PART 224—IMPLEMENTATION OF
THE PROGRAM FRAUD CIVIL
REMEDIES ACT

§ 224.1 Basis and purpose.
(b) Purpose. This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to the Agency for International Development or to its agents, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 224.2 Definitions.
A.I.D. means the Agency for International Development.
ALJ means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.
Benefit means, in the context of “statement,” anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.
Claim means any request, demand, or submission—
(a) Made to A.I.D. for property, services, or money (including money representing grants, loans, insurance, or benefits);
(b) Made to a recipient of property, services, or money from A.I.D. or to a party to a contract with A.I.D.—
(1) For property or services if the United States—
(i) Provided such property or services;
(ii) Provided any portion of the funds for the purchase of such property or services; or
(iii) Will reimburse such recipient or party for the purchase of such property or services; or
(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

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(i) Provided any portion of the money requested or demanded; or
(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or
(c) Made to A.I.D. which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under §224.7.

Defendant means any person alleged in a complaint under §224.7 to be liable for a civil penalty or assessment under §224.3.

Government means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ required by §224.10 or §224.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General for A.I.D. or an officer or employee of the Office of Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule.

Knows or has reason to know, means that a person, with respect to a claim or statement—
(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;
(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or
(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, making or made, shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, or private organization and includes the plural of that term.

Representative means an attorney who is a member in good standing of the bar of any State, Territory, or possession of the United States or the District of Columbia or the Commonwealth of Puerto Rico.

Reviewing official means the General Counsel of A.I.D. or his designee who is:
(a) Not subject to supervision by, or required to report to, the investigating official;
(b) Not employed in the organizational unit of A.I.D. in which the investigating official is employed; and
(c) Is serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS–16 under the General Schedule.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—
(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or
(b) With respect to (including relating to eligibility for)—
(1) A contract with, or a bid or proposal for a contract with; or
(2) A grant, loan, or benefit from, A.I.D., or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

§224.3 Basis for civil penalties and assessments.

(a) Claims (1) Any person who makes a claim that the person knows or has reason to know—
(i) Is false, fictitious, or fraudulent;
(ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;
(iii) Includes or is supported by any written statement that—
(A) Omits a material fact;
(B) Is false, fictitious, or fraudulent as a result of such omission; and
(C) Is a statement in which the person making such statement has a duty to include such material fact; or
(2) In any other such contract or for such grant, loan, or benefit.
(iv) Is for payment for the provision of property or services which the person has not provided as claimed; shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,000 for each such claim.

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to A.I.D., a recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of A.I.D. or such recipient or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) Statements. (1) Any person who makes a written statement that—
   (i) The person knows or has reason to know—
      (A) Asserts a material fact which is false, fictitious, or fraudulent; or
      (B) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement had a duty to include in such statement; and
   (ii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy and may be prescribed by law, to a civil penalty of not more than $5,000 for each such statement.

   (2) Each written representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to A.I.D. when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of A.I.D.

(c) No proof of specific intent to defraud is required to establish liability under this section.

(d) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

§ 224.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

   (1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued, and shall identify the records of documents sought;

   (2) The investigating official may designate a person to act on his or her behalf to receive the documents sought; and

   (3) The person receiving such subpoena shall be required to tender to the investigating official or the person designated to receive the documents a certification that the documents sought have been produced, or that such documents are not available and the reasons therefore, or that such documents, suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.
(c) Nothing in this section shall preclude or limit an investigating official’s discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 224.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under §224.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under §224.3 of this part, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official’s intention to issue a complaint under §224.7.

(b) Such notice shall include—

(1) A statement of the reviewing official’s reasons for issuing a complaint;
(2) A statement specifying the evidence that supports the allegations of liability;
(3) A description of the claims or statements upon which the allegations of liability are based;
(4) An estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of §224.3 of this part;
(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and
(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

§ 224.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under §224.7 only if:

(1) The Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1); and
(2) In the case of allegations of liability under §224.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money or the value of property or services demanded or requested in violation of §224.3(a) does not exceed $150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official’s authority to join in a single complaint against a person claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

§ 224.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in §224.8.

(b) The complaint shall state:

(1) Allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;
(2) The maximum amount of penalties and assessments for which the defendant may be held liable;
(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant’s right to request a hearing by filing an answer and to be represented by a representative; and
(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessments without right to appeal, as provided in §224.10.
§ 224.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or his representative.

§ 224.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.

