

<i>Control(s)</i>	<i>Country chart</i>
* * * * *	* * * * *
AT applies to entire entry (refer to 4A994 for controls on "digital computers" with a APP > 0.0128 but ≤ to 1.5 WT)	AT Column 1.
* * * * *	* * * * *

Note 1: For all destinations, except those countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR, no license is required (NLR) for computers with an "Adjusted Peak Performance" ("APP") not exceeding 1.5 Weighted TeraFLOPS (WT) and for "electronic assemblies" described in 4A003.c that are not capable of exceeding an "Adjusted Peak Performance" ("APP") exceeding 1.5 Weighted TeraFLOPS (WT) in aggregation, except certain transfers as set forth in § 746.3 (Iraq).

Note 2: Special Post Shipment Verification reporting and recordkeeping requirements for exports of computers to destinations in Computer Tier 3 may be found in § 743.2 of the EAR.

* * * * *

List of Items Controlled

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Items:

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b. "Digital computers" having an "Adjusted Peak Performance" ("APP") exceeding 1.5 weighted TeraFLOPS (WT);

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Dated: June 15, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011-15842 Filed 6-23-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. FDA-2003-N-0212; (formerly Docket No. 2003N-0355)]

Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation to confirm, with one change, the interim final rule (IFR) entitled "Medical Devices; Exception From

General Requirements for Informed Consent." This final rule confirms the IFR's establishment of a new exception from the general requirements for informed consent to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. FDA has created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational. This final rule adds a requirement that the investigator submit the required documentation to FDA, in addition to submitting it to the reviewing Institutional Review Board (IRB).

DATES: The rule is effective June 24, 2011.

FOR FURTHER INFORMATION CONTACT: Claudia M. Gaffey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5516, Silver Spring, MD 20993-0002, 301-796-6196.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of Final Rule

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA published an Interim Final Rule that established an exception from the general requirements for informed consent to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in specified circumstances. The IFR amended 21 CFR 50.23, to add paragraph (e). The rule was issued under the authority set forth in section 520(g)(3)(D) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)(3)(D)). FDA gave interested parties 60 days to comment on the IFR. FDA is publishing this final rule that incorporates one change in response to comments that the rule did not protect against misuse of the exception. This change is described in section II of this document.

B. Legal Authority

This regulation is being issued under the statutory authority provided in section 520(g)(3)(D) of the FD&C Act, which outlines the criteria under which an exemption from informed consent may be permissible. Under section 520(g)(3)(D) of the FD&C Act, informed consent is required unless the investigator determines the following in writing: (1) There exists a life

threatening situation involving the human subject of such testing which necessitates the use of such device; (2) it is not feasible to obtain informed consent from the subject; and (3) there is not sufficient time to obtain such consent from the subject's legally authorized representative. Further, a licensed physician uninvolved in the testing must agree with this three-part determination in advance of using the device unless use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

II. Highlights of Final Rule

The preamble to the IFR described the provisions of this rule in detail (71 FR 32827). In issuing this final rule, FDA is making one change to the IFR, in response to comments that the rule did not protect against misuse of this limited exception from informed consent requirements. In response to those concerns, FDA is adding a requirement that investigators also send the required documentation to FDA, not just to the reviewing IRB. This new requirement provides an additional level of oversight to help ensure that the limited exception criteria are met.

III. Comments on the IFR

The Agency received comments on the IFR from nine different entities. Comments were received from four individual consumers, two from consumer groups, and one each from a health professional, a health professional group, and a local government. A summary of the comments received, grouped by subject matter follows.

A. General Comments

(Comment 1) Three comments expressed support for the IFR, noting that the rule is needed and greatly improves the ability of public health laboratories to respond to a public health emergency. In contrast, six comments expressed general concern that the rule presents too much risk to the consumer. Some comments raised issues that are beyond the scope of this rulemaking. For example, one of these comments suggested that informed consent documents have a line addressing in vitro diagnostic testing; another encouraged the production of templates to easily provide the detailed information required to be included in the reports.

(Response) FDA agrees with the comments recognizing that the rule will enable better response in public health emergencies. FDA also shares the

general concerns related to ensuring human subject protections. To that end, the Agency has ensured that the rule confers several layers of human subject protection, including IRB review, review and evaluation of the determinations made by the investigator by an independent physician, and disclosure of the investigational status of device to the subject's health care provider. FDA believes the rule balances the need to ensure human subjects are protected with the need to act quickly during a public health emergency and avoid potentially dangerous delays in using investigational devices to identify chemical, biological, radiological, or nuclear agents in human specimens.

