2. For the purpose of these special conditions, the following definition applies:

Critical Functions: Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on April 17, 2002.

Lirio Liu-Nelson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 02–9943 Filed 4–26–02; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-ANE-39-AD; Amendment 39-12668; AD 2002-04-11]

RIN 2120-AA64

Airworthiness Directives; General Electric Company GE90 Series Turbofan Engines; Correction

AGENCY: Federal Aviation Administration, DOT. **ACTION:** Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2002–04–11 applicable to General Electric Company GE90 series turbofan engines that was published in the Federal Register on March 4, 2002 (67 FR 9582). The Table in the regulatory text section is incorrect. This document corrects that Table. In all other respects, the original document remains the same.

EFFECTIVE DATE: April 8, 2002.

FOR FURTHER INFORMATION CONTACT: Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7178, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A final rule airworthiness directive (FR Doc. 02–5003) applicable to General Electric Company GE90 series turbofan engines, was published in the **Federal Register** on March 4, 2002 (67 FR 9582). The following corrections are needed:

§39.13 [Corrected]

1. On page 9583, in the third column entitled, Inspect per engine manual chapter, in the third entry, (HPCR, Disk, Stage 7) "72–31–07–200–001–001 Fluorescent Penetrant Inspection

(subtask 72-31-07-230-051), and 72-31-07-200-001-001 Eddy Current Inspection (subtask 72-31-07-250-051 or 72-31-07-230-052 or 72-31-07-230-053" is corrected to read "72-31-07-200-001-001 Fluorescent Penetrant Inspection (subtask 72-31-07-230-051), and 72-31-07-200-001-001 Eddy Current Inspection of the Rim Boltholes (subtask 72-31-07-250-051 or 72-31-07-250-052 or 72-31-07-250-053".

2. On the same page, in the same column entitled, Inspect per engine manual chapter, in the nineth entry, (HPTR Disk, Stage 1) "72–53–02–200–001–002 Fluorescent Penetrant Inspection (subtask 72–53–02–160–051), and 72–53–02–200–001–002 Eddy Current Inspection of the Bore " is corrected to read "72–53–02–200–001–002 Fluorescent Penetrant Inspection (subtask 72–53–02–230–052), and 72–53–02–200–001–002 Eddy Current Inspection of the Bore".

Issued in Burlington, MA, on April 18, 2002.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service. [FR Doc. 02–10273 Filed 4–26–02; 8:45 am]

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regs. No. 4 and 16]

RIN 0960-AF20

Administrative Procedure for Imposing Penalties for False or Misleading Statements

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: The interim final rules published at 65 FR 42283 on July 10, 2000, are adopted as final without change. These rules reflect and implement section 207 of the Foster Care Independence Act of 1999. This provision amended the Social Security Act (the Act) by adding a new section 1129A which provides for the imposition by SSA of a penalty on any person who knowingly (knew or should have known or acted with knowing disregard for the truth) makes a statement that is false or misleading or omits a material fact for use in determining any right to or the amount of monthly benefits under titles II or XVI of the Act. The penalty is nonpayment for a specified number of months of benefits under title II that would otherwise be payable to the

person and ineligibility for cash benefits under title XVI (including State supplementary payments made by SSA according to § 416.2005).

EFFECTIVE DATE: These regulations were effective July 10, 2000, the date they were published in the **Federal Register** as interim final rules (65 FR 42283).

FOR FURTHER INFORMATION CONTACT: Bill Hilton, Social Insurance Specialist, Office of Program Benefits, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–2468 or TTY (410) 966–5609. For information on eligibility, claiming benefits, or coverage of earnings, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778.

SUPPLEMENTARY INFORMATION:

Background

Section 207 of the Foster Care Independence Act of 1999 (Pub. L. 106-169) amended title XI of the Act by adding section 1129A to help prevent and respond to fraud and abuse in SSA's programs and operations. Section 1129A provides for the imposition by SSA of a penalty on an individual who makes, or causes to be made, a statement or representation of a material fact that the person knows or should know is false or misleading or omits a material fact, or that the person makes with a knowing disregard for the truth. The statement must be made for use in determining eligibility for or the amount of benefits under title II or XVI. The penalty is nonpayment for 6, 12 or 24 months of benefits under title II that would otherwise be payable to the person and ineligibility for the same period of time for cash benefits under title XVI (including State supplementary payments made by SSA according to § 416.2005).

Section 207 of Pub. L. 106-169 directs the Commissioner of Social Security to develop rules prescribing the administrative process for making determinations under section 1129A, including when periods of penalty shall commence, and providing guidance on the exercise of discretion as to whether the penalty should be imposed in particular cases. Consequently, we published interim final rules on July 10, 2000, which added new rules at §§ 404.459 and 416.1340 to reflect and implement section 1129A. We provided a 60-day period for interested individuals and organizations to comment. Summaries of the comments we received and our responses thereto are set out later in this preamble. After consideration of all the comments received, we have decided not to revise

the interim final rules we published on July 10, 2000.

