

STATEMENT OF SCOTT AVIATION DIVISION
OF A-T-O INC. 12
TO THE NIOSH PUBLIC MEETING ON TESTING & CERTIFICATION

Scott Aviation welcomes this opportunity to participate in this public meeting which has been convened to receive public comment on the role of NIOSH in testing and certifying personal protective equipment and hazard measuring instruments. I am Rob Cyr, Director of Engineering for Scott Aviation Division of A-T-O Inc.

While Scott's products are presently limited to respiratory protective equipment and hazard measuring instruments, we are of course interested in all aspects of the regulatory climate as it affects the industrial safety equipment industry. This is especially true since what is done by NIOSH and OSHA is beginning to affect other markets of prime interest to Scott - namely the Military and Aviation communities, and Foreign Nations, all of which utilize similar apparatus for personal protection and life support but are not necessarily covered under the OSHA Act.

I would like to direct some attention to the unfortunate development of what seems to be an adversary relationship between the respirator manufacturing industry and NIOSH in general and the DSR at Morgantown in particular. Speaking from Scott's standpoint, our association with the Bureau of Mines and NIOSH TCL personnel had always been one of friendship and cooperation in achieving our mutual goal of improved protection for those in need of protective breathing apparatus and Hazard Measuring Instruments - that is until the last 18 months to two years. We deplore this change and fervently hope that what goes on here today will lead to a more workable and beneficial relationship.

The June 18, 1980 issue of the Federal Register and the consultants report of November 21, 1979 provides a fertile field for comments. While our viewpoint may be identical or similar to others presented here, we would like to present our recommendations and comments as follows, and I am limiting myself here to respiratory protection which is Scott's main concern at present.

It seems from our consideration of many pertinent factors including what we know of the applicable legislation, that NIOSH does not belong in a regulatory role. Research on the need for and extent of respiratory protection plus development of performance criteria for respiratory protective devices should be the main NIOSH role. OSHA is the basic regulatory agency and the requirements for use of protective equipment and the degree of protection to be provided is definitely in their area. What Scott would really like to see is that NIOSH-OSHA assume a modus operandi on apparatus approvals that is patterned after the FAA's procedure for issuance of TSO's (Technical Standard Orders) which is one of the four methods by which materials, parts, processes, or appliances may be approved for use on aircraft. Following are quotes from recent revisions to the TSO authorization procedure as reported in the Federal Register on June 9, 1980:

" One of the several methods of obtaining approval is by designing and testing the article (material, part, process, or appliance) in accordance with a TSO which contains minimum performance and quality control standards for specific articles. The standards for each TSO are those the Administrator finds necessary to ensure that the article concerned will operate satisfactorily. Since compliance with a TSO is only one method of obtaining an approval, the standards contained in the TSO are not mandatory but are only an optional way of obtaining approval for a particular article. For example, an applicant can obtain approval to deviate from a particular TSO if it shows that the design features provide an equivalent level of safety.

A TSO is not a standard of general or particular applicability designed to implement or prescribe law or policy. It does not fall within the definition of "rule" contained in the Administrative Procedure Act (5 U.S.C.551). There is no requirement that a TSO be published as a notice of proposed rule making in the Federal Register.

Future TSO's will, through incorporation by reference, make maximum practical use of "voluntary standards" as defined by the Office of Management and Budget (OMB) Circular A-119 "Federal Participation in the Development and Use of Voluntary Standards," issued January 17, 1980 (45 FR 4326). By definition of OMB Circular A-119, "voluntary standards" are established generally by the private sector "voluntary standards bodies" and are available for use by any person or organization, private or government. The term includes what are commonly referred to as "industry standards" as well as "consensus standards" but does not include professional standards of personal conduct, private standards of individual firms, or standards mandated by law. "Voluntary standards bodies" are nongovernmental bodies which are broad based, multimember, domestic, and multinational organizations including; for example, nonprofit organizations, industry association, and professional technical societies which develop, establish, or coordinate voluntary standards."

