exports and reexports to India by about 150 to 200 annually.

Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing the burden, to David Rostker, OMB Desk Officer, by e-mail at *david_rostker@omb.eop.gov* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable.

List of Subjects

15 CFR Part 738

Exports, Foreign Trade.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

■ Accordingly, parts 738, 742 and 744 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

PART 738—[AMENDED]

■ 1. The authority citation for 15 CFR part 738 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 2, 2005, 70 FR 45273 (August 5, 2005).

Supplement No. 1 to Part 738 [Amended]

■ 2. Supplement No. 1 to part 738—(Commerce Country Chart) is amended by removing the ''X'' from the column heading NP 2 in the row for India.

PART 742—[AMENDED]

■ 3. The authority citation for part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; Sec. 1503, Pub. L. 108–11,117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of November 4, 2004, 69 FR 64637 (November 8, 2004); Notice of August 2, 2005, 70 FR 45273 (August 5, 2005).

■ 4. Section 742.3 is amended by revising paragraph (a)(2) to read as follows:

§ 742.3 Nuclear Nonproliferation.

(a) * * *

(2) If NP Column 2 of the Country Chart (Supplement No. 1 to part 738 of the EAR) is indicated in the applicable ECCN, a license is required to Country Group D:2 (see Supplement No. 1 to part 740 of the EAR) except India.

* * * * *

PART 744—[AMENDED]

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of November 4, 2004, 69 FR 64637 (November 8, 2004); Notice of August 2, 2005, 70 FR 45273 (August 5, 2005).

Supplement No. 4 to Part 744 [Amended]

■ 6. Supplement No. 4 to part 744, under the country of India is amended by:

■ a. Removing the following subordinate entities from the entry for the Indian Space Research Organization (ISRO): ISRO Telemetry, Tracking and Command Network (ISTRAC), ISRO Inertial Systems Unit (IISU), Thiruvananthapuram, and Space Applications Center (SAC), Ahmadabad;

■ b. Adding to the entry for ''Nuclear reactors (including power plants) not under International Atomic Energy Agency (IAEA) safeguards, fuel processing and enrichment facilities, heavy water production facilities and their collocated ammonia plants,'' immediately following the word ''safeguards,'' the phrase ''(excluding Kundankulam 1 and 2)'; and

■ c. Removing, in its entirety, the second entry for the Department of Atomic Energy which reads: ''The following Department of Atomic Energy entities: Nuclear reactors (including power plants) subject to International Atomic Energy Agency (IAEA) safeguards: Tarapur (TAPS 1 & 2), and ''Rajasthan (RAPS 1 & 2).''

* * * * *

Dated: August 24, 2005.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 05–17241 Filed 8–29–05; 8:45 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulation No. 4]

RIN 0960–AF32

Revised Medical Criteria for Evaluating Impairments That Affect Multiple Body Systems

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving impairments that affect multiple body systems. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect current medical knowledge, methods of evaluating impairments that affect multiple body systems, treatment, and our adjudicative experience.

DATES: These regulations are effective October 31, 2005.

ADDRESSES: *Electronic Version:* The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*. It is also available on the

Internet site for SSA (*i.e.*, Social Security Online): *http://www.socialsecurity.gov/regulations/final-rules.htm*.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Regulations, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1769 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet Web site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on December 23, 2002 (67 FR 78196). We provide a summary of the provisions of the final rules below, with an explanation of the changes we have made from the proposed rules. We then provide a summary of the public comments and our reasons for adopting or not adopting the recommendations in the summaries of the comments in the section, ''Public Comments.'' The text of the final rules follows the preamble.

What Programs Do These Final Rules Affect?

These final rules affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these final rules also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above that results in . . .
Title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
Title XVI	an individual age 18 or older	the inability to do any SGA.
TitleXVI	an individual under age 18	marked and severe functional limitations.

How Do We Decide Whether You Are Disabled?

If you are seeking benefits under title II of the Act, or if you are an adult seeking benefits under title XVI of the Act, we use a five-step ''sequential evaluation process'' to decide whether you are disabled. We describe this five-step process in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working, and is the work you are doing substantial gainful activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.

2. Do you have a ''severe'' impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under SSI. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.424, 416.994, and 416.994a of our regulations. However, all of these processes include steps at which we consider whether your impairment(s) meets or medically equals one of our listings.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI benefits based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations, we incorporate them by reference in the SSI program in § 416.925 of our regulations and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. If the listings in part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What If You Do Not Have an Impairment(s) That Meets or Medically Equals a Listing?

We use the listings only to decide that individuals are disabled or that they are still disabled. We will not deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If you are not working and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the ''sequential evaluation process.'' Likewise, we will not decide that your disability has ended only because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide that you have experienced medical improvement in your condition(s). (See § 416.994a(b)(2).)

Why Are We Revising the Listings for Impairments That Affect Multiple Body Systems?

We are updating the listings for impairments that affect multiple body systems to update the medical criteria in the listings, to provide more information about how we evaluate impairments that affect multiple body systems, and to reflect our adjudicative experience. We last published final rules revising the adult listings for impairments that affect multiple body systems in the **Federal Register** on May 19, 2000 (65 FR 31800); the rules were effective on June 19, 2000. We last published final rules revising the childhood listings for impairments that affect multiple body systems in the **Federal Register** on December 12, 1990 (55 FR 51204).

What Do We Mean by ''Final Rules'' and ''Prior Rules''?

Even though these rules will not go into effect until 60 days after publication of this notice, for clarity we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date. We will continue to use our prior rules until the effective date of these final rules. When these final rules become effective, we will apply them to new applications filed on or after the effective date of these rules and to claims pending before us, as we describe below.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date when we make a determination or decision, including those claims in which we make a determination or decision after remand to us from a Federal court. With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the administrative law judge's (ALJ's) decision if the ALJ's decision is the final decision of the Commissioner. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court reverses the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

How Long Will These Final Rules Be Effective?

These final rules will no longer be effective 8 years after the date on which they become effective, unless we extend them, or revise and issue them again.

What Revisions Are We Making With These Final Rules?

We are:

- Changing the name of this body system from ''Multiple Body Systems'' to ''Impairments That Affect Multiple Body Systems'';
- Expanding, updating, and reorganizing the guidance in the introductory text to the listings;
- Removing prior listing 110.07;
- Making conforming changes in related regulations; and
- Making nonsubstantive editorial changes.

Why Are We Changing the Name of This Body System?

