

§ 1404.115

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

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 subtler 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

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