OFFICE OF ECONOMIC ANALYSIS
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JAN 25 1996

Before the
Federal Communications Commission
Washington, D.C. 20554

ET Docket No. 95-177

In the Matter of

Amendment of Part 15 of the
Commission's Rules to Permit Operation
of Biomedical Telemetry Devices on
VHF TV Channels 7-13 and on
UHF TV Channels

NOTICE OF PROPOSED RULE MAKING

Adopted: December 5, 1995; Released: January 25, 1996

Comment Date: April 16, 1996
Reply Comment Date: May 16, 1996

By the Commission:

INTRODUCTION

1. By this action, the Commission proposes to amend Part 15 of the its rules to expand the available frequencies and increase the permitted power for unlicensed biomedical telemetry devices operating on VHF and UHF television channels. This is in response to a petition for rule making, filed on December 23, 1994, by the Critical Care Telemetry Group (CCTG).[1] CCTG maintains that a serious shortage of usable spectrum has placed at risk the continued viability of medical telemetry services and, in turn, the safety of patients who rely on the interference-free provision of these services. In adopting this Notice of Proposed Rule Making (Notice), we are seeking to provide reasonable access to additional spectrum to meet the needs of CCTG and the health care industry while protecting existing television and future advanced digital television (DTV) services from potential interference.

BACKGROUND

2. Biomedical telemetry devices are used in hospitals to transmit patient measurement data to a nearby receiver, while offering to a patient both mobility and improved comfort. Typical devices include heart, blood pressure and respiration monitors. The use of these devices allows patients to walk around early in their recovery while still being monitored for adverse symptoms. With such devices, one health care worker can monitor several patients remotely, thus decreasing health care costs. Part 15 of the Commission's rules, 47 CFR 15, permits operation of biomedical telemetry devices in the 174-216 MHz band[2] (VHF TV channels 7-13) with field strengths of 1500 microvolts-per-meter, measured at three meters, and in the 512-566 MHz band[3] (UHF TV channels 21-29) with field strengths of 200 microvolts-per-meter, measured at three meters. Biomedical telemetry devices are also authorized at higher power levels in the 450-470 MHz bands under Part 90.[4]

3. In its petition, CCTG requests that we modify the Part 15 rules to allow operation of biomedical telemetry devices with power levels not in excess of 5 milliwatts on VHF TV channels in the 174-216 MHz band and on all UHF TV channels. It is somewhat difficult to compare the power level requested by CCTG with the field strength limits currently in our rules. However, assuming the use of a typical dipole antenna, the existing rules permit powers of approximately 0.0004 milliwatts in the 174-216 MHz band and 0.000007 milliwatts on the UHF TV channels. CCTG states that frequency congestion and the current field strength restrictions make operation under Part 15 extremely difficult. Specifically, CCTG claims that the 174-216 MHz band is severely overcrowded and that the level of ambient electrical noise in healthcare facilities is becoming so high as to threaten the continued usefulness of this band. CCTG further states that not a single member of CCTG has developed equipment to operate in the 512-566 MHz band due to the restrictive field strength levels imposed in that band. CCTG indicates that heavy use of the 450-470 MHz band by land mobile operations has caused severe interference to licensed biomedical telemetry operations. CCTG adds that our proposals to increase spectrum efficiency in the Land Mobile bands in the Commission's refarming proceeding, PR Docket No. 92-235, will increase interference to licensed biomedical telemetry devices.[5] CCTG argues that the Commission's proposals to create narrowband channels with higher operating powers for land mobile users could create a scenario of several mobile users interfering with a single existing telemetry channel.[6]

4. CCTG proposes to implement co-channel separation requirements to eliminate any potential for interference being caused to television reception. It states that these separation requirements can be implemented by using either frequency-selectable devices that are installed by trained persons or fixed-frequency devices that are preset for use in a given area. CCTG adds that any interference potential is further reduced by limiting the use of these

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[1] CCTG consists of Hewlett-Packard Company Medical Products Group, Marquette Electronics, Inc., Pacific Communications, Siemens Medical Systems, Inc., and SpaceLabs Medical, Inc.

