

■ 2. Subpart E is added to part 46 to read as follows:

Subpart E—Registration of Institutional Review Boards

Sec.

- 46.501 What IRBs must be registered?
- 46.502 What information must be provided when registering an IRB?
- 46.503 When must an IRB be registered?
- 46.504 How must an IRB be registered?
- 46.505 When must IRB registration information be renewed or updated?

§ 46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under § 46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§ 46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:
(i) All active protocols; and
(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 05-312; FCC 08-256]

Digital Television Distributed Transmission System Technologies

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of six months,

the information collection(s) associated with section 73.626(f) of the rules, and that this rule will take effect as of the date of this notice. On December 5, 2008, the Commission published the summary document of the Report and Order, *In the Matter of the Digital Television Distributed Transmission System Technologies*, MB Docket No. 05-312, FCC 08-256, at 73 FR 74047. The Ordering Clause of the Report and Order stated that the Commission would publish a notice in the **Federal Register** announcing when OMB approval for this rule section which contains information collection requirements has been received and when the revised rule will take effect. This notice is consistent with the statement in the Report and Order.

DATES: Effective January 15, 2009.

FOR FURTHER INFORMATION CONTACT: For additional information, please contact Evan Baranoff, Evan.Baranoff@fcc.gov, of the Media Bureau, Policy Division, (202) 418-2120.

SUPPLEMENTARY INFORMATION: This document announces that, on December 29, 2008, OMB approved, for a period of six months, the information collection requirement(s) contained in Section 73.626(f) of the rules. The Commission publishes this notice to announce the effective date of this rule. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1-C823, 445 12th Street, SW., Washington, DC 20554. Please include OMB Control Numbers 3060-0027 and 3060-0029, in your correspondence. The Commission will also accept your comments via the Internet if you send them to PRA@fcc.gov.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on December 29, 2008, for the information collection requirement(s) contained in the Commission's rules at 47 CFR 73.626(f).

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of

information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid OMB Control Number.

The OMB Control Numbers are 3060–0027 and 3060–0029 and the total annual reporting burdens for respondents for these information collections are as follows:

OMB Control Numbers: 3060–0027.

OMB Approval Date: December 29, 2008.

Expiration Date: June 30, 2009.

Title: Application for Construction Permit for Commercial Broadcast Station, FCC Form 301.

Form Number: FCC Form 301.

Type of Review: Revision to a currently approved collection.

Respondents: Business or other for profit entities; Not for profit institutions.

Number of Respondents/Responses: 4,378 respondents; 7,814 responses.

Estimated Hours per Response: 1–5 hours per response.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 14,808 hours.

Total Annual Cost: \$52,580,197.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act Assessment: No impact(s). *Needs and Uses:* On November 3,

2008, the Commission adopted a Report and Order, In the Matter of Digital Television Distributed Transmission System Technologies; MB Docket No. 05–312, FCC 08–256 (released Nov. 7, 2008). In this Report and Order, the Commission adopts rules for the use of distributed transmission system (“DTS”) technologies in the digital television (“DTV”) service. See 47 CFR 73.626. DTS technology allows stations to employ multiple synchronized transmitters spread around a station’s service area, rather than the current single-transmitter approach. Each transmitter would broadcast the station’s DTV signal on the same channel, similar to analog TV booster stations but more efficiently. Due to the synchronization of the transmitted signals, DTV receivers should be able to treat the multiple signals as reflections or “ghosts” and use “adaptive equalizer” circuitry to cancel or combine them to produce a single signal.

Congress has mandated that after February 17, 2009, full-power television broadcast stations must transmit only in digital signals, and may no longer transmit analog signals. Emergency OMB approval is necessary for this collection to allow full-power DTV stations to use DTS technologies to meet their statutory responsibilities and begin operations on their final, post-transition (digital) channels by their construction deadlines. DTS will provide DTV broadcasters with an important tool for providing optimum signal coverage for their viewers. For some broadcasters that are changing channels or transmitting locations for their digital service, DTS may offer the best option for continuing to provide over-the-air service to current analog viewers, as well as for reaching viewers that have historically been unable to receive a good signal due to terrain or other interference.

FCC Form 301 is being revised to accommodate the filing of DTS applications.

OMB Control Numbers: 3060–0029.

OMB Approval Date: December 29, 2008.

Expiration Date: June 30, 2009.

Title: Application for TV Broadcast Station License, Form FCC 302–TV; Application for DTV Broadcast Station License, FCC Form 302–DTV; Application for Construction Permit for Reserved Channel Noncommercial Educational Broadcast Station, FCC Form 340; Application for Authority to Construct or Make Changes in an FM Translator or FM Booster Station, FCC Form 349.

Form Number: FCC Forms 302–TV, 302–DTV, 340 and 349.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for profit entities; Not for profit institutions.

Number of Respondents/Responses: 4,425 respondents; 6,425 responses.

Estimated Hours per Response: 1–4 hours per response.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 14,450 hours.

Annual Burden Cost: \$21,869,625.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act Assessment: No impact(s).

Needs and Uses: On November 3, 2008, the Commission adopted a Report

and Order in the Matter of Digital Television Distributed Transmission System Technologies; MB Docket No. 05–312, FCC 08–256 (released Nov. 7, 2008). In this Report and Order, the Commission adopts rules for the use of distributed transmission system (“DTS”) technologies in the digital television (“DTV”) service. See 47 CFR 73.626. DTS technology allows stations to employ multiple synchronized transmitters spread around a station’s service area, rather than the current single-transmitter approach. Each transmitter would broadcast the station’s DTV signal on the same channel, similar to analog TV booster stations but more efficiently. Due to the synchronization of the transmitted signals, DTV receivers should be able to treat the multiple signals as reflections or “ghosts” and use “adaptive equalizer” circuitry to cancel or combine them to produce a single signal.

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FCC Form 340 is being revised to accommodate the filing of DTS applications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

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