

directions for use, to treat the indicated aesthetic use.

(4) Clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use to achieve the intended aesthetic results.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Instructions for cleaning the device must be validated.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety, including the mechanical integrity, of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include:

(i) Warnings, precautions, and contraindications to ensure the safe use of the device for the over-the-counter users.

(ii) A statement that the safety and effectiveness of the device's use for uses other than the indicated aesthetic use are not known.

(iii) A summary of the clinical information used to establish effectiveness for each indicated aesthetic usage and observed adverse events.

Dated: June 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-15381 Filed 6-28-16; 8:45 am]

BILLING CODE 4164-01-P

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 205

RIN 0412-AA69

Participation by Religious Organizations in USAID Programs

AGENCY: U.S. Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This rule amends AID regulations to address provisions which are more restrictive than relevant Federal case law and relevant legal opinions issued by the United States Department of Justice with respect to the applicability of the Establishment Clause to the use of Federal funds.

DATES: This rule will be effective July 29, 2016.

FOR FURTHER INFORMATION CONTACT:

Mark Brinkmoeller, Director, Center for Faith-Based and Community Initiatives, USAID, Room 6.07-023, 1300 Pennsylvania Avenue NW., Washington,

DC 20523; *telephone:* (202) 712-4080 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On October 20, 2004, USAID published its final rule (the "Current Rule") on participation by religious organizations in USAID programs (69 FR 61716, codified at 22 CFR parts 202, 205, 211, and 226). The Current Rule implemented Executive Branch policy that, within the framework of Constitutional guidelines, religious organizations should be able to compete on an equal footing with other organizations for USAID funding. The Current Rule revised USAID regulations pertaining to grants, cooperative agreements and contracts awarded for the purpose of administering grant programs to ensure their compliance with this policy and to clarify that religious organizations are eligible to participate in programs on the same basis as any other organization, with respect to programs for which such other organizations are eligible.

Among other things, the Current Rule provided that USAID funds could be used for the acquisition, construction, or rehabilitation of structures only to the extent that those structures were used for conducting eligible activities under the specific USAID program. Where a structure also is used for inherently religious activities, the Current Rule clarified that USAID funds could not exceed the cost of those portions of the acquisition, construction, or rehabilitation that were attributable to eligible activities. The Current Rule went on to state that USAID funds could not be used for acquisition, construction, or rehabilitation of sanctuaries, chapels, or any other room that a religious congregation that is a recipient or sub-recipient of USAID assistance uses as its principal place of worship. Since the implementation of the Current Rule, USAID has found that this provision has constricted its ability to pursue the national security and foreign policy interests of the United States overseas.

The Supreme Court has not addressed whether the Establishment Clause applies extraterritorially. In *Lamont v. Woods*, 948 F.2d 825, 834 (2d Cir. 1991), the Second Circuit concluded that the Establishment Clause applies to government grants to foreign religious institutions located abroad. In dicta in *Lamont*, the court said that "domestic Establishment Clause jurisprudence has more than enough flexibility to accommodate any special circumstances created by the foreign situs of the expenditures, although the international

dimension does . . . enter into the analysis."¹ The Second Circuit also suggested that the requirements of the Establishment Clause might be relaxed in certain circumstances, noting that "the fact that a particular grantee is the only channel for aid, or that a given country has no secular education system at all, may warrant overriding the usual Establishment Clause presumption." *Id.*, at 842. Under these circumstances, the Second Circuit said, "[t]he court would then scrutinize the manner in which the institution may use its grant in an attempt to ascertain whether, in reality, the grant would have the principal or primary effect of advancing religion." *Id.* The Second Circuit also indicated that the foreign policy ramifications of the case made it particularly inappropriate to adopt a mechanical approach to the Establishment Clause. The final rule will permit USAID to take these considerations into account, in consultation with DOJ.

In addition, the Current Rule is more restrictive than at least two legal opinions written by the U.S. Department of Justice's Office of Legal Counsel. In a September 25, 2002 Memorandum Opinion for the General Counsel of FEMA, *Authority of FEMA to provide Disaster Assistance to Seattle Hebrew Academy*, the Office of Legal Counsel concluded that FEMA could provide a disaster assistance grant to the Seattle Hebrew Academy, for repairs to the Academy following the Nisqually Earthquake on February 28, 2001. The Current Rule may not permit USAID to provide assistance under similar circumstances to a religious school or other religious structure in the aftermath of a natural disaster overseas. In an April 30, 2003 Memorandum Opinion for the Solicitor of the Department of the Interior, *Authority of the Department of the Interior to Provide Historic Preservation Grants to Historic Religious Properties Such as the Old North Church*, the Office of Legal Counsel concluded that the Establishment Clause did not bar the award of historic preservation grants to the Old North Church or other active houses of worship that qualify for such assistance. The current rule does not permit the use of USAID funds for acquisition, construction, or rehabilitation of structures to the extent that those structures are used for inherently religious activities, and further does not permit the acquisition, construction, or rehabilitation of sanctuaries, chapels, or any other room that a religious congregation uses as its principal place of worship, and thus likely would not

¹ *Id.* at 841.

permit USAID to provide similar historic preservation assistance to religious structures overseas.

Because the Current Rule is more restrictive than the Office of Legal Counsel opinions in *Seattle Hebrew Academy* and *Old North Church*, and because it does not afford USAID the flexibility to evaluate the validity and scope of the *Lamont* considerations in specific contexts, USAID has concluded that the Current Rule unnecessarily limits its ability to effectively implement the foreign assistance programs of the United States. In carrying out its statutory mission, USAID should not unnecessarily adhere to a regulation that is more restrictive than the Establishment Clause requires. Accordingly, USAID is publishing this Final Rule so that part 205 will not prohibit USAID funds from being used for activities that are consistent with the Establishment Clause. The goal of USAID in promulgating this Final Rule is to ensure compliance with the Establishment Clause. This Final Rule does not include changes in response to Executive Order 13559; USAID, as part of a larger interagency effort, issued a Final Rule incorporating changes required by this Executive Order on April 4, 2016 in coordination with other agencies similarly updating their rules.

II. Rulemaking History

On March 25, 2011, USAID published a proposed rule (the “Proposed Rule”) in the **Federal Register** (76 FR 16712) that would amend part 205 to more accurately reflect current Establishment Clause jurisprudence with respect to the use of Federal funds. Interested parties were given 45 days to comment on the Proposed Rule. During the 45-day comment period, USAID received comments from 9 respondents. These comments are discussed below by topic.

Comment: One commenter stated that the Proposed Rule did not differ very much from the Current Rule and questioned whether the proposed changes would lessen or alleviate the restrictions placed on USAID by the Current Rule.

USAID Response: The Current Rule prohibits the use of USAID funds for the acquisition, construction, or rehabilitation of structures to the extent that those structures are used for inherently religious activities. Thus, for example, under the Current Rule USAID might be prohibited from constructing or rehabilitating public schools in Afghanistan, since all schools in the public education system in Afghanistan require at least one course in Islamic education. However, under the Final Rule promulgated today, USAID would

be permitted to pay the full costs for the construction or rehabilitation of public schools in Afghanistan if funding conformed to the requirements of the Establishment Clause. Similarly, under the Current Rule USAID might be prohibited from constructing or rehabilitating religious schools that have suffered damage as a result of a manmade or natural disaster overseas. However, under the Final Rule, consistent with the Establishment Clause, USAID may be permitted to pay such costs, when such assistance is consistent with the Establishment Clause.

Comment: A number of comments expressed concern that the Proposed Rule was contrary to Establishment Clause jurisprudence in that it proposed a “new, untried, expansive standard” and, as a result, would permit the use of direct aid for inherently religious activities or programs. In particular, concern was expressed that under the Proposed Rule USAID would use funds “to acquire or construct houses of worship and other religious structures” or would “make grants to . . . congregations to cover the entire cost of constructing church buildings, synagogues, temples, and mosques.” Concerns also were expressed because the Proposed Rule did not state whether it would apply only to the use of USAID funds outside of the United States or whether it also would apply to domestic use of such funds.

Commenters pointed out that the standard, or criteria, set forth in the Proposed Rule appeared to be derived from Justice Thomas’ plurality opinion in *Mitchell v. Helms*, 530 U.S. 793 (2000), which is not binding precedent, rather than from Justice O’Connor’s concurring (and controlling) opinion in *Mitchell*, which prohibits direct funding of religious activities. Commenters also cited the Supreme Court’s decisions in *Tilton v. Richardson*, 403 U.S. 672 (1971), *Hunt v. McNair*, 413 U.S. 734 (1973), and *Committee for Public Education v. Nyquist*, 413 U.S. 756 (1973), for the proposition that Federal funds may not be used for the construction, maintenance or repair of buildings in which religious activities take place.

USAID Response: First, this Final Rule is intended only to apply to the use of USAID funds overseas. While USAID funds are expended in the United States for such activities as agricultural and scientific research, and training and education of foreign participants, USAID funds are not spent domestically for the acquisition, construction, or rehabilitation of physical structures (other than for USAID staff).

Second, it is not USAID’s intent to acquire or construct new houses of worship or other, similar religious structures (as opposed to rehabilitating or restoring existing religious structures). USAID has no plans to engage in such activity nor can USAID envision a factual scenario under which the agency would engage in such activity.

Third, USAID agrees that the standard, or criteria, set forth in the Proposed Rule did not fully reflect the analysis of Justice O’Connor’s concurring opinion in *Mitchell*. USAID did not intend for paragraph (d) of part 205.1, as revised in the Proposed Rule, to constitute the entire Establishment Clause analysis. Rather, USAID intended to conduct a more comprehensive legal analysis including but not limited to the criteria set forth in revised paragraph (d). Nevertheless, USAID acknowledges the validity of the concerns expressed by the commenters, and has decided not to adopt a formulaic approach to addressing the permissibility of the use of funds for future, proposed acquisition, construction, or rehabilitation of structures overseas. Rather, this Final Rule eliminates an attempt to define in a regulation the current state of appropriate Establishment Clause analysis as it applies to overseas programs, and instead reiterates that USAID programs must conform to the requirements of the Establishment Clause.

While USAID agrees that current Establishment Clause jurisprudence requires the Agency to more closely track Justice O’Connor’s concurring opinion in *Mitchell*, the Agency does not agree that the decisions in *Tilton* and *Nyquist* would prohibit the use of USAID funds for programs contemplated under the Proposed Rule. In its *Seattle Hebrew Academy* opinion, the Department of Justice’s Office of Legal Counsel stated that FEMA disaster assistance grants are “more closely analogous to the provision of ‘general’ government services” that the Court had approved “than to the construction grants at issue in *Tilton* and *Nyquist* which were available only to educational institutions.” In its *Old North Church* opinion, the Office of Legal Counsel stated that “‘significant portions’ of the reasoning in *Tilton* and *Nyquist* are ‘subject to serious question in light of more recent decisions.’” USAID intends to issue guidance to its staff outlining the types of activities it contemplates funding and when and how staff should consult with USAID’s legal counsel. USAID’s legal counsel

may in turn consult with the Department of Justice when appropriate.

Comment: Some commenters stated that the Proposed Rule was inconsistent with President Obama's November 17, 2010 Executive Order on Fundamental Principles and Policymaking Criteria for Partnerships With Faith-Based and Other Neighborhood Organizations (Executive Order 13559). In particular, concern was expressed that the Proposed Rule would authorize religious organizations to use USAID funds for the acquisition or construction of houses of worship or other structures used for inherently or explicitly religious activity. Direct support for such structures, according to comments received, would contravene Executive Order 13559, thereby conflicting with Administration policy. It also was pointed out that the Proposed Rule referred to "inherently religious activities," while Executive Order 13559, in response to recommendations made by President Obama's Advisory Council on Faith-Based and Neighborhood Partnerships, uses the term "explicitly religious activities" instead.

USAID Response: It is not USAID's intention to permit recipients to use Federal funds for inherently religious activities, as such term is used in the Current Rule or for "explicitly religious activities" in contravention of Executive Order 13559. The Agency does not believe the Proposed Rule suggested otherwise. Nevertheless, with this Final Rule, USAID makes clear that its programs must conform to the requirements of the Establishment Clause.

USAID is aware of the changes, or amendments, made to Executive Order 13279 (issued by President Bush on December 12, 2002) by Executive Order 13559 (issued by President Obama on November 17, 2010), and began procedures to effect those changes through further amendment to part 205. In that regard, USAID was an active member in an interagency working group, established pursuant to section 3 of Executive Order 13559, to review and evaluate existing agency regulations, guidance documents and policies that have implications for faith-based and other neighborhood organizations. The working group issued its report in April 2012. In August 2013, OMB issued guidance reconvening the Working Group to develop a plan for agency implementation of the Executive Order. USAID participated in that Working Group's development of a plan and issued a Notice of Proposed Rulemaking (NPRM) on August 6, 2015. Following the Working Group's review and

analysis of comments received pursuant to that NPRM, USAID published a Joint Final Rule on that topic in conjunction with the other relevant agencies on April 4, 2016. This Final Rule does not affect the changes made by the April 4, 2016 Joint Final Rule.

Comment: One commenter suggested that the Proposed Rule had been published without benefit or review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA).

USAID Response: This is not correct. The Proposed Rule was indeed shared with OIRA prior to publication. The proposed rule was not deemed a significant regulatory action under Executive Order 12866. This Rule was submitted to OIRA for review prior to its publication in the **Federal Register**, and was deemed a significant regulatory action by OIRA.

Comment: One commenter asserted that the Proposed Rule would create non-uniform rules across the U.S. Government. This would be inconsistent, according to the commenter, with Executive Order 13559 which calls for "uniformity in agencies' policies."

USAID Response: The quoted language in Executive Order 13559 refers to the purpose for which the President ordered the establishment of an Interagency Working Group on Faith-Based and Other Neighborhood Partnerships. The Executive Order does not address the issue of acquisition, construction, or rehabilitation of physical structures.

Comment: Some comments expressed the view that the activities described in the Proposed Rule reflected unwise policy or that they violated fundamental, or core, principles of religious freedom and, therefore, should be rejected. Recognizing that the Constitution guarantees free exercise of religion, the commenters contended that the Constitution's prohibition on establishment of religion would preclude USAID from using taxpayer funds to construct and maintain houses of worship.

USAID Response: As has been stated above, it is not USAID's intent to use funds to acquire or construct new houses of worship or other, similar religious structures (as opposed to rehabilitation or restoration of existing religious structures under certain circumstances) that are dedicated to religious activities. Thus, many of the concerns expressed should be alleviated. In addition, it should be noted that USAID would fund programs under this Final Rule for reasons that are neutral with respect to religion and

do not take account of the religious or non-religious nature of the activities that might take place within the structure.

USAID implements programs in countries where the principle of separation of church and state is not embraced, where there may be state-sponsored religion (e.g., there may be a Ministry of Religion), where there is only a religious school system, where the judicial system may be based upon or strongly influenced by state religion, and where there may be little religious diversity. Consequently, even guided by purely secular, developmental and foreign policy considerations, USAID may fund such programs as temporary structures used by Catholic parochial schools following an earthquake, or restoration of Buddhist temples as part of cultural and historical preservation programs. In none of these instances would USAID take action based on religious considerations. In none of these instances would USAID take action whose purpose was to support the explicitly religious activities conducted in these structures. Under such circumstances, USAID does not believe that funding of these programs would infringe the Constitution's principles of religious freedom, nor does USAID believe that such funding would promote the "establishment" of religion in these foreign countries. See the Memorandum Opinions of the Department of Justice's Office of Legal Counsel in *Seattle Hebrew Academy* and *Old North Church*.

Under the Final Rule, USAID may identify circumstances where, when considering implementing a program involving the acquisition, construction, or rehabilitation of structures that are used for explicitly religious activities in a country with an environment such as that described above, it might believe it necessary to go beyond the parameters set forth in the OLC opinions in *Seattle Hebrew Academy* and the *Old North Church* cases. In such cases, USAID would only implement such a program after consultation with the Department of Justice. To promote transparency, USAID commits to publishing a description of any specific program involving the acquisition, construction, or rehabilitation of structures it implements following such consultation on its Web site. USAID expects this to occur only on rare occasions. This Final Rule makes this consultation and publication commitment clear with additional text in section (d).

Comment: One commenter referred to USAID's regulations on branding and marking and expressed concern that a house of worship or religious school

constructed with USAID funds would have a durable sign, plaque or other marking installed, thereby reflecting USAID (and U.S. Government) support for the religion observed in the house of worship or school.

USAID Response: As previously stated, USAID has no intent to use funds to acquire or construct new houses of worship or other, similar religious structures (as opposed to rehabilitation or restoration of existing religious structures) that are dedicated to religious activities. Also, as previously stated, the likelihood that USAID would find circumstances where it would finance the construction of such structures is slim. In any event, USAID's regulations governing branding and marking include waiver provisions based on "compelling political concerns." Should USAID funds be used for rehabilitation or restoration of existing religious structures, such as following a natural disaster overseas, the agency would avail itself of this waiver authority and would not install any type of sign, plaque or other marking identifying the structure with the U.S. Government.

III. Findings and Certifications or Impact Assessment

Regulatory Planning and Review

This is a significant regulatory action and, therefore, is subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804. USAID has concluded that the current rule goes beyond the requirements of the Establishment Clause and other Federal law, and unnecessarily and unduly constrict USAID's ability to pursue the national security and foreign policy interests of the United States overseas. The changes do not, however, pose any new paperwork or reporting requirements, nor would they represent an increase in costs to either applicants for USAID funding or to USAID itself.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), USAID has considered the economic impact of the proposed rule and has determined that its provisions would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 22 CFR Part 205

Foreign aid, Grant programs, Nonprofit organizations.

For the reasons stated in the preamble, USAID amends chapter II of

title 22 of the Code of Federal Regulations as follows:

PART 205—PARTICIPATION BY RELIGIOUS ORGANIZATIONS IN USAID PROGRAMS

■ 1. The authority citation for part 205 continues to read as follows:

Authority: 22 U.S.C. 2381(a).

■ 2. Amend § 205.1 as follows:

■ a. Revise paragraph (d).

■ b. Redesignate paragraphs (j) and (i) as paragraphs (i) and (k) respectively.

■ c. Add a new paragraph (j).

The revision and addition read as follows:

§ 205.1 Grants and cooperative agreements.

* * * * *

(d) USAID must implement its programs in accordance with the Establishment Clause. Nothing in this part shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law. USAID will consult with the U.S. Department of Justice if, in implementing a specific program involving overseas acquisition, rehabilitation, or construction of structures used for explicitly religious activities, there is any question about whether such funding is consistent with the Establishment Clause. USAID will describe any program implemented after such consultation on its Web site.

* * * * *

(j) Nothing in this part shall be construed as authorizing the use of USAID funds for the acquisition, construction, or rehabilitation of religious structures inside the United States.

Mark Brinkmoeller,

Director, Center for Faith-Based and Community Initiatives.

[FR Doc. 2016-15293 Filed 6-28-16; 8:45 am]

BILLING CODE 6116-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2016-0181]

Drawbridge Operation Regulation; North Landing River, Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from drawbridge regulations; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the S165 (North Landing Road) Bridge across the North Landing River, mile 20.2, at Chesapeake, VA. This modified deviation is necessary to perform emergency bridge repairs and provide for safe navigation. This modified deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 6 p.m. on June 30, 2016, through 6:00 p.m. on September 30, 2016.

ADDRESSES: The docket for this deviation, [USCG-2016-0181] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard, telephone 757-398-6222, email Hal.R.Pitts@uscg.mil.

SUPPLEMENTARY INFORMATION: On March 11, 2016, the Coast Guard published a temporary deviation entitled "Drawbridge Operation Regulation; North Landing River, Chesapeake, VA" in the **Federal Register** (81 FR 12824) and on April 8, 2016, the Coast Guard published a modified temporary deviation entitled "Drawbridge Operation Regulation; North Landing River, Chesapeake, VA" in the **Federal Register** (81 FR 20529). These documents were necessary to authorize a temporary deviation from the operating regulations to perform repairs to the south swing span of the bridge due to damage sustained as a result of a vessel allision with the bridge that occurred on March 1, 2016. The United States Army Corps of Engineers, Norfolk District Office, who owns and operates the S165 (North Landing Road) Bridge, has requested a modified temporary deviation from the current operating regulations to perform repairs to the south swing span of the bridge, following completion of an ongoing roadway construction project on Elbow Road, Chesapeake, VA, in which the S165 (North Landing Road) Bridge is currently serving as a detour route. The modified temporary deviation request is necessary to provide for public safety and access during the roadway construction project.

The current operating schedule is set out in 33 CFR 117.1021. Under this modified temporary deviation, the north span of the bridge will open-to-navigation on the hour and half hour, upon request, from 6 a.m. to 7 p.m., and