

Preponderance of the evidence. Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Principal. Officer, director, owner, partner, key employee, or other person within a participant with primary management or supervisory responsibilities; or a person who has a critical influence on or substantive control over a covered transaction, whether or not employed by the participant. Persons who have a critical influence on or substantive control over a covered transaction are:

- (1) Principal investigators.

Proposal. A solicited or unsolicited bid, application, request, invitation to consider or similar communication by or on behalf of a person seeking to participate or to receive a benefit, directly or indirectly, in or under a covered transaction.

Respondent. A person against whom a debarment or suspension action has been initiated.

State. Any of the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency of a State, exclusive of institutions of higher education, hospitals, and units of local government. A State instrumentality will be considered part of the State government if it has a written determination from a State government that such State considers that instrumentality to be an agency of the State government.

Suspending official. An official authorized to impose suspension. The suspending official is either:

- (1) The agency head, or
- (2) An official designated by the agency head.

Suspension. An action taken by a suspending official in accordance with these regulations that immediately excludes a person from participating in covered transactions for a temporary period, pending completion of an investigation and such legal, debarment, or Program Fraud Civil Remedies Act proceedings as may ensue. A person so excluded is "suspended."

Voluntary exclusion or voluntarily excluded. A status of nonparticipation or

limited participation in covered transactions assumed by a person pursuant to the terms of a settlement.

[57 FR 56263, Nov. 27, 1992, as amended at 60 FR 33041, 33045, June 26, 1995]

§ 1404.110 Coverage.

(a) These regulations apply to all persons who have participated, are currently participating or may reasonably be expected to participate in transactions under Federal nonprocurement programs. For purposes of these regulations such transactions will be referred to as "covered transactions."

(1) *Covered transaction.* For purposes of these regulations, a covered transaction is a primary covered transaction or a lower tier covered transaction. Covered transactions at any tier need not involve the transfer of Federal funds.

(i) *Primary covered transaction.* Except as noted in paragraph (a)(2) of this section, a primary covered transaction is any nonprocurement transaction between an agency and a person, regardless of type, including: Grants, cooperative agreements, scholarships, fellowships, contracts of assistance, loans, loan guarantees, subsidies, insurance, payments for specified use, donation agreements and any other nonprocurement transactions between a Federal agency and a person. Primary covered transactions also include those transactions specially designated by the U.S. Department of Housing and Urban Development in such agency's regulations governing debarment and suspension.

(ii) *Lower tier covered transaction.* A lower tier covered transaction is:

(A) Any transaction between a participant and a person other than a procurement contract for goods or services, regardless of type, under a primary covered transaction.

(B) Any procurement contract for goods or services between a participant and a person, regardless of type, expected to equal or exceed the Federal procurement small purchase threshold fixed at 10 U.S.C. 2304(g) and 41 U.S.C. 253(g) (currently \$25,000) under a primary covered transaction.

(C) Any procurement contract for goods or services between a participant

§ 1404.115

and a person under a covered transaction, regardless of amount, under which that person will have a critical influence on or substantive control over that covered transaction. Such persons are:

(1) Principal investigators.

(2) Providers of federally-required audit services.

(2) *Exceptions.* The following transactions are not covered:

(i) Statutory entitlements or mandatory awards (but not subtier awards thereunder which are not themselves mandatory), including deposited funds insured by the Federal Government;

(ii) Direct awards to foreign governments or public international organizations, or transactions with foreign governments or foreign governmental entities, public international organizations, foreign government owned (in whole or in part) or controlled entities, entities consisting wholly or partially of foreign governments or foreign governmental entities;

(iii) Benefits to an individual as a personal entitlement without regard to the individual's present responsibility (but benefits received in an individual's business capacity are not excepted);

(iv) Federal employment;

(v) Transactions pursuant to national or agency-recognized emergencies or disasters;

(vi) Incidental benefits derived from ordinary governmental operations; and

(vii) Other transactions where the application of these regulations would be prohibited by law.

(b) *Relationship to other sections.* This section describes the types of transactions to which a debarment or suspension under the regulations will apply. Subpart B, "Effect of Action," §1404.200, "Debarment or suspension," sets forth the consequences of a debarment or suspension. Those consequences would obtain only with respect to participants and principals in the covered transactions and activities described in §1404.110(a). Sections §1404.325, "Scope of debarment," and §1404.420, "Scope of suspension," govern the extent to which a specific participant or organizational elements of a participant would be automatically included within a debarment or suspension action, and the conditions under

21 CFR Ch. III (4-1-01 Edition)

which affiliates or persons associated with a participant may also be brought within the scope of the action.

(c) *Relationship to Federal procurement activities.* In accordance with E.O. 12689 and section 2455 of Public Law 103-355, any debarment, suspension, proposed debarment or other governmentwide exclusion initiated under the Federal Acquisition Regulation (FAR) on or after August 25, 1995 shall be recognized by and effective for Executive Branch agencies and participants as an exclusion under this regulation. Similarly, any debarment, suspension or other governmentwide exclusion initiated under this regulation on or after August 25, 1995 shall be recognized by and effective for those agencies as a debarment or suspension under the FAR.

[57 FR 56263, Nov. 27, 1992, as amended at 60 FR 33041, 33045, June 26, 1995]

§ 1404.115 Policy.

(a) In order to protect the public interest, it is the policy of the Federal Government to conduct business only with responsible persons. Debarment and suspension are discretionary actions that, taken in accordance with Executive Order 12549 and these regulations, are appropriate means to implement this policy.

(b) Debarment and suspension are serious actions which shall be used only in the public interest and for the Federal Government's protection and not for purposes of punishment. Agencies may impose debarment or suspension for the causes and in accordance with the procedures set forth in these regulations.

(c) When more than one agency has an interest in the proposed debarment or suspension of a person, consideration shall be given to designating one agency as the lead agency for making the decision. Agencies are encouraged to establish methods and procedures for coordinating their debarment or suspension actions.

Subpart B—Effect of Action

§ 1404.200 Debarment or suspension.

(a) *Primary covered transactions.* Except to the extent prohibited by law, persons who are debarred or suspended