(b) In the answer, the defendant:

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant’s representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant may, before the expiration of 30 days from service of the complaint, file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting the requirements of paragraph (b) of this section. The reviewing official shall file promptly with the ALJ the complaint, the general answer denying liability, and the request for an extension of time as provided in §224.11. For good cause shown, the ALJ may grant the defendant up to 30 additional days within which to file an answer meeting the requirements of paragraph (b) of this section.

§ 224.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in §224.9(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on defendant in the manner prescribed in §224.8, a notice that an initial decision will be issued under this section.

(c) The ALJ shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under §224.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ’s decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying defendant’s motion under paragraph (e) of this section is not subject to reconsideration under §224.38.
(h) The defendant may appeal to the A.I.D. Administrator the decision denying a motion to reopen by filing a notice of appeal with the A.I.D. Administrator within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the A.I.D. Administrator decides the issue.

(i) If the defendant files a timely notice of appeal with the A.I.D. Administrator, the ALJ shall forward the record of the proceeding to the A.I.D. Administrator.

(j) The A.I.D. Administrator shall decide expeditiously whether extraordinary circumstances excuse the defendant’s failure to file a timely answer based solely on the record before the ALJ.

(k) If the A.I.D. Administrator decides that extraordinary circumstances excused the defendant’s failure to file a timely answer, the A.I.D. Administrator shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(l) If the A.I.D. Administrator decides that the defendant’s failure to file a timely answer is not excused, the A.I.D. Administrator shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the A.I.D. Administrator issues such decision.

§ 224.15 Ex parte contacts.

No party or person (except employees of the ALJ’s office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.
§ 224.16 Disqualification of reviewing official or ALJ.
(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.
(b) A party may file with the ALJ a motion for disqualification of a reviewing official or ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.
(c) Such motion and affidavit shall be filed promptly upon the party’s discovery of reasons requiring disqualification, or such objections shall be deemed waived.
(d) Such affidavit shall state specific facts that support the party’s belief that personal bias or other reason for disqualification exists and the time and circumstances of the party’s discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.
(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.
(f)(1) If the ALJ determines that the reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.
(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.
(g) Present oral arguments at the hearing as permitted by the ALJ; and
(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 224.17 Rights of parties.
Except as otherwise limited by this part, all parties may:
(a) Be accompanied, represented, and advised by a representative;
(b) Participate in any conference held by the ALJ;
(c) Conduct discovery;
(d) Agree to stipulations of fact or law, which shall be made part of the record;
(e) Present evidence relevant to the issues at the hearing;
(f) Present and cross-examine witnesses;
(g) Present oral arguments at the hearing as permitted by the ALJ; and
(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 224.18 Authority of the ALJ.
(a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.
(b) The ALJ may:
(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;
(2) Continue or recess the hearing in whole or in part for a reasonable period of time;
(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
(4) Administer oaths and affirmations;
(5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;
(6) Rule on motions and other procedural matters:
(7) Regulate the scope and timing of discovery;
(8) Regulate the course of the hearing and the conduct of representatives and parties;
(9) Examine witnesses;
(10) Receive, rule on, exclude, or limit evidence;
(11) Upon motion of a party, take official notice of facts;
(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and
(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.
(c) The ALJ does not have the authority to find Federal statutes or regulations invalid.

§ 224.19 Prehearing conferences.
(a) The ALJ may schedule prehearing conferences as appropriate.
(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may use prehearing conferences to discuss the following:
   (1) Simplification of the issues;
   (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
   (3) Stipulations and admissions of fact or as to the contents and authenticity of documents;
   (4) Whether the parties can agree to submission of the case on a stipulated record;
   (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;
   (6) Limitation of the number of witnesses;
   (7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
   (8) Discovery;
   (9) The time and place for the hearing; and
   (10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ shall issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 224.20 Discovery.

(a) The following types of discovery are authorized:
   (1) Requests for production of documents for inspection and copying;
   (2) Requests for admissions of the authenticity of any relevant document or the truth of any relevant fact;
   (3) Written interrogatories; and
   (4) Depositions.

(b) For the purpose of this section and §§224.22 and 224.23, the term “documents” includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) Motions for discovery. (1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.
   (2) Within ten days of service a party may file an opposition to the motion and/or a motion for protective order as provided in §224.24.

(3) The ALJ may grant a motion for discovery only if he finds that the discovery sought:
   (i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;
   (ii) Is not unduly costly or burdensome;
   (iii) Will not unduly delay the proceeding; and

§ 224.21 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under §224.4(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in §224.5 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to §224.9.
§ 224.22 Exchange of witness lists, statements, and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 224.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefore not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in §224.8. A subpoena on a party or upon an individual under the control of a party may be served by first-class mail.

