683–5100; internet *https://www.safranaerosystems.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0345.

### Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0345; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain AVOX System Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on but not limited to various transport airplanes. The NPRM published in the **Federal Register** on May 1, 2020 (85 FR 25353). The NPRM was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. In the NPRM, the FAA proposed to require an inspection of the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. For assemblies and parts with certain serial numbers, the NPRM proposed to require a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, and replacement of assemblies having unacceptable gaps (removing affected assemblies and installing serviceable assemblies). The NPRM also proposed to require reporting and returning of affected parts to the manufacturer. The FAA is issuing this AD to address oxygen leakage from the cylinder, which could result in decreased or insufficient oxygen supply during a depressurization event; and heating or flow friction, which could cause an ignition event in the valve assembly.

### Discussion of Final Airworthiness Directive

### Comments

The FAA received comments from one commenter, Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

The FAA received additional comments from five commenters, including American Airlines (AAL), Delta Air Lines (DAL), FedEx Express (FedEx), United Airlines (UAL), and an individual. The following presents the comments received on the NPRM and the FAA's response to each comment.

### Request To Revise Applicability

AAL and UAL suggested revising the applicability statement to include more aircraft manufacturers and models. AAL suggested adding all airplane models that affected assemblies could be installed on, in particular, Boeing Model 737–NG (Next Generation models are 737–600, –700, –700C, –800, –900, and –900ER series), 737–MAX, 777–200, and 777–300 series airplanes. UAL also suggested adding Model 737–NG airplanes. AAL stated that the applicability statement as proposed in the NPRM could mislead operators into believing that the AD would apply only to the airplanes identified in paragraphs (c)(1) through (12) of the AD. UAL believed the suggested change will be beneficial and assist operators in determining if their fleets are affected.

The FAA disagrees with the commenters' request. The FAA does not have a comprehensive list of all possible affected aircraft. To address the incomplete list, paragraph (c) of this AD identifies specific airplane models in paragraph (c) of this AD, but also notes that the assemblies are ''not limited to.'' The FAA has not changed the AD in this regard.

**Request To Revise Compliance Time for Parts**

AAL stated that the 60-day compliance time should apply only to valve assemblies that are installed on the aircraft and not ones in stock. AAL believes the unsafe condition only exists when an assembly is installed on an airplane, and for those assemblies that are not installed on an airplane, the proposed requirements in paragraph (k) of the proposed AD would ensure that the unsafe condition is addressed before that assembly is installed on an aircraft.

The FAA disagrees with the request to revise the compliance time. The FAA agrees that an affected spare part that is uninstalled and stored off an aircraft would not cause an unsafe condition on an aircraft. The 60-day compliance time applies to parts already installed on an aircraft, and paragraph (k) requires that action to be done on affected spare parts before installation, which could result in a spare part being inspected before the 60-day compliance time. In developing the compliance time for this AD, the FAA considered the urgency associated with the subject unsafe condition and the availability of required parts. The FAA determined that the 60-day compliance time for parts already installed on an aircraft is appropriate for accomplishing the actions required by this AD while maintaining an adequate level of safety. The FAA has not changed this AD in this regard.

**Request To Remove Inspection for Serial Numbers or Include Only Valve P/Ns**

AAL requested that the inspection to verify the serial number of the oxygen cylinder and entire assembly not be required. DAL requested that paragraphs (c), (h), (i), and (k) of the proposed AD be revised to remove reference to cylinder part numbers (P/Ns) and apply only to valve assembly P/Ns. AAL stated that it reviewed the service information and it seems that the defective part is only the valve assembly or ''hand valve.'' DAL also reasoned that the unsafe condition applies only to the valve assembly and not the cylinder. AAL then reasoned that the inspection to verify the serial number should apply only to the valve assembly or ''hand valve.'' AAL also stated that paragraph (i) of the proposed AD also seems to require the actions of paragraph (h)(1) through (3) of the proposed AD if a serial number of a cylinder was affected and a valve assembly not affected, even though it seems that it should not require those actions.

The FAA disagrees with the request. The parts of the oxygen cylinder and valve assemblies are interrelated, and valves from matched sets could have fit-up issues between parts or be mixed up or swapped during maintenance operations. The serial number inspection as proposed would address this interchangeability. The valve and cylinder that are part of those assemblies must also be inspected to address the unsafe condition, not just the assemblies themselves. Therefore, the FAA specifies to inspect the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. The FAA has not changed this AD in this regard.