We are changing the name of this body system from ''Multiple Body Systems'' to ''Impairments That Affect Multiple Body Systems'' to more accurately indicate that we use the listings in this body system to evaluate single impairments that affect two or more body systems.

How Are We Changing the Introductory Text to the Adult Multiple Body Systems Listings?

10.00—Impairments That Affect Multiple Body Systems

We are expanding, updating, and reorganizing the introductory text to provide additional guidance for evaluating impairments under this body system. A detailed description of the revised introductory text follows.

Final 10.00A—What Impairment Do We Evaluate Under This Body System?

In this section, we are expanding and clarifying prior 10.00A, ''Down syndrome (except for mosaic Down syndrome),'' and provide a description of Down syndrome. There are four subsections:

- In final 10.00A1, we explain that we evaluate non-mosaic Down syndrome under this body system.
- Final 10.00A2 is a new paragraph that describes Down syndrome and explains that it exists in ''non-mosaic'' and ''mosaic'' forms. We are revising the language we proposed in the NPRM for medical accuracy, clarity, and consistency with final 10.00A3. However, there are no substantive changes from the NPRM.

• In final 10.00A3a, we describe non-mosaic Down syndrome. Similar to the changes in final 10.00A2, we are making minor editorial revisions from the NPRM for medical accuracy and clarity. In final 10.00A3b, we explain that we evaluate non-mosaic Down syndrome under final listing 10.06. We also explain that, if you have confirmed non-mosaic Down syndrome, we consider you disabled from birth. This provision was part of prior listing 10.06, but we are moving it to the introductory text because it is not a criterion for meeting the listing. It explains only when your disability began. We are also moving the examples of common impairments associated with Down syndrome from proposed 10.00A2 to this section and revising them slightly for clarity.

• We describe mosaic Down syndrome in final 10.00A4a. In final 10.00A4b, we explain that we evaluate adults with confirmed mosaic Down syndrome under the listing criteria in any affected body system(s) on an individual case basis, and we refer to 10.00C for an explanation of how we adjudicate claims involving mosaic Down syndrome. We are making minor editorial revisions from the NPRM consistent with the changes we are making in final 10.00A2 and A3.

Final 10.00B—What Documentation Do We Need To Establish That You Have Non-Mosaic Down Syndrome?

In this section, we are expanding and modifying prior 10.00B. We explain the documentation we need to establish that you have non-mosaic Down syndrome. We are also revising this section as we proposed it in the NPRM to reflect our adjudicative experience, to eliminate an unnecessary requirement in the prior rules, and to reflect modern medical practices. We are also making minor revisions for clarity.

We proposed two paragraphs in 10.00B in the NPRM; there are three paragraphs in these final rules. In final 10.00B1, we explain the basic requirement in our disability programs that the documentation we need to establish the existence of a medically determinable impairment must come from an acceptable medical source, as defined in §§ 404.1513(a) and 416.913(a) of our regulations.

In final 10.00B2, we provide that we will find that you have non-mosaic Down syndrome based only on a report from an acceptable medical source indicating that you have the impairment when that report includes the actual laboratory report of definitive chromosomal analysis showing that you have non-mosaic Down syndrome. We define the phrase ''definitive chromosomal analysis'' as meaning karyotype analysis. Karyotype analysis is currently the most accurate and reliable indicator of the existence of non-mosaic Down syndrome. It is also the kind of analysis that is used most often and the test we refer to in our internal operating instructions.

Based on our adjudicative experience, we have determined that a report from an acceptable medical source indicating that you have non-mosaic Down syndrome that is supported by definitive chromosomal karyotype analysis is sufficient to establish the existence of non-mosaic Down syndrome. We do not additionally require a clinical description of the diagnostic physical features of the impairment when we have this evidence, as we required under the prior rules and in the NPRM, because karyotype analysis shows definitively whether you have non-mosaic Down syndrome. Chromosomal analysis has become much more common in recent years and is often in the medical evidence we obtain. This was not the case in 1990 when we published the original rules for children, the rules we used as a basis for the adult listing we first published on May 19, 2000. See 65 FR 31800. Moreover, physicians generally order chromosomal testing for Down syndrome when their clinical findings suggest that an individual might have Down syndrome, so we believe that we can reasonably presume that the diagnostic physical features are present.

In these final rules, we require the laboratory report to be submitted by an acceptable medical source because in this situation it will be the objective medical evidence we rely on to establish the existence of the medically determinable impairment. This does not mean that an acceptable medical source must conduct the actual karyotype analysis, only that an acceptable medical source must submit the evidence together with an opinion that you have non-mosaic Down syndrome.

In final 10.00B3, we explain that, when we do not have the actual laboratory report of definitive chromosomal analysis, we need evidence from an acceptable medical source that includes a clinical description of the diagnostic physical features of Down syndrome, and that is persuasive that a positive diagnosis has been confirmed by definitive chromosomal analysis at some time prior to our evaluation. This is essentially the same alternative provision that we included in prior 10.00B and in proposed 10.00B2 of the NPRM. The section includes the guidance in prior 10.00B about what we mean by medical evidence that is ''persuasive.''

We are also making other changes from proposed 10.00B2 in final 10.00B3. As in the NPRM, we include examples of other evidence that may help to establish that you have the impairment, such as your educational history or the results of psychological testing. In response to a comment, we are adding references to limitations in adaptive functioning and to mental disorders that may be associated with non-mosaic Down syndrome in these final rules because these findings are frequently in the evidence we obtain and are useful for establishing the diagnosis. We are also revising the proposed examples to remove the reference to ''the description of abnormal physical findings'' we included in the NPRM because it might be confused with the requirement for ''a clinical description of the diagnostic physical features of Down syndrome'' we included earlier in the same paragraph. Finally, we are making a number of editorial changes for clarity and for consistency with other changes that we are making in these final rules.

We are also making other nonsubstantive editorial changes throughout final 10.00B. For example, we are changing the heading of the section to refer specifically to non-mosaic Down syndrome because that is the only impairment we list in this body system. (We are not making the same change to the heading in 110.00B because the childhood listings include other multiple body system impairments.) In final 10.00B3 (proposed 10.00B2), we are also removing the phrase ''if available,'' referring to the example of psychological testing, because it is unnecessary. It is self-evident that the results of psychological testing would have to be available or we would not be able to use them.

Final 10.00C—How Do We Evaluate Other Impairments That Affect Multiple Body Systems?