"The FAA has determined, for the reasons stated in Notice 79-15, published in the Federal Register on October 1, 1979 (44 FR 56370), that, in the interest of safety, it is appropriate to adopt new public procedures to facilitate the issuance of TSO's for specified articles used on civil aircraft. The safety aspect of this rule making is particularly important. The fact that TSO's have been part of the complex regulatory structure of the FAA has caused a substantial lag time between regulations and state of the technology. This procedural change should advance by months and even years the implementation of technological improvements in the U.S. aviation system.

Interested persons have been afforded an opportunity to participate in the making of these amendments, and due consideration has been given to all matters presented. Significant comments received in response to Notice 79-15 are discussed below. A number of substantive, editorial, and clarifying changes have been made to the proposed rules based on relevant comments and on further review within the FAA. Except for minor editorial and clarifying changes and the changes discussed below, these amendments and the reasons for their adoption are the same as those contained in Notice 79-15 (Comments have been omitted)

These amendments are consistent with the agency's responsibility to review the continuing need for regulations and the need to eliminate unnecessary regulations. By eliminating TSO's from the regulations, previously published as Subpart B of 14 CFR Part 37, and making them available through the multiple procedures described below, the FAA has improved the availability of the TSO's and made it easier for the public to locate the most up-to-standard. In addition, by removing TSO's from the agency's regulatory process, the time available for other matters within the regulatory system will be increased. This will enable the agency to respond in a more timely manner to other issues submitted by the public. This improvement of the regulatory process, to be more responsive to the public, is consistent with Executive Order 12044, issued by President Carter on March 23, 1978. "

"Public Procedure

The following is the public procedure, in detail, the FAA will use to develop and issue final TSO's for specified articles used on civil aircraft:

- The FAA will continue to develop draft TSO's and will continue to use, by reference in the TSO, documents prepared and issued by organizations such as the Radio Technical Commission for Aeronautics (RTCA) and the Society of Automotive Engineers (SAE). Notices of RTCA meetings and invitations will continue to be published in the Federal Register. This will allow public participation at the early stages of document development.
- Any interested person may request the Administrator to revise or issue a new TSO by submitting a description of the revision sought or a description of the new article for which a TSO is requested.
- The FAA will use several methods to ensure that the public is afforded early opportunities to take part in the TSO decisionmaking process. A draft TSO will be circulated for public comment through the use of mailing lists. Any individual or organization can request to be placed on the TSO mailing list. All those on the list will receive drafts of each TSO. In addition, Advisory Circular 20-110, Index of Aviation Technical Standard Orders, will list those TSO's the FAA anticipates will be issued within the succeeding 12 months. Advisory Circular 20-110 will also list each current TSO and provide information on how to obtain copies of those desired. Finally, the FAA will publish periodically a notice in the Federal Register of each proposed TSO and provide notice of how to obtain a copy.
- Any individual or organization wishing to obtain copies of Advisory Circular 20-110, specific draft TSO's or all such TSO's proposed by the FAA may be placed on a mailing list by submitting a request addressed to the Federal Aviation "

- " Administration, Office of Airworthiness, Aircraft Engineering Division, Systems Branch (AWS-130), 800 Independence Avenue, S.W., Washington, D.C. 20501, or by telephoning (202) 426-8395. Interested persons will receive copies of the Advisory Circular and copies of those draft TSO's requested. Any person wishing to submit comments on a proposed TSO will be given 90 days from its issuance date to submit comments.
- All comments received on or before the closing date for comments will be considered by the Administrator before issuing a final TSO.
 - All comments submitted will be available, both before and after the closing date for comments, for examination by interested persons in Room 335, FAA Headquarters Building (FOB-10A), 800 Independence Avenue, S. W., Washington, D.C. 20501, between 8:30 a.m. and 5:00 p.m.
 - Copies of the final TSO will be mailed to all persons on the mailing list. As in the past, documents prepared and issued by an organization that are incorporated by reference in the TSO will continue to be available to any interested person only from that organization. Final TSO's will not be published in the Federal Register.
 - Copies of all draft and final TSO's will also be available at FAA Headquarters in the Office of Airworthiness, Aircraft Engineering Division, Systems Branch (AWS-130), and at all regional Flight Standards Engineering and Manufacturing offices.

