

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

3. In § 411.406, paragraph (e) is revised to read as follows:

**§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.**

\* \* \* \* \*

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a PRO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 11, 1995.

Bruce C. Vladeck,  
*Administrator, Health Care Financing Administration.*

Dated: September 12, 1995.

Donna E. Shalala,  
*Secretary.*

Note: This addendum will not appear in the Code of Federal Regulations.

Addendum—Criteria for Categorization of Investigational Devices

*Category A: Experimental/ Investigational*

Category A devices include the following:

(1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments<sup>1</sup> Class III devices, refer to the criteria under Category B).

<sup>1</sup> Pre-amendments devices are devices that were marketed before the enactment of the 1976 Medical

(2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

*Category B: Non-experimental/ Investigational*

Category B devices include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required.

(5) Pre-amendments Class III devices that become the subject of an IDE after the FDA requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the FDA required the submission of an IDE.

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the FDA will agree on the additional criteria to be used. The FDA will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 95-23132 Filed 9-13-95; 4:00 pm]

BILLING CODE 4120-01-P

Device Amendments to the Food, Drug, and Cosmetic Act; that is, in commercial distribution before May 28, 1976.

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Pat 73**

[MM Docket No. 90-189; RM-6904, RM-7114, RM-7186, 7415, RM-7298]

**Radio Broadcasting Services; Farmington, Grass Valley, Jackson, CA**

AGENCY: Federal Communications Commission.

ACTION: Final rule.

**SUMMARY:** This document allots Channel 232A to Farmington, California, and substitutes Channel 232B1 for Channel 232A at Grass Valley, California, and modifies the license of Station KNCO, Grass Valley to specify operation on Channel 232B1. to accommodate these actions, this document substitutes Channel 259A for Channel 232A at Jackson, California, and modifies the license of Station KNGT, Jackson, California, to specify operation on Channel 259A. The reference coordinates for the Channel 232A allotment at Farmington, California, are 37-57-00 and 121-00-00. The reference coordinates for Channel 232B1 at Grass Valley, California, are 39-14-44 and 120-57-52. The reference coordinates for Channel 259A at Jackson, California, are 38-20-24 and 120-43-13. See 55 FR 13810 (April 12, 1990).

**EFFECTIVE DATE:** October 27, 1995.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Mass Media Bureau, (202) 776-1654.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the *First Report and Order* in MM Docket No. 90-189, adopted September 1, 1995, and released September 12, 1995. The full text of this decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

Authority: Secs.303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel 232A at Farmington.

3. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232A and adding Channel 232B1 at Grass Valley.

4. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232A and adding Channel 259A at Jackson.

Federal Communications Commission.

John A. Karousos,

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 95-22943 Filed 9-18-95; 8:45 am]

BILLING CODE 6712-01-F

**47 CFR Part 73**

[FCC 95-385]

**Mass Media: AM Expanded Band Allotment Plan**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; Interpretation.

**SUMMARY:** On September 1, 1995, in response to requests for reconsideration, the FCC adopted a Memorandum Opinion and Order which rescinded its original AM Expanded Band Allotment Plan, released October 14, 1994, and provides a thirty-day period for comments to correct the AM database and a thirty-day period for comments on the procedures which will be used to generate a new plan based on recalculated ranking factors. A fifteen-day reply period is also provided. This will enable an accurate AM expanded Band Allotment Plan to be issued by the FCC.

**DATES:** Comments to correct the AM database must be filed on or before October 19, 1995. Comments regarding the procedures which will be used to generate a new Allotment Plan must be submitted on or before October 19, 1995. Reply comments are due on or before November 3, 1995.

**ADDRESSES:** Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Jim Burtle, Audio Services Division, Mass Media Bureau, (202) 418-2670.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Memorandum Opinion and Order adopted September 1, 1995, and released September 6, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M St., NW, Washington, DC (See MM Docket 87-267). The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, 1990 M St., NW, Suite 640, Washington, DC 30036.

The FCC rescinded the AM Expanded Band Allotment Plan Adopted October 14, 1994 (DA 94-1154). The Allotment Plan identified stations that were eligible to apply for authorization for specific expanded band (1605 kHz-1705 kHz) frequency allotments. The Commission also verified that certain errors existed in the AM database used to generate the improvement factor rankings on which the Allotment Plan was based (June 30, 1993-A database) and rescinded the improvement factor ranking list. The Commission called for changes to the June 30, 1993-A AM database to be filed within thirty days of the publication of this Memorandum Opinion and Order in the Federal Register.

The FCC further identified and clarified the standards used to implement a new Allotment Plan and gave interested parties a period of thirty days from the publication of the Memorandum Opinion and Order in the Federal Register to comment thereon. Reply comments may be filed within fifteen days of the comment date.

**Final Regulatory Flexibility Analysis**

The FCC granted in part requests for reconsideration and review of the AM Expanded Band Allotment Plan adopted October 14, 1994 (DA 94-1154) and rescinded the Allotment Plan and improvement factor ranking list. The Commission will receive requests to change the June 30, 1993-A database during a thirty-day comment period. The FCC also sets forth the procedures to implement the Allotment Plan and provides for a thirty-day comment period and fifteen-day reply period, thereon.

This action is authorized under Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, and 303(r), and Section 553(b)(3)(A) of the Administrative Procedures Act.

**Ordering Clause**

Accordingly, it is ordered that the public is afforded thirty days from September 19, 1995 to change the June 30, 1993-A database, thirty days from September 19, 1995 to comment on the allotment plan procedures; and fifteen days from the comment date to file replies to the comments.

**List of Subjects in 47 CFR Part 73****Radio.**

Federal Communications Commission.

William F. Caton,

*Acting Secretary.*

[FR Doc. 95-23171 Filed 9-18-95; 8:45 am]

BILLING CODE 6712-01-M