Section 1129A of the Act applies to statements and representations made on or after December 14, 1999, the date of enactment of the Foster Care Independence Act of 1999.

Explanation of Changes

In our interim final rules, we added new §§ 404.459 and 416.1340 to our regulations. The organization and wording of these two sections are essentially identical. These sections make it clear, and as Congress provided, that if an individual knowingly (knew or should have known or acted with knowing disregard for the truth) made a false or misleading statement with respect to one program, the penalty shall apply to benefits under both the title II and XVI programs. Applying the penalty to both programs helps protect the integrity of both programs from further fraud by the same person and helps to maintain public confidence in the integrity of our programs. A subsection-by-subsection discussion of these rules follows.

Subsection (a) describes the conditions under which you will be subject to a penalty by SSA for knowingly making a false or misleading statement of a material fact.

Subsection (b) explains that the penalty is both nonpayment of benefits under title II and ineligibility for cash benefits under title XVI. When we impose a penalty on you, you cannot receive benefits under either title II or title XVI even if the false or misleading statement was made in connection with benefits under only one of the two programs. We further explain that, as provided by the law, if we impose a penalty on your title XVI benefits, you also will not be eligible to receive State supplementary payments that SSA pays by agreement with the State.

Subsection (c) explains how long the penalty for making a false or misleading statement will last. As provided in section 1129A, the penalty will last six consecutive months the first time we penalize you, twelve consecutive months the second time we penalize you, and twenty-four consecutive months the third or subsequent times we penalize you. The penalty will not begin to run until you would otherwise be eligible for payment of benefits under either title II or title XVI. You will be ineligible to receive benefits at any time during the penalty period. If more than one penalty period has been imposed but they have not yet run, the penalties will run consecutively, not concurrently.

Subsection (d) explains, as provided in section 1129A, that the imposition of a penalty will affect only your own eligibility for benefits under titles II and XVI. If we impose a penalty on you, the penalty will not affect the eligibility or amount of benefits payable under titles II or XVI to another person. For example, another person (such as your spouse or child) may be entitled to benefits under title II based on your earnings record. Benefits would still be payable to that person to the extent that you would be receiving such benefits if the penalty had not been imposed. As another example, if you are receiving title II benefits that are limited under the family maximum provision (§ 404.403) and we stop your benefits because we impose a penalty on you, we will not increase the benefits of other family members who are limited by the family maximum provision simply because you are not receiving benefits as a result of the penalty. As a third example, if you and your spouse are receiving title XVI benefits, those benefit payments to your spouse based on the benefit rate for a couple will not be affected because of the penalty. Your spouse will continue to receive one half of the couple rate.

Section 1129A also specifically provides that the imposition of a penalty will not affect your eligibility for Medicare and Medicaid benefits (titles XVIII and XIX of the Act).

Subsection (e) explains that to impose a penalty on you, we must find that you knowingly made a false or misleading statement or omitted a material fact. "Knowingly" means that you knew or should have known that the statement was false or misleading or omitted a material fact, or you made the statement with a knowing disregard for the truth. We will base our decision to impose a penalty on the evidence and the reasonable inferences that can be drawn from that evidence, not on mere speculation or suspicion. In determining whether you knowingly made a false or misleading statement or omitted a material fact, we will consider all of the evidence in the record, including any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have had at the time. In determining whether you acted knowingly, we will also consider the significance of the statement in terms of its likely impact on your benefits under titles II and/or XVI.

The Office of the Inspector General may investigate your false or misleading statement for fraud for civil monetary penalty purposes (see section 1129 of the Act) and you may be prosecuted civilly or criminally by the United States Attorney's Office. We may impose a penalty under these rules in addition to any other penalties that may be prescribed by law.

Subsection (f) explains that if you disagree with our initial determination to impose a penalty, you have the right to request reconsideration of the penalty decision, as discussed in §§ 404.907 and 416.1407. If you do request reconsideration, you will be able to present your case in one of three ways:

1. Case review—We will give you an opportunity to review the evidence in our files and then to present oral and written evidence to us;

2. Informal conference—In addition to following the procedures of a case review, we will give you an opportunity to present witnesses; and

3. Formal conference—In addition to following the procedures of an informal conference, we will give you an opportunity to request us to subpoena adverse witnesses and relevant documents and to cross-examine adverse witnesses.

After reconsideration, if you do not agree with our reconsidered determination you may follow the normal administrative and judicial review process by requesting a hearing before an administrative law judge, Appeals Council review and Federal court review, as described in §§ 404.900 and 416.1400.