In this section, we expand and clarify prior 10.00C, ''Other chromosomal abnormalities; *e.g.*, mosaic Down syndrome.'' We explain how we evaluate impairments that affect multiple body systems other than non-mosaic Down syndrome. There are three subsections:

• In final 10.00C1, we explain that, if you have a severe impairment(s) other than non-mosaic Down syndrome that affects multiple body systems, we must consider whether your impairment(s) meets the criteria of a listing in another body system. In these final rules, we are

making minor editorial changes from the NPRM for clarity. For example, instead of referring to non-mosaic Down syndrome as a ''common impairment'' that affects multiple body systems, we are clarifying that it is an impairment that ''commonly affects'' multiple body systems. Although Down syndrome occurs more commonly than other genetic disorders, it still occurs relatively rarely, in only one out of every 750–800 live births in the United States. We are also changing the word ''severe'' in the first sentence to ''significant'' because the word ''severe'' has a special meaning in our rules and this will remove any confusion about our intent.

- In final 10.00C2, we give some examples of the many other impairments that can affect multiple body systems, such as triple X syndrome (XXX syndrome), fragile X syndrome, phenylketonuria (PKU), caudal regression syndrome, and fetal alcohol syndrome. (In an editorial change from the NPRM, we revised the reference to ''trisomy X syndrome'' from the NPRM to refer to two of the more commonly used names of the syndrome: ''triple X syndrome'' and ''XXX syndrome.'') We also explain that, because these impairments can affect various body systems, and the effects on each person can vary widely, we evaluate these impairments under the listing criteria in any affected body system on an individual case basis. Final 10.00C2 generally corresponds to prior 10.00C.
- In final 10.00C3, we explain that, if you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. If it does not, we will proceed to the fourth and, if necessary, fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. We also explain that we follow the rules in §§ 404.1594 and 416.994, as appropriate, when we decide whether you continue to be disabled.

As in final 10.00B, we are also making nonsubstantive editorial changes from the NPRM throughout final 10.00C.

How Are We Changing the Criteria in the Listing for Non-Mosaic Down Syndrome in Adults?

Final 10.06—Non-Mosaic Down Syndrome

We are simplifying the heading to make it clear that we evaluate only non-mosaic Down syndrome under this listing. As already noted, we are also moving the last sentence of prior listing 10.06 to final 10.00A3b. Because of the changes we are making in final 10.00B2, we are revising the proposed rule toremove the requirement for ''clinical and laboratory'' findings in every case. Instead, we are requiring that you show that you have non-mosaic Down syndrome ''established as described in 10.00B.''

What Changes Are We Making for Children?

The following is an explanation of the changes we are making in part B, the listings for individuals who are under age 18. Except as described below, if we use the same criteria in both the adult and childhood rules, we are making these changes in the childhood rules for the same reasons we made the changes in the adult rules.

We describe below only the changes in the final rules in part B that are substantively different from the changes in part A. We do not describe minor, nonsubstantive differences in the language of the final rules specifically to address children.

How Are We Changing the Introductory Text to the Child Multiple Body Systems Listing?

Final 110.00A—What Kinds of Impairments Do We Evaluate Under This Body System?

In final 110.00A1, we provide a general description of the kinds of impairments we evaluate under this body system. We also provide a brief description of the effects that these impairments generally have on a child's ability to perform age-appropriate activities. We also explain that, when we use the term ''very seriously'' in these listings, we mean an ''extreme'' limitation as we define it in § 416.926a(e)(3) of our regulation for functional equivalence. To correct an error in the NPRM, we deleted the reference to mosaic Down syndrome as one of the impairments we evaluate under these listings. There is no listing for mosaic Down syndrome in these final rules.

In final 110.00A5a, we describe what we mean by ''catastrophic congenital abnormalities or diseases.'' We explain that they are present at birth and that it is reasonably certain that they will result in early death or interfere very seriously with development. In final 110.00A5b, we explain that we evaluate catastrophic congenital abnormalities or diseases under final listing 110.08.

Final 110.00B—What Documentation Do We Need To Establish That You Have an Impairment That Affects Multiple Body Systems?

We are making the same change in final 110.00B2 that we made in final 10.00B2, which provides that we will find that you have non-mosaic Down syndrome based on definitive chromosomal analysis (that is, karyotype analysis) if we have a copy of the laboratory report and it is submitted by an acceptable medical source who tells us that you have non-mosaic Down syndrome. In such cases, as in the final adult rules, we do not additionally require a clinical description of the diagnostic physical features of Down syndrome. As in final 10.00B3, we are also expanding the list of examples in final 110.00B3 to include examples of limitations in adaptive functioning or signs of a mental disorder.

Final 110.00B differs from final 10.00 because the listings in final 110.00 include other kinds of multiple body system impairments besides non-mosaic Down syndrome. Final 110.00B2a and 110.00B2b correspond to final 10.00B2 and 10.00B3. They explain we need to establish the existence of non-mosaic Down syndrome under final listing 110.06. Final 110.00B3 explains the evidence we need to establish the existence of the catastrophic congenital abnormalities and diseases we evaluate under final listing 110.08. Final 110.00B3a, explains how we document genetic disorders (such as Trisomy 13 or 18, chromosomal deletion syndromes, and genetic metabolic disorders) under final listing 110.08. Final 110.00B3b explains how we document other kinds of catastrophic congenital abnormalities (such as anencephaly and cyclopia) under final listing 110.08. In both cases, we need a clinical description of the physical abnormalities that are diagnostic for the impairments. In the case of genetic disorders under final listing 110.08, we also need the report of the definitive laboratory testing (for example, genetic analysis or evidence of biochemical abnormalities) appropriate to the impairment. However, as in the case of non-mosaic Down syndrome, we can also use a report from an acceptable medical source that is persuasive that appropriate testing was done in the past and that is consistent with the other information in the case record. In response to a comment, we are also including in final 110.00B3a examples of genetic disorders that we evaluate under final listing 110.08.

Final 110.00B is also different from final 10.00B in other ways. For example, we are not changing the heading of final

110.00B even though we changed the heading in 10.00B because we list a number of different impairments in 110.00 in addition to non-mosaic Down syndrome.

Final 110.00C—How Do We Evaluate Impairments That Affect Multiple Body Systems and That Do Not Meet the Criteria of the Listings in This Body System?