**Request To Clarify Which Components Need To Be Identified**

UAL requested a change to the wording of which components need the serial number inspection. UAL stated that the statement in paragraph (h) of the proposed AD can be misconstrued as requiring that each of the three components (valve, cylinder, and entire assembly) be inspected individually for suspect serial numbers. UAL inferred that the intention is to inspect for the serial number of the entire cylinder and valve assembly, and not the individual components. UAL also stated that, for new oxygen cylinder assemblies from AVOX, there are individual placards that itemize the P/N and serial number for each component, and that for some cylinder assemblies, the serialization of the entire cylinder and valve assembly is nearly identical in format to the serialization of sub-component valve assemblies, which could lead to inaccurate reporting of results. The FAA infers that UAL suggested that the relevant numbers on the placards could be confused with other numbers.

The FAA disagrees. Each part and assembly stated in paragraph (h) of this AD are interrelated and must be inspected. The valve and cylinder components that are part of those assemblies must also be inspected for serial numbers, not just the assemblies themselves. If the serial number markings are unclear or missing, the service information contains information on identifying the parts and part assemblies. The FAA has not changed this AD in this regard.

**Request To Revise Conditions for Gap Inspection and Related Actions**

AAL and DAL requested changes to address concerns about what actions are required if a part is missing a blue dot. DAL stated that it seems best to prohibit all affected serial numbers to avoid a case where an inspected and marked part is installed, but the blue dot fades. AAL pointed to paragraph (i) of the proposed AD that would clarify that only the affected serial numbers of the valve assembly would need additional work, and, for valve assemblies marked with a blue dot, a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body would not be required. AAL stated that, as written, the proposed AD seems to suggest that an inspection of the gap would be required regardless of the presence of a blue dot.

The FAA disagrees with the request. The service information specifies that if there is a doubt on the condition of a part, such as missing serial numbers or a blue dot not definitively identified, then the follow-on inspections are required to ensure that no discrepant or affected part is missed. Paragraph (k) of this AD prohibits installation of assemblies with affected serial numbers unless the actions of paragraph (i) of this AD are accomplished. The FAA has not changed this AD in this regard.

**Request To Remove Inspection Report Requirement**

DAL requested that the compliance times for the inspection report be removed from paragraph (j)(1) of the proposed NPRM, and if not, the inspection report itself be removed. AAL requested removing the proposed requirement to submit an inspection report after accomplishing the requirements (*i.e.,* gap inspection) of paragraph (i) of the proposed AD. FedEx stated reporting should not be required for units that pass the inspection, and that sending units that failed the inspection to the vendor should be sufficient for reporting those failures. FedEx noted that any reporting requirements should consider the difficulties in reporting findings in a short period of time and noted that the inspector might not have access to the internet, email, and a device capable of printing and scanning. FedEx opined that its proposal would maintain accurate reporting and accommodate the realities of a global workplace. AAL and DAL stated that the reporting seems unnecessary and does not contribute to any additional level of safety. AAL

added that the NPRM would give operators the responsibility of ensuring that any affected part is returned to the manufacturer, and asserted that an equivalent level of safety would be maintained even if the reporting is not accomplished. DAL reasoned that if a cylinder valve assembly is unacceptable, it would be in the operator's best interest to report that finding to AVOX anyways so that it can receive a replacement assembly.

The FAA disagrees. In this case, the inspection results need to be reported to assist in tracking affected parts that are in circulation. In addition, reporting all findings gives assurance that an inspection was performed on an assembly with a given serial number. The FAA has not changed this AD in this regard.

**Request To Remove Compliance Time for Returning Parts**

AAL, DAL, and UAL requested revising paragraph (j)(2) of the proposed AD to remove a compliance time for returning discrepant parts to the manufacturer. AAL stated that a compliance time would not contribute to the level of safety. AAL also stated that all discrepant assemblies would be returned in a timely manner that is sufficient to the operator. DAL stated that it would be an unnecessary burden on operators to wait for AVOX's response before sending an unacceptable or discrepant part back within the compliance time in exchange for a free-of-charge replacement. DAL also stated that it would also be in the operator's best interest to send in the assembly so that it can qualify for a free-of-charge replacement if AVOX determines the part is unacceptable or discrepant. UAL stated it also believes the instruction to contact AVOX for shipping instructions could impede compliance with the 30-day limit to ship discrepant parts back to AVOX. UAL also stated that it wants to know how, for accurate AD-compliance reporting, it would be determined that a part is being shipped back as a result of this finding from AD-required inspections, or as a result of other, normal repair order processes.