Subsection (g) explains when the penalty period begins and ends. That section explains that the penalty period will not begin until the month you would otherwise be eligible to receive payments under either title II or title XVI. In addition, the point at which the penalty period begins may depend on whether you request reconsideration of our initial determination to penalize you. If you do not request reconsideration, the penalty period will begin no earlier than the first day of the second month following the month in which the time limit for requesting reconsideration ends. If you request reconsideration and our reconsidered determination does not change our original decision to penalize you, the penalty period will begin no earlier than the first day of the second month following the month we notify you of our reconsidered determination. The penalty period ends on the last day of the final month of the penalty period. Once a penalty period begins it will run continuously even if payments are intermittent.

Comments on Interim Final Rules

As noted above, on July 10, 2000 we published the interim final rules in the

Federal Register at 65 FR 42283 and provided a 60-day comment period. We received comments from twenty-five individuals and organizations. Some of the comments, however, pertained to matters that were not within the scope of these proposed rules. We do not address them in this preamble. Following are summaries of the comments and our responses to them.

Comment: Thirteen of the comments concerned what was perceived as vagueness in the regulation, including the meaning of the phrase "knew or should have known." The commenters thought more specific guidelines and instructions are necessary in order to make the process fair and equitable. One commenter specifically mentioned that much of the information SSA makes available to the public is not readily accessible to those with visual impairments so the use of the phrase "should have known" may be suspect. Several others were concerned about how individuals with mental impairments may be adversely affected by the phrase "should have known" and believe SSA should monitor these actions closely to ensure equity. They were all concerned that the lack of detailed definitions and guidelines in the regulation may cause SSA to find that an individual should have known something when the impairment prevented the person from knowing the information.

Response: Section 1129A of the Act specifically provides for the imposition by SSA of a penalty if a person makes a statement or representation "that the person knows or should know is false or misleading." These rules provide that, in determining whether a person "knew or should have known," we will consider all the evidence in the record. including any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that the person may have had at the time. In addition, the rules provide that a decision to impose a penalty will be documented with the basis and rationale for that decision and will be based on the evidence and the reasonable inferences that can be drawn from that evidence, not on speculation or suspicion.

Further, operating instructions provide guidelines for SSA personnel to follow when making a determination that a person knew or should have known that a statement was false or misleading. In addition to considering any physical or mental impairment, these guidelines instruct personnel to consider the significance of the false or misleading statement in terms of its

likely impact on the person's benefits, and the individual's:

- Understanding of reporting requirements;
- Knowledge of events that have occurred and should have been reported;
- Efforts to comply with requirements;
- Understanding of the obligation to return payments not due;
- Ability to understand and comply with reporting requirements;
- Experience in dealing with government agencies;
- Past history of providing inaccurate information; and
- Understanding of the language used by SSA.

We also note that a determination to impose an administrative sanction is an initial determination. Accordingly, an individual may follow the normal administrative and judicial review process by requesting reconsideration, a hearing before an administrative law judge, Appeals Council review and Federal Court review. A separate component of SSA will also review all penalty determinations to ensure uniformity in applying these instructions.

In developing these rules, instructions, and procedures, we have taken into account both the need for SSA to deal effectively with those situations in which individuals knowingly provide false and material evidence and the need to ensure that all claimants and beneficiaries are treated fairly.

Comment: Five comments were from people who work with individuals who are disabled and want to return to work. They believe there is "widespread ignorance" of the fact that people receiving disability benefits need to report income from work. They also believe that many reports of attempted work are not acted upon by SSA. They are concerned that failure to report income and incorrect processing by SSA personnel may lead to penalties against "innocent" individuals.

Response: A penalty will only be imposed when a person knowingly makes or causes to be made a statement or representation that is false or misleading or omits a material fact. A penalty will not be imposed solely because an individual has failed to make a report of work activity.

Comment: One commenter agreed that a penalty should be imposed if a person lies or makes a misleading statement about his or her medical condition if it is clearly in contrast with medical evidence. However, the commenter believes that a misleading statement

about his or her personal life and activities should not be punishable.

Response: A penalty will only be imposed when a person knowingly makes a false or misleading statement of a material fact for use in determining any right to or the amount of benefits under titles II or XVI. Statements not related to eligibility for benefits or payment amounts will not cause a penalty.

Comment: Another commenter noted that benefits will continue while we make a reconsideration determination. After the reconsideration, the penalty will start the second month after notice of our reconsidered determination. He asks whether benefits will continue through higher levels of appeal or if this option was intentionally omitted for this procedure. He suggests that, if the intent is to reduce fraud and abuse of the system, this same philosophy should be applied to cessation and childhood redetermination cases that allow benefits to continue until all avenues of appeal are exhausted.