In final 110.00C2, as in the final adult rules and the NPRM, we explain that there are many other impairments that affect multiple body systems apart from the ones we include in these listings. However, because these impairments can vary widely in their effects on children, we need to evaluate their particular effects under the body system or body systems appropriate to those effects. In response to a comment about our proposed deletion of listing 110.07, we are also expanding final 110.00C2 to refer to specific categories of impairments involving multiple body systems, such as congenital anomalies, chromosomal disorders, and dysmorphic syndromes. As in the NPRM, we are also including some examples of specific impairments that can affect multiple body systems, such as triple X syndrome (XXX syndrome), fragile X syndrome, PKU, caudal regression syndrome, and fetal alcohol syndrome.

In final 110.00C3, we explain that, if you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. If your impairment(s) does not meet or medically equal a listing, we will consider whether it functionally equals the listings. In the last sentence of final 110.00C3, we explain that we use the rules in § 416.994a when we consider whether you continue to be disabled. In a change from the NPRM, we are deleting the phrase ''If you are receiving SSI payments,'' which we proposed for the beginning of the last sentence. This will clarify that we use the rules in § 416.994a whenever we consider whether you continue to be disabled. This may occur, for example, when we make a ''closed period'' determination or decision; that is, a determination or decision that you were disabled and eligible for payments at the time you filed your application for SSI but, at the same time, that you are now no longer disabled. In such a situation you will not yet have received any SSI payments.

How Are We Changing the Criteria in the Listings for Evaluating Impairments That Affect Multiple Body Systems in Children?

If the same criteria exist in both the adult and childhood rules, we are making the same changes in the childhood rules that we made for the adult rules for the same reasons we made the changes in the adult rules. The following is an explanation of the changes where they differ substantively from the final adult rules.

Final 110.01—Category of Impairments, Impairments That Affect Multiple Body Systems

Prior Listing 110.07—Multiple Body Dysfunction

We are removing prior listing 110.07 for two reasons.

- First, we established listing 110.07A in 1990 to help us evaluate physical impairments in infants and young children. However, we wrote this listing before we had the policy of functional equivalence in § 416.926a, which we first published in 1991 and have updated several times, and before we updated several listings to better evaluate impairments in such children. All children who could qualify under any of the provisions of prior listing 110.07 will continue to qualify under other listings or the rules for functional equivalence. Therefore, prior listing 110.07A has become outdated and unnecessary.
- Second, the remaining criteria, prior listings 110.07B through F, were solely reference listings that referred adjudicators to other listings in other body systems. As we update the listings in each of the body systems in the Listing of Impairments, we are removing reference listings because they are redundant.

Final Listing 110.08—A Catastrophic Congenital Abnormality or Disease

In the final rules, we provide listings for two kinds of catastrophic congenital abnormalities or diseases:

- Ones in which death usually is expected within the first months of life, and the rare individuals who survive longer are profoundly impaired (final listing 110.08A); and
- Ones that interfere very seriously with development (final listing 110.08B).

In the final listing, we are changing the references to incompatibility with ''extrauterine life'' in prior listing 110.08A and ''life outside of the uterus'' in the proposed listing to recognize that some children with the kinds of abnormalities listed may live for months or even a few years. The final language, ''Death usually is expected within the first months of life, and the rare individuals who survive longer are profoundly impaired,'' explains our intent more clearly.

In final listing 110.08B, we are changing the phrase ''attainment of the growth and development of 2 years is not expected to occur'' from the prior listing to ''interferes very seriously with development.'' This language in the final listing takes into consideration advances in the evaluation and management of these abnormalities and diseases, and will include under the listing some children with very serious limitations in development who were not included under the prior listing. This revised language is also consistent with our definition of ''extreme'' limitation in § 416.926a(e)(3). We are also clarifying in response to a comment that, for those diseases that have both infantile-onset and later-onset forms (for example, Tay-Sachs disease), only the earlier onset forms, which tend to be associated with more serious outcomes, are included under this listing.

Finally, we are making final listing 110.08 clearer and easier to understand by:

- Changing the word ''abnormalities'' from prior listing 110.08 to ''abnormality'' to emphasize that there need be only a single abnormality or disease involved.
- Removing the requirement for ''a positive diagnosis'' from prior listings 110.08A and B and instead cross-referring to 110.00B in the opening statement of final listing 110.08. This is a nonsubstantive change from the provision we proposed in the NPRM, which continued to use the phrase ''a positive diagnosis.'' We believe the phrase is unnecessary because 110.00B describes the evidence we need to establish whether a child has an impairment listed under 110.08.
- Updating, in response to a comment, the examples of ''trisomy D and trisomy E'' in final listing 110.08A to their more modern and medically accurate names, ''trisomy 13'' and ''trisomy 18,'' and updating and clarifying the examples in final listing 110.08B.

What Other Rules Are We Changing?

We are revising sections 8.00E3 and 108.00E3 in our skin body system listings for consistency with the changes we are making in final sections 10.00B and 110.00B. We recently published these final rules in the **Federal Register**. See 69 FR 32260 (June 9, 2004). In the final skin listings, we established new listings 8.07A and 108.07A for

xeroderma pigmentosum (XP), and listings 8.07B and 108.07B for other genetic photosensitivity disorders. In 8.00E3 and 108.00E3 in the introductory text to those listings, we provided rules for establishing the existence of XP and other genetic photosensitivity disorders that we based on the prior rules for establishing the existence of non-mosaic Down syndrome. Under those rules, we required both a clinical description of the impairment and evidence of definitive genetic laboratory studies establishing the impairment. See 69 FR 32263. Our reasons for the changes in these final rules for establishing the existence of non-mosaic Down syndrome apply equally to our rules for establishing the existence of XP and other genetic photosensitivity disorders. Therefore, we are revising 8.00E3 and 108.00E3 for consistency with final 10.00B and 110.00B. As in the final multiple body system listings, the changes will simplify our rules for establishing the existence of the impairments.

We are also replacing the last sentence of 101.00B2c(2), ''How we assess inability to perform fine and gross movements in very young children,'' in the introductory text of the childhood musculoskeletal body system listings, because it refers adjudicators to prior 110.07A, which we are removing from the multiple body system listings. The final provision is based on the language of 101.00B2b(2), which addresses the assessment of the ability to ambulate effectively in very young children, but in terms relevant to the inability to perform fine and gross movements in such children.

What Other Changes Are We Making?

We are making a number of editorial changes from the NPRM in these final rules. The changes simplify and clarify language, change some sentences to active voice, and improve consistency between the provisions of part A and part B. These are not substantive changes, and we do not intend for them to change the meaning of the language we proposed in the NPRM.

What Rules Are We Not Changing?