(f) A party or individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 224.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or, with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;
(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
(3) That the discovery may be had only through a method of discovery other than that requested;
(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;
(5) That discovery be conducted with no one present except persons designated by the ALJ;
(6) That the contents of discovery or evidence be sealed;
(7) That a deposition after being sealed be opened only by order of the ALJ;
(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding or other administrative investigation not be disclosed or be disclosed only in a designated way; or
(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 224.25 Fees.
The party requesting a subpoena shall pay the cost of the fee and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in the United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of A.I.D., a check for witness fees and mileage need not accompany the subpoena.

§ 224.26 Form, filing and service of papers.
(a) Form. (1) Documents filed with the ALJ shall include an original and two copies.
(2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (e.g., motion to quash subpoena).
(3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.
(4) Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.
(b) Service. A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than those required to be served as prescribed in §224.8, shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid and addressed, to the party’s last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual party.
(c) Proof of service. A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§ 224.27 Computation of time.
(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day.
(b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government shall be excluded from the computation.
(c) Where a document has been served or issued by placing it in the mail, an additional five days will be added to the time permitted for any response.

§ 224.28 Motions.
(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.
§ 224.29 Sanctions.

(a) The ALJ may sanction a person, including any party or representative for:
(1) Failing to comply with an order, rule, or procedure governing the proceeding;
(2) Failing to prosecute or defend an action; or
(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party’s control, or a request for admission, the ALJ may:
(1) Draw an inference in favor of the requesting party with regard to the information sought;
(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;
(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and
(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 224.30 The hearing and burden of proof.

(a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under §224.3, and if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) A.I.D. shall prove defendant’s liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§ 224.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the A.I.D. Administrator, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the A.I.D. Administrator in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:
§ 224.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 224.22(a).

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to—

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as
§ 224.34 Evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence, where appropriate, e.g., to exclude unreliable evidence.

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to §224.24.

§ 224.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from ALJ at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the A.I.D. Administrator.

(c) The record of the hearing may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to §224.24.

§ 224.36 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ shall fix the time for filing briefs, at a time not exceeding 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 224.37 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portion thereof, violate §224.3;

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds
in the case, such as those described in § 224.31.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the A.I.D. Administrator. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the A.I.D. Administrator, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the A.I.D. Administrator and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 224.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the ALJ.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) If the ALJ denies a motion for reconsideration, the initial decision shall constitute the final decision of the A.I.D. Administrator and shall be final and binding on the parties 30 days after the ALJ denies the motion, unless the initial decision is timely appealed to the A.I.D. Administrator in accordance with § 224.39.

(g) If the ALJ issues a revised initial decision, that decision shall constitute the final decision of the A.I.D. Administrator and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the A.I.D. Administrator in accordance with § 224.39.

§ 224.39 Appeal to A.I.D. Administrator.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the A.I.D. Administrator by filing a notice of appeal with the A.I.D. Administrator in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the ALJ issues an initial decision. However, if another party files a motion for reconsideration under § 224.38, consideration of the appeal shall be stayed automatically pending resolution of the motion for reconsideration.

(2) If a motion for reconsideration is timely filed, a notice of appeal may be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) The A.I.D. Administrator may extend the initial 30 day period for an additional 30 days if the defendant files with the A.I.D. Administrator a request for an extension within the initial 30 day period and shows good cause.

(c) If the defendant files a timely notice of appeal with the A.I.D. Administrator, and the time for filing motions for reconsideration under § 224.38 has expired, the ALJ shall forward the record of the proceeding to the A.I.D. Administrator.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.
§ 224.40  Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the A.I.D. Administrator a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the A.I.D. Administrator shall stay the process immediately. The A.I.D. Administrator may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 224.41  Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the A.I.D. Administrator.

(b) No administrative stay is available following a final decision of the A.I.D. Administrator.

§ 224.42  Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the A.I.D. Administrator imposing penalties or assessments under this part and specifies the procedures for such review.

§ 224.43  Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 224.44  Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under §224.42 or §224.43, or any amount agreed upon in a compromise or settlement under §224.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under the subsection against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 224.45  Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 224.46  Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any
time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The A.I.D. Administrator has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under §224.42 or during the pendency of any action to collect penalties and assessments under §224.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under §224.42 or during the pendency of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the A.I.D. Administrator, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the A.I.D. Administrator, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 224.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in §224.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under §224.10(b) shall be deemed notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

PART 225—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v-1(b), unless otherwise noted.

SOURCE: 56 FR 28012, 28020, June 18, 1991, unless otherwise noted.

§ 225.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §225.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §225.102(e) must be reviewed and approved, in compliance with §§225.101, 225.102, and §§225.107 through 225.117 of this policy.