Response: As required by section 223 of the Act, disability benefit payments may continue beyond the reconsideration level during appeals of disability cessation decisions. This benefit continuation does not apply to non-medical decisions such as the decision to impose a penalty. For a penalty period of non-payment, the benefit payments will stop beginning the second month after we send notice of our reconsidered determination.

Comment: One commenter was concerned about whether a penalty could apply to an SSA employee who makes a false or misleading statement or an omission of a material fact. He was concerned that the definition could apply to employees who omit a material fact by neglecting to follow written procedures. He thought this would place an additional burden on personnel by "adding an extra level of meticulousness" in preparing decisions and work products. Finally, he asks whether this regulation will require that a person who witnesses an act which could cause a penalty must report such an act and whether SSA will defend the reporting person in the event of civil action against the reporter.

Response: These regulations apply to people who claim benefits under title II or title XVI of the Act and make or cause to be made, a false or misleading statement of a material fact in connection with that claim. They do not impose any additional requirements on SSA employees and how they perform their official duties. Rules of employee conduct are not affected by these regulations in any way. Finally, these

changes do not impose any new reporting requirement on any individuals.

Comment: One commenter was concerned about the financial effect the penalty will have on the individual. He believes that SSA has been able to recover its overpayments in the past using current methods and that imposing a penalty on an individual may result in the individual being placed on public assistance.

Response: Section 207 authorizes the Commissioner to impose a penalty to help prevent and respond to fraud and abuse in SSA's programs. These penalties are intended to deter individuals from providing false or misleading information about material facts in connection with a claim for benefits. Penalties will have little, if any, effect on the collection of overpayments. By law, Social Security benefits under title II and title XVI are paid only if certain eligibility requirements are met. SSA must ensure that those requirements are met based on proven facts. The penalty process is intended to help deter people from trying to meet those requirements fraudulently. It is possible that a person who does not meet the requirements for Social Security payments may qualify for public assistance just as he or she does now. We do not expect this change to have any substantial effect on the number of people on public assistance.

Comment: One commenter believes that a penalty should continue until all benefits obtained as a result of the false or misleading statement or omission of a material fact are recovered. She also believes that a penalty should apply to all individuals on a record, not just the person being sanctioned.

Response: This regulation is a result of a legislated change in the Social Security Act. The legislation itself prescribes the length of the penalty period. The length of the period is not affected by the amount of the benefits involved nor by the time required to recover any overpayment. The legislation also specifically states that the penalty will affect only the individual who makes, or causes to be made, the false or misleading statement.

Comment: One comment proposed that administrative law judges should be allowed to impose penalties.

Response: Any SSA employee may identify a case where a penalty may be appropriate and this may lead to the initiation of the penalty process. The decision to impose the penalty, however, is an initial determination. In order to allow the claimant the full range of appeal rights, this decision will be made at the initial level by the claims

representative. The claims representative will also issue the notice of penalty and input the suspension action.

For the reasons discussed above, we have not changed the interim final rules based on the public comments. Therefore, the interim final rules adding 20 CFR 404.459 and 416.1340 published in the **Federal Register** (65 FR 42283) on July 10, 2000 are adopted as final without change.

Executive Order 12866

The Office of Management and Budget has reviewed these final rules in accordance with Executive Order (E.O.) 12866, as amended by E.O. 13258.

Regulatory Flexibility Act

We certify that these final rules will not have a significant impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis, as provided in the Regulatory Flexibility Act, as amended is not required.

Paperwork Reduction Act

This final rule imposes no reporting or recordkeeping requirements requiring clearance by the Office of Management and Budget.

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age Survivor and Disability Insurance, Reporting and recordkeeping requirement, Social Security Income.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirement, Supplemental Security Income.

Dated: February 15, 2002.

Jo Anne B. Barnhart,

Commissioner of Social Security.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Accordingly, the interim final rules adding 20 CFR Part 404.459 published at 65 FR 42283 on July 10, 2000 are adopted as final without change.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND AND DISABLED

Accordingly, the interim final rules adding 20 CFR Part 416.1340 published

at 65 FR 42283 on July 10, 2000 are adopted as final without change.

[FR Doc. 02–10467 Filed 4–26–02; 8:45 am] BILLING CODE 4191–02–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 97P-0210]

Medical Devices; Ear, Nose and Throat Devices; Reclassification of the Endolymphatic Shunt Tube With Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls). The device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease. FDA is also identifying the guidance document entitled "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA" (the guidance) as the special control that the agency believes will reasonably ensure the safety and effectiveness of the device. This reclassification is based on new information submitted in a reclassification petition by E. Benson Hood Laboratories, Inc. (Hood Laboratories). FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. Elsewhere in this issue of the Federal Register, FDA is publishing a notice announcing the guidance. **DATES:** This rule is effective May 29, 2002.

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and

Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 15, 2001 (66 FR 42809), FDA published a proposed rule to reclassify the