The FAA agrees to clarify. Paragraph (j)(2) of this AD requires returning the assembly to the manufacturer in accordance with paragraph 3.D.(2) or 3.D.(3), as applicable, of the applicable service information. However, the service information does not include instructions to wait for a response from AVOX before returning the part. In addition, the FAA has revised paragraph (j)(2) of this AD to clarify that contacting AVOX for shipping instructions in not required. AVOX is tracking parts that are returned to it during accomplishment of the AD for data collection or analysis of manufacturing issues, and AVOX is also re-conditioning parts where possible. The FAA determined that having a 30-day compliance time for returning the part after an inspection finding is appropriate for this AD. However, under the provisions of paragraph (m) of this AD, an operator may request an approval of an alternative method of compliance (AMOC). The FAA has not changed this AD in this regard.

**Request To Allow Later Revisions of Service Information**

AAL requested that all the references to the AVOX service information be revised to allow use of subsequent revisions. AAL reasoned that this revision would reduce the number of AMOC requests each time a referenced service bulletin is revised.

The FAA disagrees. In an AD, the FAA may not refer to any document that does not yet exist. In general terms, the FAA is required by the Office of the Federal Register (OFR) regulations for approval of materials incorporated by reference, as specified in 1 CFR 51.1(f), to either publish the service document contents as part of the actual AD language; or submit the service document to the OFR for approval as referenced material, in which case the FAA may only refer to such material in the text of an AD. The AD may refer to the service document only if the OFR approved it for incorporation by reference. See 1 CFR part 51. The FAA disagrees with revising the AD to include specific airplane models based on the corresponding service information because the agency does not have a comprehensive list of the applicable aircraft to which specific AVOX service information could apply. The FAA has not changed this AD in this regard.

**Request To Clarify AD Applicability With Reference to Service Information**

A commenter requested clarifying paragraph (c) of the proposed AD by including reference to the service information that was identified in paragraph (h) of the proposed AD. The commenter suggested revising the paragraph so that the applicability would include information on the service information definition of the affected units. AAL also requested adding the airplane configuration information in the text of the AD to add further clarification to operators and release the technical data in a more organized fashion.

The FAA disagrees. The definition of the affected units does not need to be moved to paragraph (c) of the AD. The effectivity of the service information is limited to specific airplane models, but the applicability of this AD applies to all aircraft. Because the affected parts could be installed on additional aircraft models, the FAA has determined that the affected parts could later be installed on aircraft that were initially delivered with acceptable parts, thereby subjecting those aircraft to the unsafe condition. The FAA has not changed this AD in this regard.

**Request To Revise Compliance Time for Parts Identification**

DAL and UAL requested revising the compliance time proposed in paragraph (h) of the proposed NPRM. DAL and UAL stated that since many operators have parked their aircraft or severely reduced usage of aircraft, an extension of the compliance time (either with additional calendar days or adding an option for flight hours and flight cycles), would allow operators additional time for compliance. UAL also stated that the supply chain could be affected due to potential increased shipping time and workforce reductions.

The FAA disagrees with the request to extend the compliance time. The FAA acknowledges the effects that the pandemic response might have on operators' fleet use, supply chain, and maintenance personnel. In developing an appropriate compliance time for this action, the FAA considered the degree of urgency associated with addressing the subject unsafe condition, the manufacturer's recommendation for an appropriate compliance time, and the practical aspect of accomplishing the required inspection within a period of time that corresponds to the normal scheduled maintenance for most affected operators. In addition, the FAA notes that some aircraft may have been in service during the pandemic and must comply within the required compliance time. Operators do have the option to inspect the airplane before the first flight following storage if the airplane is in storage for more than 27 months. However, under the provisions of paragraph (m) of this AD, the FAA will consider requests for an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

**Request To Allow Use of Alternatives for Parts Marking**

FedEx requested that the specification to use oil-based blue ink markers be

modified to allow alternative methods and colors such as black indelible ink. FedEx stated that oil-based blue paint markers are not readily available or kept in stock regularly. FedEx suggested that a list of part numbers for approved, aircraft grade, oil-based paint be provided.