In summary, the new procedure has numerous opportunities for the public to participate in the development of each TSO. These are: (1) participation in the development of documents prepared and issued by industry organizations, which the FAA may use by reference in a TSO; (2) mailing lists to circulate a draft TSO to the public"

" for comment; (3) an advisory circular to list for the public each TSO the FAA anticipates will be issued within the succeeding 12 months; (4) notice in the Federal Register announcing the availability of each draft TSO and invitation for comment; and (5) at least 90 days to submit comments. "

"Especially pertinent Sections are given as follows:

21.3 REPORTING OF FAILURES, MALFUNCTIONS, AND DEFECTS

(a) Except as provided in paragraph (d) of this section, the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a TSO authorization, or the licensee of a Type Certificate shall report any failure, malfunction, or defect in any product, part, process, or article manufactured by it that it determines has resulted in any of the occurrences listed in paragraph (c) of this section.

(b) The holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a TSO authorization, or the licensee of a Type of Certificate shall report any defect in any product, part, or article manufactured by it that has left its quality control system and that it determines could result in any of the occurrences listed in paragraph (c) of this section.

(c) The following occurrences must be reported as provided in paragraphs (a) and (b) of this section:

(1) Fire caused by a system or equipment failure, malfunction, or defect.

(2) An engine exhaust system failure, malfunction, or defect which causes damage to the engine, adjacent aircraft structure, equipment, or components.

(3) The accumulation or circulation of toxic or noxious gases in the crew compartment or passenger cabin.

(4) A malfunction, failure, or defect of a propeller control system. "

"(5) A propeller or rotocraft hub or blade structural failure.

(6) Flammable fluid leakage in areas where an ignition source normally exists.

(7) A brake system failure caused by structural or material failure during operation.

(8) A significant aircraft primary structural defect or failure caused by any autogenous condition (fatigue, understrength, corrosion, etc.).

(9) Any abnormal vibration or buffeting caused by a structural or system malfunction, defect, or failure.

(10) An engine failure.

(11) Any structural or flight control system malfunction, defect, or failure which causes interference with normal control of the aircraft or which derogates the flying qualities.

(12) A complete loss of more than one electrical power generating system or hydraulic power system during a given operation of the aircraft.

(13) A failure or malfunction of more than one attitude, air-speed, or altitude instrument during a given operation of the aircraft.

(d) The requirements of paragraph (a) of this section do not apply to - - -

(1) Failures, malfunctions, or defects that the holder of a Type Certificate (including a Supplemental Type Certificate), Parts Manufacturer Approval (PMA), or TSO authorization, or the licensee of a Type Certificate - - -

(i) Determines were caused by improper maintenance or improper usage;

(ii) Knows were reported to the FAA by another person under the Federal Aviation Regulations;"

" (iii) Has already reported under the accident reporting provisions of Part 430 of the regulations of the National Transportation Safety Board.

(2) Failures, malfunctions, or defects in products, parts, or articles manufactured by a foreign manufacturer under a U.S. Type Certificate issued under 21.29 or 21.617, or exported to the United States under 21.502.

(e) Each report required by this section - - -

(1) Shall be made to the FAA Regional Office in which the holder is located within 24 hours after the holder has determined that the failure, malfunction, or defect required to be reported has occurred, except that a report due on a Saturday or a Sunday may be delivered on the following Monday and one that is due on a holiday may be delivered on the next workday;

(2) Shall be transmitted in a manner and form acceptable to the Administrator by the most expeditious method available; and

(3) Shall include as much of the following information on the article as is available and applicable:

(i) Aircraft serial number.

(ii) When the failure, malfunction, or defect is associated with an article approved under a TSO authorization, the article serial number and model designation, as appropriate.

(iii) When the failure, malfunction, or defect is associated with an engine or propeller, the engine or propeller serial number, as appropriate.

(iv) Product model.

(v) Identification of the part, component, or system involved.

The identification must include the part number. "

" (vi) Nature of the failure, malfunction, or defect.