In the NPRM, we proposed to change prior § 416.934(g), which was a provision in one of our regulations about presumptive disability and presumptive blindness payments under SSI. The prior provision used language that was out-of-date. However, on August 28, 2003, we published final rules that made this change. (See ''Revised Medical Criteria for Evaluating Amyotrophic Lateral Sclerosis,'' 68 FR 51689, 51692.) Therefore, we are not including the change in these final rules because we have already made it. We did not receive any public comments about the proposed change.

Public Comments

In the NPRM we published on December 23, 2002 (67 FR 78196), we provided the public with a 60-day period in which to comment. The period ended on February 21, 2003. We mailed electronic copies to national medical organizations and professionals who have expertise in the evaluation of impairments that affect multiple body systems. As a part of our outreach efforts, we invited comments from advocacy groups and legal services organizations.

We received comments from six commenters. We carefully considered all of the comments. Because some of the comments were long, we have condensed, summarized, and paraphrased them. We have tried to summarize the commenters' views accurately, and to respond to all of the significant issues raised by the commenters that were within the scope of these rules.

Final Section 10.00B—What Documentation Do We Need To Establish That You Have Non-Mosaic Down Syndrome?

Final Section 110.00B—What Documentation Do We Need To Establish That You Have an Impairment That Affects Multiple Body Systems?

Comment: One commenter stated that the provisions of prior 10.00B and 110.00B did not permit the use of mental and adaptive behaviors to be used in conjunction with laboratory tests to confirm a probable positive diagnosis of Down syndrome. The commenter said that the wording appeared to require the description of abnormal physical findings to confirm the diagnosis in all cases. The commenter suggested that when we consider the full range of signs, symptoms, and laboratory findings we include, in addition to physical findings, mental and adaptive clinical evidence.

Response: We adopted the comment in final 10.00B3 and 110.00B2b.

Final Listings 10.06 and 110.06—Non-Mosaic Down Syndrome

Comment: A commenter said that the proposed listings were silent on the issues of how many biopsies and chromosome evaluations, and of how many different body tissues, would be necessary to absolutely and definitively rule out the presence of mosaicism. The commenter believed that we should specify how non-mosaicism must be established. The commenter asked whether a treating physician's assertion would be sufficient or a chromosomal analysis of only one body tissue and, if so, of which tissue.

Response: The standard diagnostic test for Down syndrome in both the non-mosaic and mosaic forms is a blood chromosomal (karyotype) analysis, and the great majority of people with Down syndrome have the non-mosaic form. Mosaic Down syndrome is rare: only about 1 to 2 percent of people who have Down syndrome have the mosaic form.

In these final rules, we are making clear in response to this comment that a treating physician's statement alone is not sufficient to establish whether Down syndrome is mosaic or non-mosaic, although a treating physician's statement, supported by karyotype analysis, as outlined in 10.00B2 and 110.00B2a, will be sufficient to establish that you have non-mosaic Down syndrome. Under final listings 10.06 and 110.06, either a report of definitive chromosomal analysis alone or a physician's statement that there was chromosomal testing together with the physician's description of the diagnostic physical findings will support a finding of disability.

Final Listing 110.07—Multiple Body Dysfunction

Comment: One commenter said that, although prior listing 110.07 was basically a reference listing, it served to reinforce the need to assess multiple body dysfunction regardless of the underlying condition. The commenter believed that the listing served as a valuable reminder of this basic concept, and that we should retain it, especially for adjudicators who are less experienced.

Response: We did not adopt the comment. We do not agree that the prior reference listing would be especially helpful to adjudicators, even newer ones. All children who could qualify under any of the provisions of prior listing 110.07 will continue to qualify under other listings or the rules for functional equivalence. Also, as we have already noted, because reference listings are redundant, we are removing them from all the body systems as we revise them; therefore, retaining one reference listing in this body system would be anomalous.

We did include information about the SSI childhood disability regulations in the introductory text to these final listings as a reminder about our other rules. Additionally, because the last sentence of 101.00B2c(2) in the introductory text of the childhood

musculoskeletal listings referred adjudicators to prior 110.07A, we are replacing that sentence with clearer guidance for assessing extreme limitation of fine and gross movements in very young children, similar to the guidance in 101.00B2b(2).

Final Listing 110.08—Catastrophic Congenital Abnormality or Disease

Comment: One commenter asked whether proposed listings 110.08A and B would include trisomies 8, 9, 13, and 18, as well as 21. The commenter also asked if the deletions listed under proposed listing 110.08B included the deletions for chromosomes 5, 8, 11, 13, 18, 21, and 22. Finally, the commenter asked whether our example of Tay-Sachs disease was meant to suggest that other conditions, such as medium- and long-chain dehydrogenase deficiencies, Zellweger syndrome, Niemann-Pick disease, Krabbe disease and mucolipidosis, should also be included in this category.

Response: We clarified the listing in response to this comment. We also included similar clarifications in final 110.00B3a of the introductory text.

In 110.08A, we changed the examples of trisomy D and E to their more currently accepted names, trisomy 13 and 18, respectively. Most children born with trisomy 13 or 18 die relatively shortly after birth. Trisomy 21 is Down syndrome, so it is covered under final listing 110.06.

Most of the other non-mosaic trisomy syndromes in which a lifespan beyond age 1 is generally expected are associated with profound developmental retardation, and so would be included under final listing 110.08B. However, when the clinical course of a trisomy syndrome is variable, we will evaluate the impairment under the affected body system(s).

With regard to deletion syndromes, we clarified in final 110.08B that the example of ''5p-syndrome'' (cri du chat syndrome) was an example of a deletion syndrome: ''deletion 5p syndrome.'' Any of the other chromosomal deletion syndromes that are associated with profound developmental retardation will also meet the requirements of final listing 110.08B. When the clinical course of a deletion syndrome is more variable, we will evaluate the impairment under the affected body system(s).

In response to this comment, we are also clarifying our intent in final listing 110.08B. We are clarifying that the example of Tay-Sachs disease—which is a metabolic disease (beta-hexosaminidase deficiency)—refers to the infantile onset form; we will evaluate the later onset forms of Tay-Sachs disease under the affected body systems. This policy principle will also apply to other deficiency/storage diseases, such as medium-chain dehydrogenase deficiency, Niemann-Pick disease, and Krabbe disease. The infantile onset forms, which are associated with the most serious outcomes, will meet listing 110.08B, and we will evaluate the effects of other forms under the appropriate body systems.

