#### (k) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: barbara.caufield@faa.gov.

### (l) Material Incorporated by Reference

- (1) The Director of the Federal Register approved the incorporation by reference 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) Transport Canada ÂD CF-2022-22, dated April 22, 2022.
  - (ii) [Reserved]
- (3) For Transport Canada AD CF–2022–22, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663–3639; email:
- TC.AirworthinessDirectives-Consignesde navigabilite.TC@tc.gc.ca. You may find this material on the Transport Canada website at tc.canada.ca/en/aviation.
- (4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.
- (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, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibrlocations.html.

Issued on March 24, 2023.

# Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service. [FR Doc. 2023–08624 Filed 4–24–23; 8:45 am]

[FK Doc. 2023-00024 Filed 4-24-25, 0.45 diff

BILLING CODE 4910-13-P

# **DEPARTMENT OF TRANSPORTATION**

## **Federal Aviation Administration**

## 14 CFR Part 39

[Docket No. FAA-2023-0665; Project Identifier MCAI-2022-00625-R; Amendment 39-22405; AD 2023-07-03]

RIN 2120-AA64

# Airworthiness Directives; Leonardo S.p.a. Helicopters

**AGENCY:** Federal Aviation Administration (FAA), DOT. **ACTION:** Final rule; request for

comments.

**SUMMARY:** The FAA is adopting a new airworthiness directive (AD) for all Leonardo S.p.a. Model AB412 and AB412 EP helicopters. This AD was

prompted by a report of a fatigue crack in a left-hand (LH) fin spar cap. This AD requires cleaning and repetitively inspecting certain part-numbered LH fin spar caps, and repetitively inspecting the exterior of the fin skin and, depending on the results, accomplishing corrective action. This AD also prohibits certain corrective actions as a terminating action for the repetitive inspections unless the corrective actions have been approved as a terminating action, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective May 10, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 10, 2023.

The FAA must receive comments on this AD by June 9, 2023.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to regulations.gov. Follow the instructions for submitting comments.
  - Fax: (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M— 30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2023–0665; 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, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material that is incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@ easa.europa.eu.; internet: easa.europa.eu. You may find this IBR material on the EASA website at ad.easa.europa.eu.
- You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the

FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2023–0665.

Other Related Service Information: For Leonardo Helicopters service information identified in this final rule, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone (+39) 0331–225074; fax (+39) 0331–229046; or at customerportal. leonardocompany.com/en-US/. This service information is also available at the FAA contact information under Material Incorporated by Reference above.

### FOR FURTHER INFORMATION CONTACT:

Gregory Koenig, Aerospace Engineer, Airframe & Administrative Services Section, Chicago ACO Branch, Compliance & Airworthiness Division, FAA, 2300 E Devon Ave., Des Plaines, IL 60018; telephone (847) 294–7127; email *Gregory.L.Koenig@faa.gov*.

### SUPPLEMENTARY INFORMATION:

#### **Comments Invited**

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under ADDRESSES. Include "Docket No. FAA-2023-0665; Project Identifier MCAI-2022-00625-R" at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

## **Confidential Business Information**

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate

the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Gregory Koenig, Aerospace Engineer, Airframe & Administrative Services Section, Chicago ACO Branch, Compliance & Airworthiness Division, FAA, 2300 E Devon Ave., Des Plaines, IL 60018; telephone (847) 294-7127; email Gregory.L.Koenig@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

## **Background**

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0084, dated May 11, 2022 (EASA AD 2022–0084), to correct an unsafe condition for Leonardo S.p.A. Model AB212, AB412, and AB412EP helicopters, all serial numbers

This AD was prompted by a report of a fatigue crack in a LH fin spar cap. The FAA is issuing this AD to detect a crack, a loose or missing rivet, damage, or distortion. The unsafe condition, if not addressed, could result in stress concentrations at the edge of the rivet hole, possibly resulting in reduced structural integrity of the fin spar and subsequent loss of control of the helicopter. See EASA AD 2022–0084 for additional background information.

# Related Service Information Under 1 CFR Part 51

EASA AD 2022–0084 requires cleaning and repetitively inspecting certain part-numbered LH fin spar caps for a crack, loose rivet, and other damage, and repetitively inspecting the exterior of the fin skin in the area in contact with the fin spar cap for a crack, loose rivet, and distortion. If any discrepancy is detected, EASA AD 2022–0084 also requires contacting Leonardo S.p.A. for approved repair instructions and accomplishing the repair. Additionally, EASA AD 2022-0084 prohibits certain corrective actions as terminating action for the repetitive inspections, unless stated otherwise in the repair instructions.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in ADDRESSES.

#### **Other Related Service Information**

The FAA also reviewed Leonardo Helicopters Service Bulletin No. 412-168, dated May 19, 2021, which specifies procedures to clean certain parts, and using a 10x magnifying glass and a bright light, inspect both flanges of the LH fin spar cap part number 212-030-447-117 for cracks, loose rivets, and other damage. This service information also specifies procedures to inspect the exterior of the fin skin in the area in contact with the fin spar cap for cracks, loose rivets, and distortion, and if any cracks or damage are found, to contact Leonardo Helicopters and send a compliance form to absereng.aw@ leonardocompany.com.

### **FAA's Determination**

These products have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

### **AD Requirements**

This AD requires accomplishing the actions specified in EASA AD 2022–0084, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD and except as discussed under "Differences Between this AD and the EASA AD."