(f) Whenever the investigation of an accident or service difficulty report shows that an article manufactured under a TSO authorization is unsafe because of a manufacturing or design defect, the manufacturer shall, upon request of the Administrator, report to the Administrator the results of its investigation and any action taken or proposed by the manufacturer to correct that defect. If action is required to correct the defect in existing articles, the manufacturer shall submit the data necessary for the issuance of an appropriate airworthiness directive to the Chief, Engineering and Manufacturing Branch (or in the case of the Western Region, the Chief, Aircraft Engineering Division), of the FAA regional office in the region in which it is located.

21.305 APPROVAL OF MATERIALS, PARTS, PROCESSES, AND APPLIANCES.

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(b) Under a Technical Standard Order issued by the Administrator. Advisory Circular 20-110 contains a list of Technical Standard Orders that may be used to obtain approval. Copies of the Advisory Circular may be obtained from the U.S. Department of Transportation, Publication Section (M-443.1), Washington, D.C. 20590;

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SUBPART O - TECHNICAL STANDARD ORDER AUTHORIZATIONS

Sec.

21.601 Applicability.

21.603 TSO marking and privileges."

- " 21.605 Application and issue.
- 21.607 General rules governing holders of TSO authorizations.
- 21.609 Approval for deviation.
- 21.611 Design changes.
- 21.613 Recordkeeping requirements.
- 21.615 FAA inspection.
- 21.617 Issue of letters of TSO design approval: import appliances.
- 21.619 Noncompliance.
- 21.621 Transferability and duration.

21.601 APPLICABILITY.

(a) This subpart prescribes - -

(1) Procedural requirements for the issue of Technical Standard Order authorizations;

(2) Rules governing the holders of Technical Standard Order authorizations; and

(3) Procedural requirements for the issuance of a letter of Technical Standard Order design approval.

(b) For the purpose of this subpart - -

(1) A Technical Standard Order (referred to in this Subpart as "TSO") is issued by the Administrator and is a minimum performance standard for specified articles (for the purpose of this Subpart, articles means materials, parts, processes, or appliances) used on civil aircraft.

(2) A TSO authorization is a FAA design and production approval issued to the manufacturer of an article which has been found to meet a specific TSO. "

" (3) A letter of TSO design approval is an FAA design approval for a foreign-manufactured article which has been found to meet a specific TSO in accordance with the procedures of 21.617.

(4) An article manufactured under a TSO authorization, an FAA letter of acceptance as described in 21.603(b), or an appliance manufactured under a letter of TSO design approval described in 21.617 is an approved article or appliance for the purpose of meeting the regulations of this chapter that require the article to be approved.

(5) An article manufacturer is the person who controls the design and quality of the article products (or to be produced, in the case of an application), including the parts of them and any processes or services related to them that are procured from an outside source.

(c) The Administrator does not issue a TSO authorization if the manufacturing facilities for the product are located outside of the United States, unless the Administrator finds that the location of the manufacturer's facilities places no undue burden on the FAA in administering applicable airworthiness requirements.

21.603 TSO MARKING AND PRIVILEGES.

(a) Except as provided in paragraph (b) of this section and 21.617(c), no person may identify an article with a TSO marking unless that person holds a TSO authorization and the article meets applicable TSO performance standards."

" (b) The holder of an FAA letter of acceptance of a statement of conformance issued for an article before July 1, 1962, or any TSO authorization issued after July 1, 1962, may continue to manufacture that article without obtaining a new TSO authorization but shall comply with the requirements of 21.3, 21.607 through 21.615, 21.619, and 21.621.

(c) Notwithstanding paragraphs (a) and (b) of this section, after August 6, 1976, no person may identify or mark an article with any of the following TSO numbers:

- (1) TSO-C18, -C18a, -C18b, -C18c.
- (2) TSO-C24.
- (3) TSO-C33.
- (4) TSO-C61 or C61a.