Other Comments

Comment: Two commenters wrote to us about impairments that they wanted us to add to the multiple body systems listings. The first commenter wanted us to include chronic granulomatous disease (CGD), which he described as an impairment that, with proper treatment, does not cause any visible manifestations but that, without treatment, can be fatal in just a few years. Because of the characteristics of the disease, the commenter believed we should make determinations of disability based on how serious a person's condition is, regardless of whether he or she receives treatment.

Similarly, the second commenter asked us to include Beckwith-Wiedemann syndrome in our listings for children. He expressed a concern that, without a listing to go by, we would have a harder time finding out the severity of the disorder.

Response: Although we agree that these impairments can be disabling, we did not adopt the comments asking us to add them to the listings. CGD exists in multiple forms with variable effects and prognoses. Beckwith-Wiedemann syndrome also varies in its clinical course and its effects on different individuals.

Regulatory Procedures

Executive Order (E.O.) 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under E.O. 12866, as amended by E.O. 13258. Thus, they were subject to Office of Management and Budget review.

Regulatory Flexibility Act

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

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 says that no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget control number. In accordance with the Paperwork Reduction Act, SSA is providing notice that the Office of Management and Budget has approved the information collection requirements contained in sections 10.00B, 10.00C, 110.00B, and 110.00C. The Office of Management and Budget Control Number for this (these) collection(s) is 0960–0642, expiring March 31, 2008.

(Catalog of Federal Domestic Program Nos. 96–001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96–004, Social Security-Survivors Insurance; and 96–006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: May 20, 2005.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

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

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—[Amended]

■ 2. Item 11 in the introductory text before part A of appendix 1 to subpart P of part 404 is amended to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

11. Impairments That Affect Multiple Body Systems (10.00 and 110.00): (*Insert date 8 years after effective date of final regulations.*)

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■ 3. The list of sections for part A is amended by revising the heading of section 10.00 to read as follows:

Part A

* * * * *

10.00 Impairments That Affect Multiple Body Systems

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■ 4. In listing 8.00, Skin Disorders, section 8.00E3 and the introductory text of listing 8.07 are revised to read as follows:

* * * * *

E. How Do We Evaluate Genetic Photosensitivity Disorders?

* * * * *

3. *Clinical and laboratory findings.*

a. *General.* We need documentation from an acceptable medical source, as defined in §§ 404.1513(a) and 416.913(a), to establish that you have a medically determinable impairment. In general, we must have evidence of appropriate laboratory testing showing that you have XP or another genetic photosensitivity disorder. We will find that you have XP or another genetic photosensitivity disorder based on a report from an acceptable medical source indicating that you have the impairment, supported by definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA or genetic abnormality specific to your type of photosensitivity disorder.

b. *What we will accept as medical evidence instead of the actual laboratory report.* When we do not have the actual laboratory report, we need evidence from an acceptable medical source that includes appropriate clinical findings for your impairment and that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing at some time prior to our evaluation. To be persuasive, the report must state that the appropriate definitive genetic laboratory study was conducted and that the results confirmed the diagnosis. The report must be consistent with other evidence in your case record.

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8.01 Category of Impairments, Skin Disorders

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8.07 *Genetic photosensitivity disorders*, established as described in 8.00E.

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■ 5. Listing 10.00, Multiple Body Systems, is revised to read as follows:

* * * * *

10.00 Impairments That Affect Multiple Body Systems

A. What Impairment Do We Evaluate Under This Body System?

1. *General.* We evaluate non-mosaic Down syndrome under this body system.

2. *What is Down syndrome?* Down syndrome is a condition in which there are three copies of chromosome 21 within the cells of the body instead of the normal two copies per cell. The three copies may be separate (trisomy), or one chromosome 21 copy may be attached to a different chromosome (translocation). This extra chromosomal material changes the orderly development of the body and brain. Down syndrome is characterized by a complex of physical characteristics, delayed physical development, and mental retardation. Down syndrome exists in non-mosaic and mosaic forms.

3. *What is non-mosaic Down syndrome?*

a. Non-mosaic Down syndrome occurs when you have an extra copy of chromosome 21 in every cell of your body. At least 98 percent of people with Down syndrome have this form (which includes either trisomy or translocation type chromosomal abnormalities). Virtually all cases of non-mosaic Down syndrome affect the mental, neurological, and skeletal systems, and they are often accompanied by heart disease, impaired vision, hearing problems, and other conditions.

b. We evaluate adults with confirmed non-mosaic Down syndrome under 10.06. If you have confirmed non-mosaic Down syndrome, we consider you disabled from birth.

4. *What is mosaic Down syndrome?*

a. Mosaic Down syndrome occurs when you have some cells with the normal two copies of chromosome 21 and some cells with an extra copy of chromosome 21. When this occurs, there is a mixture of two types of cells. Mosaic Down syndrome occurs in only 1–2 percent of people with Down syndrome, and there is a wide range in the level of severity of the impairment. Mosaic Down syndrome can be profound and disabling, but it can also be so slight as to be undetected clinically.

b. We evaluate adults with confirmed mosaic Down syndrome under the listing criteria in any affected body system(s) on an individual case basis, as described in 10.00C.

B. What Documentation Do We Need To Establish That You Have Non-Mosaic Down Syndrome?

1. *General.* We need documentation from an acceptable medical source, as defined in §§ 404.1513(a) and 416.913(a), to establish that you have a medically determinable impairment.

2. *Definitive chromosomal analysis.* We will find that you have non-mosaic Down syndrome based on a report from an acceptable medical source that indicates that you have the impairment and that includes the actual laboratory report of definitive chromosomal analysis showing that you have the impairment. *Definitive chromosomal analysis* means karyotype analysis. In this case, we do not additionally require a clinical description of the diagnostic physical features of your impairment.

3. *What if we do not have the results of definitive chromosomal analysis?* When we do not have the actual laboratory report of definitive chromosomal analysis, we need evidence from an acceptable medical source that includes a clinical description of the diagnostic physical features of Down syndrome, and that is persuasive that a positive diagnosis has been confirmed by definitive chromosomal analysis at some time prior to our evaluation. To be persuasive, the report must state that definitive chromosomal analysis was conducted and that the results confirmed the diagnosis. The report must be consistent with other evidence in your case record; for example, evidence showing your limitations in adaptive functioning or signs of a mental disorder that can be associated with non-mosaic Down syndrome, your educational history, or the results of psychological testing.

