

EFFECTIVE DATE: 0901 UTC, July 20, 1995.

FOR FURTHER INFORMATION CONTACT:
Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace

System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment 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 number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, D.C. on June 2, 1995.

Thomas C. Accardi,
Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows:

PART 95—[AMENDED]

1. The authority citation for part 95 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, and 40120; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.49 (b)(2).

2. Part 95 is amended to read as follows:

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES AND CHANGEOVER POINTS

[Amendment 390 effective date, July 20, 1995]

From	To	MEA
§ 95.6225 VOR Federal Airway 225 Is Amended to Read in Part		
La Belle, FL VORTAC *1400—MOCA	Diddy, FL FIX	*2000
§ 95.6381 VOR Federal Airway 381 Is Amended to Read in Part		
Bishop, CA VOR/DME *13000—MCA Nicol FIX, SE BND *Nicol, CA FIX		**13000
**12300—MOCA.		

Airway segment		Changeover points	
From	To	Distance	From
§ 95.8003 VOR Federal Airways Changeover Points			
V-97 Is Amended by Adding			
Miami, FL VORTAC	La Belle, FL VORTAC	25	Miami.
V-521 Is Amended by Adding			
Miami, FL VORTAC	La Belle, FL VORTAC	25	Miami.

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DEPARTMENT OF COMMERCE
Bureau of Export Administration
15 CFR Part 799

General Technology and Software Notes

CFR Correction

In title 15 of the Code of Federal Regulations, parts 300 to 799, revised as of January 1, 1995, on page 661,

Supplement No. 2 to § 799.1 was removed and reserved in error. The correct text of the supplement as published in title 15, revised as of January 1, 1994, reads as follows:

§ 799.1 [Corrected]

Supplement No. 2 to § 799.1—General Technology and Software Notes

1. *General Technology Note.* The export of “technology” that is “required” for the “development,” “production,” or “use” of

products on the Commerce Control List is controlled according to the provisions in each Category.

"Technology" "required" for the "development," "production," or "use" of a controlled product remains controlled even when applicable to a product controlled at a lower level.

General License GTDR, without written assurance, is available for "technology" that is the minimum necessary for the installation, operation, maintenance (checking), and repair of those products that are eligible for General Licenses or that are exported under a validated export license.

N.B.: This does not allow release under a general license of the repair "technology" controlled by 1E02.e, 1E02.f, 7E03, or 8E02.a.

N.B.: The 'minimum necessary' excludes "development" or "production" technology and permits "use" technology only to the extent "required" to ensure safe and efficient use of the product. Individual ECCNs may further restrict export of 'minimum necessary' information.

General License GTDA is available for "technology" that is publicly available or technology arising during or resulting from fundamental research. See section 779.3 of this subchapter for details on General License GTDA.)

2. *General Software Note.* General License GTDR, without written assurance, is available for release of software that is generally available to the public by being:

a. Sold from stock at retail selling points, without restriction,¹ by means of:

1. Over the counter transactions;

2. Mail order transactions; or

3. Telephone call transactions; and

b. Designed for installation by the user without further substantial support by the supplier.

General License GTDA is available for software that is publicly available.

N.B.: The General Software Note does not apply to exports of "software" controlled by other agencies of the U.S. Government (see § 770.10 of this subchapter).

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 94N-0345]

Medical Devices; Classification of Transilluminators (Diaphanosopes or Lightscanners) for Breast Evaluation

AGENCY: Food and Drug Administration, HHS.

¹ The phrase "without restriction" clarifies that software is not "generally available to the public" if it is to be sold only with bundled hardware generally available to the public. Software that is both bundled with hardware and "generally available to the public" does qualify for General License GDTR, without written assurance.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to classify the transilluminator (diaphanoscope or lightscanner) for breast evaluation into class III (premarket approval). This action is necessary to require manufacturers of transilluminators to submit a premarket approval application that includes information concerning safety and effectiveness tests for the device. This action is being taken under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

EFFECTIVE DATE: August 17, 1995.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 13, 1995 (60 FR 3168), FDA issued a proposed rule to classify transilluminators (diaphanosopes or lightscanners) for breast evaluation into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. A period of 90 days was provided for interested persons to submit written comments to FDA. FDA did not receive any comments on the proposal. Accordingly, the proposed rule is being adopted without change.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent

with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 892.1990 is added to subpart B to read as follows:

§ 892.1990 Transilluminator for breast evaluation.

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

Dated: July 10, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95-17640 Filed 7-17-95; 8:45 am]

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