21.605 APPLICATION AND ISSUE.

(a) The manufacturer (or an authorized agent) shall submit an application for a TSO authorization, together with the following documents, to the Chief, Engineering and Manufacturing Branch, Flight Standards Division, of the region in which the applicant is located (or in the case of the Western Region, the Chief, Aircraft Engineering Division):

(1) A statement of conformance certifying that the applicant has met the requirements of this Subpart and that the article concerned meets the applicable TSO that is effective on the date of application for that article. "

" (2) One copy of the technical data required in the applicable TSO.

(3) A description of its quality control system in the detail specified in 21.143. In complying with this section, the applicant may refer to current quality control data filed with the FAA as part of a previous TSO authorization application.

(b) When a series of minor changes in accordance with 21.611 is anticipated, the applicant may set forth in its application the basic model number of the article and the part number of the components with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.

(c) After receiving the application and other documents required by paragraph (a) of this section to substantiate compliance with this Part, and after a determination has been made of its ability to produce duplicate articles under this Part, the Administrator issues a TSO authorization (including all TSO deviations granted to the applicant) to the applicant to identify the article with the applicable TSO marking.

(d) If the application is deficient, the applicant must, when requested by the Administrator, submit an additional information necessary to show compliance with this Part. If the applicant fails to submit the additional information within 30 days after the Administrator's request, the application is denied and the applicant is so notified.

(e) The Administrator issues or denies the application within 30 days after its receipt or, if additional information has been requested, within 30 days after receiving that information. "

"21.607 GENERAL RULES GOVERNING HOLDERS OF TSO AUTHORIZATIONS

Each manufacturer of an article for which a TSO authorization has been issued under this Part shall - - -

(a) Manufacture the article in accordance with this Parts and the applicable TSO.

(b) Conduct all required tests and inspections and establish and maintain a quality control system adequate to ensure that the article meets the requirements of paragraph (a) of this section and is in condition for safe operation;

(c) Prepare and maintain, for each model of each article for which a TSO authorization has been issued, a current file of complete technical data and records in accordance with 21.613; and

(d) Permanently and legibly mark each article to which this section applies with the following information:

(1) The name and address of the manufacturer.

(2) The name, type, part number, or model designation of the article.

(3) The serial number or the date of manufacture of the article or both.

(4) The applicable TSO number. "

" 21.609 APPROVAL FOR DEVIATION

a) Each manufacturer, who requests approval to deviate from any performance standard of a TSO shall show that the standards from which a deviation is requested are compensated for by factors or design features providing an equivalent level of safety.

b) The request for approval to deviate, together with all pertinent data, must be submitted to the Chief Engineering and Manufacturer Branch, Flight Standards Division, of the region in which the manufacturer is located (or in the case of the Western Region, the Chief, Aircraft Engineering Division). If the article is manufactured in a foreign country, the request for approval to deviate, together with all pertinent data, must be submitted through the civil aviation authority in that country to the FAA.

21.611 DESIGN CHANGES

a) MINOR CHANGES BY THE MANUFACTURER HOLDING A TSO AUTHORIZATION. The manufacturer of an article under an authorization issued under this Part may make minor design changes (any change other than a major change) without further approval by the Administrator. "

" In this case, the changed article keeps the original model number (part numbers may be used to identify minor changes) and the manufacturer shall forward to the appropriate Chief, Engineering and Manufacturing Branch (or in the case of the Western Region, the Chief, Aircraft Engineering Division), any revised data that are necessary for compliance with 21.605(b).

b) MAJOR CHANGES BY MANUFACTURER HOLDING A TSO AUTHORIZATION. Any design change by the manufacturer that is extensive enough to require a substantially complete investigation to determine compliance with TSO is a major change. Before making such a change, the manufacturer shall assign a new type or model designation to the article and apply for an authorization under 21.605.

c) CHANGES BY PERSON OTHER THAN MANUFACTURER. No design change by any person (other than the manufacturer who submitted the statement of conformance for the article) is eligible for approval under this Part unless the person seeking the approval is a manufacturer and applies under 21.605(a) for a separate TSO authorization. Persons other than a manufacturer may obtain approval for design changes under Part 43 or under the applicable airworthiness regulations."