The FAA disagrees. While the FAA realizes this is a limitation, there must be one standard to help avoid confusion. The procedures required by this AD specify actions based on the presence or absence of a blue dot in a specific location. The FAA has not seen any difficulties in obtaining the paint markers. However, under the provisions of paragraph (m) of this AD, any person may request an approval of an AMOC. The FAA has not revised this AD in this regard.

**Request To Allow Alternative Means of Measuring Gaps**

FedEx requested that the proposed AD be revised to allow use of feeler gauges, calipers, and other means of measuring the gap in imperial units of measure. FedEx stated that the service information specifies use of pin gauges that are made for metric units of measure, and that acquiring those metric pin gauges is an extra expense and logistical complication. FedEx recommended adding a tolerance to the gap measurement and specifying a fractional imperial measure (3⁄32-inch) that is close to the metric unit specified. FedEx suggested that if a tolerance or other measurement is not added, then a manufacturer part number (MPN) for a specific tool or supplier should be provided.

The FAA disagrees. Using other means of measuring could introduce or increase variables that could affect the accuracy of the measurement. The FAA understands that not everyone has the same resources, tools, or supplies; however, the FAA also understands that this means of measurement is easily accessible. Under the provisions of paragraph (m) of this AD, operators may request approval of an AMOC if sufficient data are submitted to substantiate that the tolerance would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

**Request To Revise Procedure for Shipping an Assembly**

FedEx requested that the proposed AD be revised to allow operators to use their own procedures for shipping dangerous goods such as unopened cylinder valve assemblies (CVAs) instead of the procedure specified in the service information. FedEx explained that it has established and accepted procedures for shipping dangerous goods, and that the disposition of an unopened CVA would be done by a department separate from the one doing the inspection. FedEx stated that following the procedures in the service information would require additional coordination time, and that the wording of the procedures would not function properly with its AD compliance mechanisms.

The FAA agrees to clarify. The design approval holder (DAH) of the affected valve assemblies has specified a method for shipping, or returning, an unopened CVA that has been found to be unacceptable or discrepant, specifically a shipping method that is compliant with DOT standard HM–224B. If FedEx has procedures that are compliant with DOT standard HM–224B, then those procedures are acceptable for compliance with this AD. For procedures that are not compliant with DOT standard HM–224B, under the provisions of paragraph (m) of this AD, the FAA will consider requests for an AMOC. The FAA has not changed this AD in this regard.

**Request for Clarification on Applicability of AD**

FedEx requested clarification on whether the proposed AD is written ''against'' the MPN or the serial numbers within that MPN. FedEx explained the effects on the operator's workload and also on the operational impact of a unit's overhaul cycle in conjunction with a 60-day compliance time and the scope of the applicability. FedEx added that a 180-day compliance time would be more reasonable.

The FAA agrees to clarify. The applicability of this AD is written against the MPN and specific serial numbers, in addition to manufacture dates of the assemblies. The FAA disagrees to revise the compliance time because the FAA has determined that requirement based on a risk calculation. The FAA has not changed this AD in that regard.

**Request To Clarify Requirement if Component Number(s) Cannot Be Determined**

UAL requested clarification on what actions are required in the event the P/N or serial number information cannot be determined. UAL stated that as a result of in-service activity, that information might be illegible, unintentionally obliterated, or missing from the placard. UAL added that under its normal practices, whenever a part or serial number cannot be determined, the part is considered suspect, made unserviceable, and removed from service. UAL stated that, when the P/N of the entire cylinder and valve assembly can be determined but not the serial number, and the date of manufacture is between January and November 2018, it wants to still be able to establish conformity by inspecting for the presence of the blue dot and accomplish the applicable service information instruction if the blue dot is missing. UAL also stated that depending on the FAA's response to this request, it may apply for an AMOC.

The FAA agrees to clarify. The service information states to inspect for the manufacturing date, serial number, and the presence of a blue dot. The service information then states that if there is doubt or a determination cannot be made (such as the numbers or dot is not clearly identified), to proceed with the follow-on inspection for proper gap spacing (this follow-on inspection is required by paragraph (i) of this AD). The FAA has not changed this AD in this regard.