C. How Do We Evaluate Other Impairments That Affect Multiple Body Systems?

1. Non-mosaic Down syndrome (10.06) is an example of an impairment that commonly affects multiple body systems and that we consider significant enough to prevent you from doing any gainful activity. If you have a different severe impairment(s) that affects multiple body systems, we must also consider whether your impairment(s) meets the criteria of a listing in another body system.

2. There are many other impairments that can cause deviation from, or interruption of, the normal function of the body or interfere with development; for example, congenital anomalies, chromosomal disorders, dysmorphic syndromes, metabolic disorders, and perinatal infectious diseases. In these impairments, the degree of deviation or interruption may vary widely from individual to individual. Therefore, the resulting functional limitations and the progression of those limitations also vary widely. For this reason, we evaluate the specific effects of these impairments on you under the listing criteria in any affected body system(s) on an individual case basis. Examples of such impairments include triple X syndrome (XXX syndrome), fragile X syndrome, phenylketonuria (PKU), caudal regression syndrome, and fetal alcohol syndrome.

3. If you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, we proceed to the fourth and, if necessary, the fifth step of the sequential evaluation process in §§ 404.1520 and 416.920. We use the rules in §§ 404.1594 and 416.994, as appropriate, when we decide whether you continue to be disabled.

10.01 Category of Impairments, Impairments That Affect Multiple Body Systems

10.06 *Non-mosaic Down syndrome,* established as described in 10.00B.

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■ 6. The list of sections for part B is amended by revising the heading of section 110.00 to read as follows:

Part B

* * * * *

110.00 Impairments That Affect Multiple Body Systems

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■ 7. Paragraph B2c(2) of the introductory text of section 101.00, Musculoskeletal System, of part B of appendix 1 of subpart P of part 404 is revised to read as follows:

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B. * * *

2. * * *

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c. * * *

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(2) *How we assess inability to perform fine and gross movements in very young children.* For very young children, we consider limitations in the ability to perform comparable age-appropriate activities involving the upper extremities compared to the ability of children the same age who do not have impairments. For such children, an extreme level of limitation means skills or performance at no greater than one-half of age-appropriate expectations based on an overall developmental assessment.

■ 8. In listing 108.00, Skin Disorders, section 108.00E3 and the introductory text of listing 108.07 are revised to read as follows:

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E. How Do We Evaluate Genetic Photosensitivity Disorders?

* * * * *

3. *Clinical and laboratory findings.*

a. *General.* We need documentation from an acceptable medical source, as defined in §§ 404.1513(a) and 416.913(a), to establish that you have a medically determinable impairment. In general, we must have evidence of appropriate laboratory testing showing that you have XP or another genetic photosensitivity disorder. We will find that you have XP or another genetic photosensitivity disorder based on a report from an acceptable medical source indicating that you have the impairment, supported by definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA or genetic abnormality specific to your type of photosensitivity disorder.

b. *What we will accept as medical evidence instead of the actual laboratory report.* When we do not have the actual laboratory report, we need evidence from an acceptable medical source that includes appropriate clinical findings for your impairment and that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing at some time prior to our evaluation. To be persuasive, the report must state that the appropriate definitive genetic laboratory study was conducted and that the results confirmed the diagnosis. The report must be consistent with other evidence in your case record.

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108.01 Category of Impairments, Skin Disorders

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108.07 *Genetic photosensitivity disorders,* established as described in 108.00E.

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■ 9. Listing 110.00, Multiple Body Systems, of part B of appendix 1 of subpart P of part 404 is revised to read as follows:

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110.00 Impairments That Affect Multiple Body Systems

A. What Kinds of Impairments Do We Evaluate Under This Body System?

1. *General.* We use these listings when you have a single impairment that affects two or more body systems. Under these listings, we evaluate impairments that affect multiple body systems due to non-mosaic Down syndrome or a catastrophic congenital abnormality or disease. These kinds of impairments generally produce long-term, if not lifelong, interference with age-appropriate activities. Some of them result in early death or interfere very seriously with development. We use the term ''very seriously'' in these listings to describe an ''extreme'' limitation of functioning as defined in § 416.926a(e)(3).

2. *What is Down syndrome?* Down syndrome is a condition in which there are three copies of chromosome 21 within the cells of the body instead of the normal two copies per cell. The three copies may be separate (trisomy), or one chromosome 21 copy may be attached to a different chromosome (translocation). This extra chromosomal material changes the orderly development of the body and brain. Down syndrome is characterized by a complex of physical characteristics, delayed physical development, and mental retardation. Down syndrome exists in non-mosaic and mosaic forms.

3. *What is non-mosaic Down syndrome?*

a. Non-mosaic Down syndrome occurs when you have an extra copy of chromosome 21 in every cell of your body. At least 98 percent of people with Down syndrome have this form (which includes either trisomy or translocation type chromosomal abnormalities). Virtually all cases of non-mosaic Down syndrome affect the mental, neurological, and skeletal systems, and they are often accompanied by heart disease, impaired vision, hearing problems, and other conditions.

b. We evaluate children with confirmed non-mosaic Down syndrome under 110.06. If you have confirmed non-mosaic Down syndrome, we consider you disabled from birth.

4. *What is mosaic Down syndrome?*

a. Mosaic Down syndrome occurs when you have some cells with the normal two copies of chromosome 21 and some cells with an extra copy of chromosome 21. When this occurs, there is a mixture of two types of cells. Mosaic Down syndrome occurs in only 1–2 percent of people with Down syndrome, and there is a wide range in the level of severity of the impairment. Mosaic Down syndrome can be profound and disabling, but it can also be so slight as to be undetected clinically.

b. We evaluate children with confirmed mosaic Down syndrome under the listing criteria in any affected body system(s) on an individual case basis, as described in 110.00C.

5. *What are catastrophic congenital abnormalities or diseases?*

a. Catastrophic congenital abnormalities or diseases are present at birth, although they may not be apparent immediately. They cause deviation from, or interruption of, the normal function of the body and are reasonably certain to result in early death or to interfere very seriously with development.

b. We evaluate catastrophic congenital abnormalities or diseases under 110.08.

B. What Documentation Do We Need To Establish That You Have an Impairment That Affects Multiple Body Systems?

1. *General.* We need documentation from an acceptable medical source, as defined in §§ 404.1513(a) and 416.913(a), to establish that you have a medically determinable impairment. In general, the documentation should include a clinical description of the diagnostic physical features associated with your multiple body system impairment, and any appropriate laboratory tests.