[2] *See* 47 CFR Section 15.241.

[3] *See* 47 CFR Section 15.209(g)(2).

[4] *See* 47 CFR Sections 90.27, 90.238 and 90.267. We note that Sections 90.267(a)(5) and 90.267(b)(8) permit hospitals or healthcare institutions that already hold Part 90 licenses to operate medical devices, without additional specific authorization, with output powers up to 20 milliwatts.

[5] *See Report and Order and Further Notice of Proposed Rule Making* in PR Docket No. 92-235, released June 23, 1995.

[6] In response to a letter by Hewlett-Packard, the Commission issued a Public Notice on August 11, 1995, DA 95-1771, that places a freeze on filings for high power operations on the current low power offset channels in the 450-470 MHz band. The freeze was imposed to address issues of frequency coordination between existing low power biomedical telemetry operations on those channels and new high power land mobile operations.

devices to health care facilities. Even with the future introduction of advanced digital television (DTV), CCTG asserts that useable spectrum would exist in any given area.

DISCUSSION

5. The CCTG petition makes persuasive arguments that additional spectrum and increased power are needed for biomedical telemetry devices. CCTG's proposal to operate on a low-power, non-interference basis on television channels supports spectrum efficiency by sharing frequencies between two services. Additionally, CCTG identifies a public interest of providing cost-efficient medical technologies to health care communities. Accordingly, we are proposing to amend our Part 15 rules as requested by CCTG.[7] Nevertheless, we have certain concerns about the implementation of the proposal that are discussed below.

6. The Commission has generally not permitted operation of unlicensed Part 15 devices in the television bands. Furthermore, we are in the process of making proposals to establish procedures and technical criteria for the introduction of DTV.[8] The goal of the spectrum allotment effort in this proceeding is to provide a 6 MHz transitional channel for each existing broadcast station to be used to implement DTV operations. The implementation plan currently involves a transition period during which broadcasters will continue existing TV operations as the new DTV operations are deployed. When the transition to DTV is completed, the spectrum used by existing TV operations may be reallocated and auctioned.[9] This might cause interference to or from biomedical telemetry devices operating in that spectrum. If interference occurs, the biomedical telemetry devices would be required to cease operation or change frequency because of their secondary status.

7. We recognize the need for additional spectrum for biomedical telemetry devices and believe that TV spectrum may be appropriate for use by biomedical telemetry devices, at least until DTV has been implemented. Accordingly, under Part 15 of our rules we propose to allow biomedical telemetry devices to operate on a non-interference basis on VHF channels 7-13 (174-216 MHz) and all UHF channels (470-806 MHz). We request comment on the extent to which sharing between TV operations and biomedical devices is feasible. We note that UHF channel 37 (608-614 MHz) is reserved exclusively for the radio astronomy service,[10] and we seek comment on whether sharing this spectrum with biomedical telemetry devices is viable and/or preferable to sharing with the television broadcast service. Additionally, we note that Land Mobile services are authorized to operate in parts of the 470-512 MHz band in some localities, and invite comment on the ability of biomedical telemetry devices to share this spectrum without creating or receiving harmful interference.[11] By allowing a broad range of operating frequencies, we believe that it will be easier for manufacturers and operators to identify and use unoccupied frequencies and therefore, help reduce any potential interference. We seek comment on the total amount of spectrum that is needed to support biomedical telemetry devices and whether there may be a range of operating frequencies that may be more favorable than others.