**Request for Clarification on Compliance Time and Method for Inspection Report**

UAL requested clarification on how a 30-day requirement for the inspection report was determined, and if a ''comprehensive'' report is acceptable. UAL stated that it understands the need for the information gathered from the reports; however, it does not understand why or how a 30-day compliance time was established. UAL also stated that it assumed that reporting of the results should be done as a single, comprehensive report and not piece-wise (individually for each assembly or aircraft), and that the report does not need to be an exact copy of the report form in the service information.

The FAA agrees to clarify. The FAA determined that the 30-day compliance time is appropriate for this AD. Also, the manufacturer is collecting information for analysis of manufacturing issues. The format of the report may be done as UAL assumed, as long as all documents are labeled correctly. However, under the provisions of paragraph (m) of this AD, an operator may request an approval of an AMOC. The FAA has not changed this AD in this regard.

**Request To Provide Clarification on Reporting Form**

UAL requested clarification on the definition of ''manufacture date'' in a recording column of a report form in the service information. UAL stated that it is implied that ''manufacture date'' in that column is the manufacture date of

the entire cylinder and valve assembly and not of the valve assembly.

The FAA agrees to clarify. The ''manufacturer date'' is not limited to the date of the entire cylinder and valve assembly, but is the manufacture date of each part or assembly that might be recorded in the inspection report, such as the assemblies listed in Appendix 1 of the service information. The FAA has not changed this AD in this regard.

**Conclusion**

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

**Related Service Information Under 1 CFR Part 51**

The FAA reviewed AVOX Systems Inc. Alert Service Bulletins 10015804–35–01, Revision 02, dated October 16, 2019; 10015804–35–02, Revision 2, dated October 31, 2019; and 10015804–35–03, Revision 02, dated October 15, 2019. This service information describes procedures for an inspection to determine the serial numbers of the oxygen cylinder and valve assemblies, and the oxygen valve assemblies, a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, parts marking, inspection report, and return of parts to the manufacturer. These documents are distinct since they apply to different assembly part numbers. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

**Costs of Compliance**

The FAA estimates that this AD affects up to 3,034 oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on various transport category airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| Serial number inspection | 1 work-hour × $85 per hour = $85 | None | $85 | $257,890 |
| Reporting | 1 work-hour × $85 per hour = $85 | 0 | 85 | 257,890 |

The FAA estimates the following costs to do any necessary follow-on actions that would be required based on the results of the inspection. The FAA has no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS *

| Action | Labor cost | Parts cost | Cost per product |
|---|---|---|---|
| Detailed inspection | 1 work-hour × $85 per hour = $85 | None | $85 |

* The FAA has received no definitive data on the cost of on-condition replacements.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators. The FAA does not control warranty coverage for affected operators. As a result, the FAA has included all known costs in the cost estimate.

**Paperwork Reduction Act**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

**Authority for This Rulemaking**

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

**Regulatory Findings**

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

**2022–04–09 AVOX Systems Inc. (formerly Scott Aviation):** Amendment 39–21951; Docket No. FAA–2020–0345; Product Identifier 2019–NM–154–AD.

**(a) Effective Date**

This airworthiness directive (AD) is effective April 4, 2022.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to AVOX Systems Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies having part number (P/N) 89794077, 89794015, 891511–14, 806835–01, 807982–01, or 808433–01; and oxygen valve assemblies (body and gage assemblies) having P/N 807206–01. These assemblies might be installed on, but not limited to, the aircraft identified in paragraphs (c)(1) through (12) of this AD, certificated in any category.

(1) Airbus SAS Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Airbus SAS Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes.

(3) Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(4) Airbus SAS Model A318–111, –112, –121, and –122 airplanes.

(5) Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, –133, and –151N airplanes.

(6) Airbus SAS Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(7) Airbus SAS Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –252N, –253N, –271N, –272N, –251NX, –252NX, –253NX, –271NX, and –272NX airplanes.

(8) Airbus SAS Model A330–201, –202, –203, –223, –243, –301, –302, –303, –321, –322, –323, –341, –342, –343, and –941 airplanes.

(9) Airbus Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes.

(10) ATR—GIE Avions de Transport Régional Model ATR42–200, –300, –320, and –500 airplanes.

(11) ATR—GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes.

(12) The Boeing Company Model 747–8 series airplanes.

**(d) Subject**

Air Transport Association (ATA) of America Code 35, Oxygen System.

**(e) Unsafe Condition**

This AD was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. The FAA is issuing this AD to address oxygen leakage from the cylinder, which could result in decreased or insufficient oxygen supply during a depressurization event; and heating or flow friction, which could cause an ignition event in the valve assembly.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Definition of Detailed Inspection**

For the purposes of this AD, a detailed inspection is an intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.