# **Explanation of Required Compliance Information**

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2022-0084 will be incorporated by reference in this FAA final rule. This AD would, therefore, require compliance with EASA AD 2022-0084 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022-0084 does not mean that operators need comply only with that section. For example, where the AD requirement refers to "all required actions and compliance times,' compliance with this AD requirement is

not limited to the section titled "Required Action(s) and Compliance Time(s)" in EASA AD 2022–0084. Service information referenced in EASA AD 2022–0084 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–0665.

# Differences Between This AD and the EASA AD

EASA AD 2022–0084 applies to Model AB212 helicopters, whereas this AD does not because that model is not FAA type-certificated. If there is any discrepancy as defined in the service bulletin, EASA AD 2022–0084 requires contacting Leonardo S.p.A. for approved repair instructions and accomplishing the repair, whereas this AD requires accomplishing the corrective actions in accordance with a method approved by the FAA, EASA, or Leonardo S.p.a. Helicopters' Design Organization Approval instead.

# Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.) 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." Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

There are currently no domestic operators of these products.
Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reasons, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

### **Regulatory Flexibility Act**

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

## **Costs of Compliance**

There are no costs of compliance with this AD because there are no helicopters with these type certificates on the U.S. Registry.

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

## 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:

**2023–07–03 Leonardo S.p.a.**: Amendment 39–22405; Docket No. FAA–2023–0665; Project Identifier MCAI–2022–00625–R.

#### (a) Effective Date

This airworthiness directive (AD) is effective May 10, 2023.

#### (b) Affected ADs

None.

## (c) Applicability

This AD applies to all Leonardo S.p.a. Model AB412 and AB412 EP helicopters, certificated in any category.

### (d) Subject

Joint Aircraft System Component (JASC) Code: 5302, Rotorcraft Tail Boom.

#### (e) Unsafe Condition

This AD was prompted by a report of a fatigue crack in a left-hand (LH) fin spar cap. The FAA is issuing this AD to detect a crack, a loose or missing rivet, damage, or distortion. The unsafe condition, if not addressed, could result in stress concentrations at the edge of the rivet hole, possibly resulting in reduced structural integrity of the fin spar and subsequent loss of control of the helicopter.

### (f) Compliance

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

#### (g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2022–0084, dated May 11, 2022 (EASA AD 2022–0084).

## (h) Exceptions to EASA AD 2022-0084

- (1) Where EASA AD 2022–0084 refers to its effective date, this AD requires using the effective date of this AD.
- (2) Where EASA AD 2022–0084 refers to flight hours, this AD requires using hours time-in-service.
- (3) Where the service information referenced in paragraph (1) of EASA AD 2022–0084 specifies to "inspect both flanges of the left hand fin spar cap between F.S. 50 and F.S. 71 using 10x magnifying glass and a bright light for cracks, loose rivets, and other damage;" for this AD, replace that text with, "inspect both flanges of the left hand fin spar cap between F.S. 50 and F.S. 71 using a 10X or higher power magnifying glass and a flashlight for a crack, a loose or missing rivet, and other damage, which may be indicated by fretting around the rivet."
- (4) Instead of complying with paragraph (2) of EASA AD 2022–0084, comply with the following; "During any inspection as required by paragraph (1) of EASA AD 2022–0084, for this AD, if there is a crack, a loose or missing rivet, other damage, or distortion, before further flight, accomplish the corrective action in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; or EASA; or Leonardo S.p.a. Helicopters' Design

Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature."

(5) This AD does not adopt the "Remarks" section of EASA AD 2022–0084.

### (i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0084 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

# (j) Alternative Methods of Compliance (AMOCs)

- (1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.
- (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.

### (k) Related Information

For more information about this AD, contact Gregory Koenig, Aerospace Engineer, Airframe & Administrative Services Section, Chicago ACO Branch, Compliance & Airworthiness Division, FAA, 2300 E Devon Ave., Des Plaines, IL 60018; telephone (847) 294–7127; email *Gregory.L.Koenig@faa.gov*.

# (l) Material Incorporated by Reference

- (1) The Director of the Federal Register approved the incorporation by reference 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) European Union Aviation Safety Agency (EASA) AD 2022–0084, dated May 11, 2022.
- (ii) [Reserved]
- (3) For EASA AD 2022–0084, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; internet: easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.
- (4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.
- (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, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibrlocations.html.

Issued on April 3, 2023.

#### Christina Underwood,

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

[FR Doc. 2023–08629 Filed 4–24–23; 8:45 am]

BILLING CODE 4910-13-P

### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 97

[Docket No. 31481; Amdt. No. 4055]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective April 25, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 25, 2023.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

### For Examination

1. U.S. Department of Transportation, Docket Ops–M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected

airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or, 4. 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.

#### Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

### FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight
Technologies and Procedures Division,
Flight Standards Service, Federal
Aviation Administration. Mailing
Address: FAA Mike Monroney
Aeronautical Center, Flight Procedures
and Airspace Group, 6500 South
MacArthur Blvd., STB Annex, Bldg. 26,
Room 217, Oklahoma City, OK 73099.
Telephone (405) 954–1139.

**SUPPLEMENTARY INFORMATION:** This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal** Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

# Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the ADDRESSES section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for Part 97 of this final rule.

#### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for **Terminal Instrument Procedures** (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and. where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial