

(8) The extent to which the study minimizes the use of defaults and assumptions, uses appropriate and strong statistical methods, and includes a robust representation of uncertainty and confidence intervals; and

(9) The study's consideration of a broad range of parametric dose-response or concentration-response models, a robust set of potential confounding variables, nonparametric models that incorporate fewer assumptions, various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity.

(e) The EPA shall also describe critical assumptions and methods used in its dose-response assessment and shall characterize the variability and uncertainty of the assessment. The EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. The EPA shall clearly explain the scientific basis for critical assumptions used in the dose-response assessment that the EPA relied on for the significant regulatory action or influential scientific information.

(f) Where the Agency is making dose-response data publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national security. Dose-response data is considered "publicly available in a manner sufficient for independent validation" when it includes the information necessary for the public to understand, assess, and reanalyze findings and may include, for example:

(1) Data (data would be made available subject to access and use restrictions);

(2) Associated protocols necessary to understand, assess, and extend conclusions;

(3) Computer codes and models involved in the creation and analysis of such information;

(4) Recorded factual materials; and

(5) Detailed descriptions of how to access and use such information.

(g) The provisions of this section apply to dose-response data underlying studies that are pivotal science, regardless of who funded or conducted the studies. The Agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national security is not possible.

§ 30.6 What role does independent peer review have in this part?

The EPA shall conduct independent peer review consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein. The EPA will evaluate whether or not to conduct additional peer review of individual studies identified as pivotal science if the studies have already undergone journal peer review. Because transparency in pivotal science includes addressing issues associated with assumptions used in analyzing dose-response data, the EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied and the implications of those assumptions for the results.

§ 30.7 May the EPA Administrator grant exemptions to this part?

(a) The Administrator may grant an exemption to this part for a study on a case-by-case basis if he or she determines that greater consideration is warranted because:

(1) Technological or other barriers render sharing of the dose-response data infeasible;

(2) The development of the dose-response data was completed or updated before January 6, 2021;

(3) Making the dose-response data available would conflict with laws and regulations governing privacy, confidentiality, confidential business information, or national security;

(4) A third-party has conducted independent validation of the study's underlying dose-response data through reanalysis; or

(5) The factors used in determining the consideration to afford to the pivotal science indicate full consideration is justified.

(b) When making a decision to grant an exemption, the Administrator may consider input from EPA staff and public commenters. The EPA shall document the rationale for exemptions granted by the Administrator in the significant regulatory action or influential scientific information.

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AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Chapter 7

RIN 0412-AA86

Leave and Holidays for U.S. Personal Services Contractors, including Family and Medical Leave; Corrections

AGENCY: Agency for International Development.

ACTION: Correcting amendments; final rule.

SUMMARY: On October 16, 2020, the U.S. Agency for International Development (USAID) issued a final rule revising provisions of the AID Acquisition Regulation (AIDAR) that pertain to the General Provision contract clause 5, entitled "Leave and Holidays" for U.S. personal services contractors (USPSCs.) This document corrects typographical errors in the final rule by revising the text of clause 5, adding the effective dates in the titles of clauses 6 and 16, and revising the authority citation.

DATES: Effective January 6, 2021.

FOR FURTHER INFORMATION CONTACT: Richard E. Spencer, Procurement Analyst, by phone at 202-916-2629, or email at rspencer@usaid.gov. All communications regarding this rule must cite AIDAR RIN No. 0412-AA86.

SUPPLEMENTARY INFORMATION: USAID is correcting errors in the final rule entitled "Leave and Holidays for U.S. Personal Services Contractors, including Family and Medical Leave," under AIDAR 48 CFR chapter 7, appendix D, which was published in the **Federal Register** on October 16, 2020 (85 FR 65734). This document corrects the following typographical errors in AIDAR appendix D. In section 12 clause 5, the title is revised to remove italics, and the last sentence of paragraph (a)(3) is revised because the final rule mistakenly included the word "either" twice, making the application of the sub-paragraphs (i) and (ii) illogical and impossible to apply. This document corrects the construction of this sentence in paragraph (a)(3) to ensure only one of the two sub-paragraphs (i) or (ii) may apply, and by using the matching terminology for "exceptional circumstances" that appears earlier in the paragraph. In the titles for clauses 6, "Differential and Allowances," and 16, "Termination", the effective dates missing from the final rule are inserted for each clause. Lastly, the final rule mistakenly included an instruction to add a parenthetical authority citation at the end, unnecessarily creating a double citation. This document instead revises

the one authority citation that already exists. This document does not make any substantive changes to the final rule.

List of Subjects in 48 CFR Chapter 7, Appendix D

Government procurement.
Accordingly, 48 CFR chapter 7 is corrected by making the following amendments:

CHAPTER 7— AGENCY FOR INTERNATIONAL DEVELOPMENT

- 1. Amend appendix D to chapter 7 by:
- a. In section 12:
- i. In clause 5, by revising the clause heading, the last sentence in paragraph (a)(3) introductory text, paragraphs (a)(3)(i) and (ii); and
- ii. In clauses 6 and 16, revising the clause headings; and

- b. Revising the parenthetical authority citation at the end of the appendix.
The revisions read as follows:

Appendix D to Chapter 7—Direct USAID Contracts with a U.S. Citizen or a U.S. Resident Alien for Personal Services Abroad

* * * * *

12. General Provisions for a Contract With a U.S. Citizen or a U.S. Resident Alien for Personal Services Abroad

* * * * *

5. Leave and Holidays

[Insert the following clause in all USPSC contracts.]

Leave and Holidays (NOV 2020)

- (a) * * *
- (3) * * * Annual leave restored must be scheduled and used no later than the earlier of either—

- (i) The end of the leave year two years after the date fixed by the approving official as the termination date of the exceptional circumstances beyond the contractor's control, which resulted in the forfeiture; or
- (ii) The end of the contract.

* * * * *

6. Differentials and Allowances (NOV 2020)

* * * * *

16. Termination (NOV 2020)

* * * * *

(Authority: Sec. 621 of Pub. L. 87–195, 75 Stat. 445, (22 U.S.C. 2381) as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; and 3 CFR 1979 Comp., p. 435)

Mark A. Walther,
Chief Acquisition Officer.
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