8. We note that any effort to accommodate biomedical telemetry devices in TV spectrum during the DTV transition period will require flexibility that could include changing of the frequency used by an existing biomedical telemetry device to avoid interfering with DTV channels. Therefore, we propose that biomedical telemetry devices be designed to be frequency selectable to operate over a given range of television channel frequencies. This proposal is intended to help avoid interference and minimize the economic impact of requiring biomedical telemetry device users to purchase new equipment due to changes in television frequency usage during the DTV transition period. A possible scenario would be that if a new DTV station is assigned a channel that is being used by biomedical telemetry devices, then the devices could simply be switched to an alternate operating channel. We seek comment on this proposal and whether devices should be required to implement a minimum number of selectable channels. We also propose that biomedical telemetry devices be required to vacate existing TV spectrum that is reallocated to other use as a result of the implementation of DTV.

9. As CCTG stated, the low operating field strength allowed in the 512-566 MHz band does not appear to be adequate for a viable service. We propose to allow biomedical telemetry devices to operate, as proposed by CCTG, at transmitter power levels not to exceed 5 milliwatts. We note that this power level is considered high compared to other operating limits for unlicensed Part 15 devices. We seek comment on the appropriateness of this power level considering the intended use of these devices. Specifically, we seek to identify an adequate operating power level that will support the service requirements with the least amount of interference potential to other services.

10. Current Part 15 rules generally are based on measurements of radiated emission field strengths and not on transmitter power. We are concerned that biomedical telemetry devices may not have a readily accessible antenna port to permit output power measurements and that transmitter power does not predict the potential for interference to other users as well as field strength measurements. Accordingly, we invite comment as to whether a radiated field strength limit should be used rather than a transmitter output power limit. The proposed 5 milliwatt output power appears to be comparable to a field strength of 165,000 microvolts-per-meter measured at 3 meters. Given variations in antennas and equipment designs, we believe an appropriate field strength limit would be 200,000 microvolts-per-meter measured at 3 meters. CCTG did not make any recommendation for limits on out-of-band emissions. We propose to keep the existing out-of-band emission limits in Section 15.241(c) of 150 microvolts-per-meter at 3 meters. We invite comment on this limit. Finally, we note that in typical operations the electrode cables serve as

[7] We note that the refarming procedure also could improve the situation for some low power operations including those by biomedical telemetry devices. An option available to low power operations would be to move to frequencies designated specifically for their use that are separate from those designated for high power operations.

[8] *See* MM Docket No. 87-268.

[9] *See Fourth Further Notice of Proposed Rule Making and Third Notice of Inquiry,* MM Docket No. 87-268, adopted July 28, 1995, paras. 86-87.

[10] *See* 47 CFR Section 73.603(c).

[11] *See* 47 CFR Part 90 Subpart L. Land mobile use is permitted only in the top 10 markets. In these areas, medical telemetry use of these frequencies may not be possible.

the antenna for these devices. Although, we are not proposing any limits on antenna gain, we seek comment as to whether there should be any restrictions on antenna gains for these devices.

11. The proposed operating power necessitates provisions to protect the television broadcast service. We propose to adopt the co-channel separation requirements proposed by CCTG. Biomedical telemetry devices would be required to be removed from existing and future co-channel television broadcast stations by not less than 107.1 km in Zone I and 131.8 km in Zones II and III for devices using VHF channels 7-13 in the 174-216 MHz band and 113.2 km for devices using the UHF channels in the bands 480-608 MHz and 614-806 MHz in all Zones.[12] We note that the proposed separation requirements are very close to those specified for Low Power Auxiliary Stations (LPAS) associated with broadcast stations.[13] Additionally, we note that LPAS are intended to transmit over distances of approximately 100 meters and are authorized to operate at much higher power levels than we propose for biomedical telemetry devices.[14] Given the lower operating power of biomedical telemetry devices and shorter transmission distances compared to LPAS, we seek comment on whether the proposed co-channel separation distances are overly restrictive. Additionally, we raise the question of who will be responsible for ensuring adherence to the separation distance requirement. Since there is no licensee that would be responsible for the installation of the equipment, we propose as suggested by CCTG that the equipment be installed by trained field personnel that would select the appropriate operating frequency for a given location. Therefore, the installer and end user would be responsible for ensuring that devices are properly deployed according to the separation requirements. In addition, the user will be responsible for resolving any interference that occurs subsequent to installation. Due to the low operating power of the biomedical telemetry devices we feel that the probability of interference to adjacent channel TV reception is very low and would only exist in a small area around a hospital. Nevertheless, we seek comment on whether any adjacent channel restrictions are needed.