2. *Non-mosaic Down syndrome (110.06).*

a. *Definitive chromosomal analysis.* We will find that you have non-mosaic Down syndrome based on a report from an acceptable medical source that indicates that you have the impairment and that includes the actual laboratory report of definitive chromosomal analysis showing that you have the impairment. *Definitive chromosomal analysis* for Down syndrome means karyotype analysis. When we have the laboratory report of the actual karyotype analysis, we do not additionally require a clinical description of the physical features of Down syndrome.

b. *What if you have Down syndrome and we do not have the results of definitive chromosomal analysis?* When you have Down syndrome and we do not have the actual laboratory report of definitive chromosomal analysis, we need evidence from an acceptable medical source that includes a clinical description of the diagnostic physical features of your impairment, and that is persuasive that a positive diagnosis has been confirmed by definitive chromosomal analysis at some time prior to our evaluation. To be persuasive, the report must state that definitive chromosomal analysis was conducted and that the results confirmed the diagnosis. The report must be consistent with other evidence in your case record; for example, evidence showing your limitations in adaptive functioning or signs of a mental disorder that can be associated with non-mosaic Down syndrome, your educational history, or the results of psychological testing.

3. *Catastrophic congenital abnormalities or diseases (110.08).*

a. *Genetic disorders.* For genetic multiple body system impairments (other than non-mosaic Down syndrome), such as Trisomy 13 (Patau Syndrome or Trisomy D), Trisomy 18 (Edwards' Syndrome or Trisomy E), chromosomal deletion syndromes (for

example, deletion 5p syndrome, also called cri du chat syndrome), or inborn metabolic disorders (for example, Tay-Sachs disease), we need evidence from an acceptable medical source that includes a clinical description of the diagnostic physical features of your impairment, and the report of the definitive laboratory study (for example, genetic analysis or evidence of biochemical abnormalities) that is diagnostic of your impairment. When we do not have the actual laboratory report, we need evidence from an acceptable medical source that is persuasive that a positive diagnosis was confirmed by appropriate laboratory analysis at some time prior to our evaluation. To be persuasive, the report must state that the appropriate definitive laboratory study was conducted and that the results confirmed the diagnosis. The report must be consistent with other evidence in your case record.

b. *Other disorders.* For infants born with other kinds of catastrophic congenital abnormalities (for example, anencephaly, cyclopia), we need evidence from an acceptable medical source that includes a clinical description of the diagnostic physical features of the impairment.

C. How Do We Evaluate Impairments That Affect Multiple Body Systems and That Do Not Meet the Criteria of the Listings in This Body System?

1. These listings are examples of impairments that commonly affect multiple body systems and that we consider significant enough to result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether your impairment(s) meets the criteria of a listing in another body system.

2. There are many other impairments that can cause deviation from, or interruption of, the normal function of the body or interfere with development; for example, congenital anomalies, chromosomal disorders, dysmorphic syndromes, metabolic disorders, and perinatal infectious diseases. In these impairments, the degree of deviation or interruption may vary widely from child to child. Therefore, the resulting functional limitations and the progression of those limitations are more variable than with the catastrophic congenital abnormalities and diseases we include in these listings. For this reason, we evaluate the specific effects of these impairments on you under the listing criteria in any affected body system(s) on an individual case basis. Examples of such impairments include, but are not limited to, triple X syndrome (XXX syndrome), fragile X syndrome, phenylketonuria (PKU), caudal regression syndrome, and fetal alcohol syndrome.

3. If you have a severe medically determinable impairment(s) that does not meet a listing, we will consider whether your impairment(s) medically equals a listing. If your impairment(s) does not meet or medically equal a listing, we will consider whether it functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether you continue to be disabled, we use the rules in § 416.994a.

110.01 Category of Impairments, Impairments That Affect Multiple Body Systems

110.06 *Non-mosaic Down syndrome,* established as described in 110.00B.

110.08 *A catastrophic congenital abnormality or disease*, established as described in 110.00B, and:

A. Death usually is expected within the first months of life, and the rare individuals who survive longer are profoundly impaired (for example, anencephaly, trisomy 13 or 18, cyclopia);

or

B. That interferes very seriously with development; for example, cri du chat syndrome (deletion 5p syndrome) or Tay-Sachs disease (acute infantile form).

* * * * *

[FR Doc. 05–17114 Filed 8–29–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–05–118]

RIN 1625–AA00

Safety Zone; Northerly Island, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Stormwater Conveyance System Construction Project located off of Northerly Island, Lake Michigan, Chicago, IL. The safety zone is necessary to protect vessels and persons from potential hazards during the initial tunneling phase of the project. This phase will involve extensive blasting operations. This safety zone is intended to restrict vessels from a portion of Lake Michigan in Chicago, IL.

DATES: This rule is effective from 8 a.m. (local) on August 22, 2005 until 8 a.m. (local) on October 22, 2005. Captain of the Port Lake Michigan or the on scene Patrol Commander may terminate this event at anytime.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of the docket (CGD09–05–118], and are available for inspection or copying at Commanding Officer, U.S. Coast Guard Marine Safety Unit Chicago, 215 W. 83rd Street Suite D, Burr Ridge, IL, 60527, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Cameron Land, U.S. Coast Guard Marine Safety Unit Chicago, at (630) 986–2155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. This safety zone is temporary in nature and limited time existed for an NPRM. The Coast Guard was not made aware that this event was to take place with sufficient time to allow for publication of an NPRM followed by a final rule. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be impracticable and immediate action is necessary to ensure the safety of personnel and vessels during the operational period. During the enforcement of this safety zone, comments will be accepted and reviewed and may result in a modification to the rule.

Background and Purpose

A temporary safety zone is necessary to ensure the safety of vessels and persons from the hazards associated with a construction project on a navigable waterway. The Captain of the Port Lake Michigan has determined this project in close proximity to watercraft (Burnham Harbor) pose significant risks to public safety and property. Blasting operations in close proximity to the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the blasting site will help ensure the safety of persons and property and minimize the associated risks. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or his designated On-Scene Representative via VHF radio Channel 16.

Discussion of Rule

The safety zone will encompass all waters of Lake Michigan bounded by the arc of a circle with a radius of 150-feet with its center at the shoreline of Northerly Island in the approximate position 41°51′12″ N, 087°36′30″ W. These coordinates are based upon North American Datum 1983 (NAD 1983). The size of this zone was determined using the safety guidelines and safety plan provided by the construction contractor and local knowledge concerning wind, waves, and currents. All commercial and recreational vessels must contact