**(h) Identification of Affected Cylinder and Valve Assemblies**

Within 60 days after the effective date of this AD, inspect the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine if the serial numbers of the valve, cylinder, and entire assembly, are listed in Appendix 1, ''Affected Shipments,'' of the applicable service information identified in paragraphs (h)(1) through (3) of this AD. A review of airplane maintenance records is acceptable in lieu of this inspection if the serial numbers can be conclusively determined from that review.

(1) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 02, dated October 16, 2019.

(2) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 2, dated October 31, 2019.

(3) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 02, dated October 15, 2019.

**(i) Inspection of the Gap, Parts Marking Actions, and Replacement**

If, during any inspection or records review required by paragraph (h) of this AD, any oxygen valve assembly, valve or cylinder of an oxygen cylinder and valve assembly, or oxygen cylinder and valve assembly having an affected serial number is found: Before further flight, do a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body, in accordance with paragraph 3.C. of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(1) If the gap is found to be acceptable, as defined in the applicable service information identified in paragraphs (h)(1) through (3) of this AD, before further flight, do the parts marking actions in accordance with paragraph 3.D.(1) of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(2) If the gap is found to be unacceptable, as defined in the applicable service information identified in paragraphs (h)(1) through (3) of this AD, before further flight, remove the affected assembly, in accordance with paragraphs 3.D.(2) or 3.D.(3), as applicable, of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD; and replace with a serviceable assembly.

**(j) Reporting and Return of Parts**

(1) Report the results of the inspection required by paragraph (i) of this AD within the applicable time specified in paragraph (j)(1)(i) or (ii) of this AD. Report the results in accordance with paragraph 3.D.(1)(a) of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(2) If, during the inspection required by paragraph (i) of this AD, any gap is found to be unacceptable, within the applicable time specified in paragraph (j)(2)(i) or (ii) of this AD, return the assembly to the manufacturer in accordance with paragraph 3.D.(2) or 3.D.(3), as applicable, of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD, except you are not required to contact AVOX for shipping instructions.

(i) If the inspection was done on or after the effective date of this AD: Return the assembly within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Return the assembly within 30 days after the effective date of this AD.

**(k) Parts Installation Limitation**

As of the effective date of this AD, no AVOX Systems Inc. oxygen valve assembly, or valve or cylinder that is part of an oxygen cylinder and valve assembly, or oxygen cylinder and valve assembly having an affected serial number identified in Appendix 1, ''Affected Shipments,'' of any AVOX Systems Inc. service information

identified in paragraphs (h)(1) through (3) of this AD may be installed on any airplane unless the requirements of paragraph (i) of this AD have been accomplished on that affected assembly.

**(l) Credit for Previous Actions**

This paragraph provides credit for the actions specified in paragraphs (h) or (i) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (l)(1) through (5) of this AD.

(1) AVOX Systems Inc. Service Bulletin 10015804–35–01, dated March 6, 2019.

(2) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 01, dated July 9, 2019.

(3) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 1, dated September 4, 2019.

(4) AVOX Systems Inc. Service Bulletin 10015804–35–03, dated April 11, 2019.

(5) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 01, dated May 21, 2019.

**(m) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(n) Related Information**

(1) For more information about this AD, contact Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov*.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (4) of this AD.

**(o) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 02, dated October 16, 2019.

(ii) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 2, dated October 31, 2019.

(iii) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 02, dated October 15, 2019.

(3) For service information identified in this AD, contact AVOX Systems Inc., 225 Erie Street, Lancaster, NY 14086; telephone 716–683–5100; internet *https://www.safranaerosystems.com*.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, *fr.inspection@nara.gov*, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on February 11, 2022.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

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**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 500, 510, 516, 520, 522, 524, 529, 556, and 558

**[Docket No. FDA–2021–N–0002]**

## New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor

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

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

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and a conditionally approved new animal drug application (cNADA) during July, August, and September 2021. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy of the regulations.

**DATES:** This rule is effective February 28, 2022. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as February 28, 2022. The incorporation by reference of other material listed in this rule was approved by the Director of the Federal Register as of November 25, 2011.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2021, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. Marketing exclusivity and patent information may be accessed in FDA's publication, ''Approved Animal Drug Products Online (Green Book)'' at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book*.

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.