12. We are also concerned about the interaction of the telemetry devices with Low Power Television (LPTV) stations. We indicated in the DTV proceeding that it may be necessary to displace existing LPTV stations in situations where spectrum is needed for DTV. One of the proposals to help mitigate the effects of the displacement of LPTV stations is to permit stations to relocate to other available television channels.[15] Relocation of LPTV stations could directly impact the ability of biomedical telemetry devices to find usable spectrum. We seek comment on the ability of biomedical telemetry devices to share spectrumwith the Low Power Television service.

13. The current Part 15 rules restrict the marketing and use of biomedical telemetry devices in the 512-566 MHz band to hospitals.[16] CCTG requests that we also permit biomedical devices to be operated at health care facilities. When we authorized operation of biomedical telemetry devices in the 512-566 MHz band, we recognized that a certain degree of interference shielding would be achieved by restricting use of these devices to hospital buildings. We believe similar shielding would occur in many healthcare facilities. Thus, we propose, as suggested by CCTG, to permit operation of these devices in hospitals and other healthcare facilities. However, we seek comment on what the definition of a healthcare facility should include. Further, we note that health care facilities may include nursing homes and assisted living facilities that may be located in residential neighborhoods. We are concerned about interference that may occur in these residential neighborhoods and seek comment on the impact of extending the operation of biomedical telemetry devices to health care facilities.

14. Finally, we propose to maintain a 200 kHz emission bandwidth. CCTG indicates that there is a growing need for enhanced biomedical telemetry devices that can provide data for multiple measurements from a single patient. We invite comment on whether a 200 kHz emission bandwidth is sufficient to meet the needs of these enhanced devices.

PROCEDURAL MATTERS

15. This is a non-restricted notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided that they are disclosed as provided in the Commission's rules. *See generally* 47 CFR Sections 1.1202, 1.1203, and 1.1206(a).

16. *Initial Regulatory Flexibility Analysis.* As required by Section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in this document. The IRFA is set forth in Appendix A. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the Initial Regulatory Flexibility Analysis. The Secretary shall send a copy of this Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act. Pub. L. No. 96-354, 94 Stat. 1164, 5 U.S.C. Section 601 *et seq* (1981).

17. *Comment Dates.* Pursuant to applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's Rules, 47 CFR Sections 1.415 and 1.419, interested parties may file comment on or before **April 16, 1996** and reply comments on or before **May 16, 1996**. To file formally, in this proceeding, you must file an original and five copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commis-

[12] *See* 47 CFR Section 73.609 for the definition of Zones I, II and III.

[13] *See* 47 CFR Section 74.802. Examples of low power auxiliary station uses include wireless microphones, cue and control communications and synchronization of TV camera signals.

[14] Under 47 CFR Section 74.861(e)(1)(i) and (ii) LPAS are authorized powers up to 50 mW on the VHF TV channels and 250 mW on UHF channels.

[15] *See Second Further Notice of Proposed Rule Making* in MM Docket No. 87-268, at para. 41 and footnote 48.

[16] *See* 47 CFR Section 15.209(g)(2).

sion, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center of the Federal Communications Commission, Room 239, 1919 M Street, N.W., Washington, DC 20554.

18. The proposed action is authorized under Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304, and 307 of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

19. For further information regarding this Notice of Proposed Rule Making, contact Anthony Serafini, Office of Engineering and Technology, (202) 418-2456.