"21.613 RECORDKEEPING REQUIREMENTS

a) KEEPING THE RECORDS. Each manufacturer holding a TSO authorization under this Part shall, for each article manufactured under that authorization, keep the following records at it's factory:

1) A complete and current technical data file for each type or model article, including design drawings and specifications.

2) Complete and current inspection records showing that all inspections and tests required to ensure compliance with this Part have been properly completed and documented.

b) RETENTION OF RECORDS. The manufacturer shall retain the records described in paragraph (a)(1) of this section until it no longer manufactures the article. At that time, copies of these records shall be sent to the Administrator. The manufacturer shall retain the records described in paragraph (a)(2) of this section for a period of at least 2 years.

21.615 FAA INSPECTION

Upon the request of the Administrator, each manufacturer of an article under a TSO authorization shall allow the Administrator to- "

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- a) Inspect any article manufactured under that authorization;
 - b) Inspect the manufacturer's quality control system;
 - c) Witness any tests;
 - d) Inspect the manufacturing facilities; and
 - e) Inspect the technical data files on that article.

21.617 ISSUE OF LETTERS OF TSO DESIGN APPROVAL: IMPORT APPLIANCES.

a) A letter of TSO design approval may be issued for an appliance that is manufactured in a foreign country with which the United States has an agreement for the acceptance of these appliances for export and import and that is to be imported into the United States if-

1) The country in which the appliance was manufactured certifies that the appliance has been examined, tested, and found to meet the applicable TSO designated in 21.305(b) or the applicable performance standards of the country in which the appliance was manufactured and any other performance standards the Administrator may prescribe to provide a level of safety equivalent to that provided by the TSO designated in 21.305(b); and "

2) The manufacturer has submitted one copy of the technical data required in the applicable performance standard through its civil aviation authority.

b) The letter of TSO design approval will be issued by the Administrator and must list any deviation granted to the manufacturer under 21.609.

c) After the Administrator has issued a letter of TSO approval and the country of manufacture issues a Certificate of Airworthiness for Export as specified in 21.502(a), the manufacturer shall be authorized to identify requirements described in 21.607(d) and in the applicable TSO. Each appliance must be accompanied by a Certificate of Airworthiness for Export as specified in 21.502(a) issued by the country of manufacture.

21.619 NONCOMPLIANCE

The Administrator may, upon notice, withdraw the TSO authorization or letter of TSO design approval of any manufacturer who identifies with a TSO marking an article not meeting the performance standards of the applicable TSO.

21.621 TRANSFERABILITY AND DURATION

A TSO authorization or letter of TSO design approval issued under this Part is not transferable and is effective until surrendered, withdrawn, or otherwise terminated by the Administrator. "

If NIOSH-OSHA should adopt a program which parallel's this TSO procedure it would in effect be implementing alternate 4 as described in the Federal Register notice on June 18th. This self-certification program would allow a manufacturer who has sufficient resources to do his own test work in his own laboratory. It would not prevent those who do not have these resources from contracting the work to third party laboratories. These third party laboratories could of course be subject to NIOSH-OSHA certification if that step is deemed necessary.

NIOSH in issuing the approval after the submission of an application by the manufacturer would review the design, performance data, and quality control information submitted. As in the TSO procedure, NIOSH could take any necessary steps to satisfy itself of the adequacy of the product and the ability of the manufacturer to build the device and control its quality and distribution.

As a company who has over the past forty or so years been in the life support equipment business and has had to deal with standards specifications, certifications, approvals, qualifications, etc. by the United States and foreign government military agencies, the FDA, the Bureau of Mines, the Coast Guard, all of the major Aircraft OEM's, the Canadian Standards Association, the Department of Transportation Hazardous Materials Section, Underwriters and Factory Mutual Laboratories, and probably a few others we feel that the FAA's system is superior. It provides a degree of control which can be made appropriate to the situation and yet is flexible enough to permit rapid distribution of new technology and improved designs to the

using public. Something which is certainly not happening with the present situation at NIOSH-TCL.

With the exception that we would like to go a step further and basically allow for self-certification we generally concur with the position expressed by Frank Wilcher for the Industrial Safety Equipment Association.