FEDERAL COMMUNICATIONS COMMISSION

William F. Caton
Acting Secretary

APPENDIX A

INITIAL REGULATORY FLEXIBILITY ANALYSIS

Reason for Action

This rule making proceeding is in response to a petition for rule making received by the Commission and is initiated to obtain comments regarding whether and how the Commission should provide additional spectrum for unlicensed biomedical telemetry devices.

Objectives

The Commission seeks to determine the feasibility of allowing expanded operation of unlicensed biomedical telemetry devices on television spectrum and the necessary provisions to permit spectrum sharing without causing interference to existing and future television service.

Legal Basis

The proposed action is authorized under Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e),h)303(f), 303(r), 304 and 307.

Reporting, Recordkeeping and Other Compliance Requirements

To receive equipment authorization to operate on the additional television channels, applicants would have to demonstrate that their biomedical telemetry devices comply with the new requirements, in addition to demonstrating compliance with applicable existing equipment authorization requirements.

Federal Rules Which Overlap, Duplicate or Conflict With These Rules

None.

Description, Potential Impact and Number of Small Entities Involved

The proposed actions in this proceeding are intended to improve and support the expansion of the use of biomedical telemetry devices. There should be no adverse impact on small entities.

Any Significant Alternatives Minimizing the Impact on Small Entities Consistent with Stated Objectives

None.

APPENDIX B - PROPOSED RULES

Part 15 of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

Part 15 -- RADIO FREQUENCY DEVICES

1. The authority citation for Part 15 is revised to read as follows:

AUTHORITY: 47 U.S.C. 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

2. Section 15.209 is amended by revising paragraph (g) to read as follows:

§ 15.209 Radiated emission limits; general requirements.

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(g) Perimeter protection systems may operate in the 54-72 MHz and 76-88 MHz bands under the provisions of this section. The use of such perimeter protection systems is limited to industrial, business and commercial applications.

3. Section 15.241 is revised to read as follows:

§ 15.241 Operation in the bands 174-216 MHz, 470-608 MHz and 614-806 MHz.

(a) Operation under the provisions of this section is restricted to biomedical telemetry devices.

(b) Emissions from a biomedical telemetry device operating under the provisions of this section shall be confined within a 200 kHz band which shall lie wholly within the frequency ranges of 174-216 MHz, 470-608 MHz and 614-806 MHz.

(c) The maximum peak transmitter output power of any biomedical telemetry device operating under the provisions of this section shall not exceed five (5) milliwatts. The field strength of emissions radiated on any frequency outside of the specified 200 kHz band shall not exceed 150 microvolts/meter at 3 meters.

(d) Biomedical telemetry devices shall be designed to include a frequency selection mechanism that permits selection or retuning of operating frequencies. Biomedical telemetry devices must not cause harmful interference to licensed TV broadcast stations or to land mobile stations operating in the 470-512 MHz band. If interference occurs, the device must immediately cease operation on the occupied frequency. If an alternate frequency meeting the requirements of paragraph (e) of this section can be found, the biomedical telemetry device, may be retuned to operate on the alternate frequency. The user is responsible for resolving any interference that occurs subsequent to installation of these devices.

(e) Biomedical telemetry device installers and users must ensure that the following minimum distance separations are maintained between a biomedical telemetry device operating under the provisions of this section and television broadcast stations, authorized under Part 73 of this chapter, operating within the same channel bandwidth (minimum distance separations vary depending upon the frequency and zone, within which the relevant television station is operated, as specified in § 73.609 of this chapter):

Frequency	*Zone(s)*	*Separation (km)*
174-216 MHz band	I	107.1
174-216 MHz band	II, III	131.8
470-806 MHz band	I, II, III	113.2

(f) The marketing and the use of biomedical telemetry devices operating under the provisions of this section shall be confined to hospitals or other healthcare facilities.