(Comment 2) Two comments noted that the IFR has no provisions to prevent abuse.

(Response) FDA disagrees that the rule has no provisions to prevent abuse. The rule requires that the investigator and an independent physician each make specific determinations and that an IRB review these determinations. The determinations that the investigator and independent physician must make require careful consideration related to the use of the device and are intended to prevent abuse. However, FDA does agree that the IFR could have included an additional measure to prevent abuse of the exception; specifically, the IFR could have required that an investigator's documentation be submitted to the Agency, not just to the reviewing IRB. Although FDA relies on IRBs to adequately monitor the procedures set forth by the rule, the Agency recognizes that the IFR did not provide a mechanism for FDA to track the use of this exception from the general requirements for informed consent. Therefore, FDA is adding a requirement that the investigator submit to FDA the documentation required in 21 CFR 50.23(e)(1) or (e)(2) within 5 working days after the use of the device, in addition to submitting this information to the IRB within the same timeframe.

(Comment 3) One comment expressed concern that the only oversight over the determinations made by the investigator and the independent physician on behalf of the subject is that of the IRB and it will take 5 days. The comment claimed that consumers do not have confidence in IRB oversight and recommended the development of an open and clear process for choosing qualified individuals to be granted the extraordinary emergency power to waive informed consent, with opportunity for public comment.

(Response) The Agency agrees that the decision to enter subjects in clinical

trials without informed consent is not a trivial matter and should be made by qualified individuals. The FD&C Act allows for carefully considered exceptions to the general requirements for informed consent in emergency circumstances. The requirements described in this rule follow section 520(g)(3)(D) of the FD&C Act. This rule is to be used during emergencies and, among other requirements, only when there are no cleared or approved available alternative methods of diagnosis to identify the chemical, biological, radiological, or nuclear agent that provides an equal or greater likelihood of saving the life of the subject.

In general, the rule assures that the determinations designed to safeguard the subject are made by two different and independent persons, i.e., the investigator and the independent physician, and that the use is then reviewed by the IRB. In the final rule, FDA is adding another level of oversight by requiring that investigators submit to FDA the same documentation they are required to submit to the IRB. FDA notes that this rule is intended for use in situations where public health laboratories must employ investigational in vitro diagnostic devices to diagnose patients when there are no approved or cleared diagnostic devices available that provide an equal or greater likelihood of saving patients' lives.

(Comment 4) Some comments contended that the rule will allow the use of experimental tests, which have an unknown rate of inaccurate test results.

(Response) FDA agrees that investigational in vitro diagnostic devices do not yet have established performance characteristics and, therefore, their accuracy is unknown until data collected during the investigation demonstrates the device's performance. FDA believes that when an investigational in vitro diagnostic device is needed to identify a chemical, biological, radiological, or nuclear agent and no cleared or approved alternative method of diagnosis is available that provides an equal or greater likelihood of saving the life of the subject, the benefits of the investigational in vitro diagnostic device outweigh the risks. The rule creates an exception to the general requirement for informed consent under these circumstances.

(Comment 5) One comment stated that if the patient is awake there is no justification for not obtaining informed consent.

(Response) The rule contemplates the scenario when the person directing the specimen collection does not know, at

the time the specimen is collected, that an investigational device may need to be used in the future, usually by reference laboratories far from where the specimen was collected. Because of the geographic and temporal separation between specimen collection and testing for a life-threatening agent, to obtain informed consent would require a number of steps and introduce unacceptable delays, independent of whether the patient is physically able to provide informed consent.

B. Notification Obligations

(Comment 6) One comment stated that the notification obligations of the investigator described in the IFR are too complex, stating it should be sufficient to have a certification by the laboratory director declaring that the investigational test was performed in accordance with the rule and to send to the subject a copy of the notice sent to the IRB. The comment also noted that the concurrence of an independent physician adds no value.

(Response) The Agency believes that the notification obligations of the investigator described in this rule, which are similar to the obligations described in other exceptions from the general requirements of informed consent under 21 CFR 50.23, are needed because they are intended to provide added human subject protections and to prevent abuses. Moreover, concurrence of an independent physician is mandated by section 520(g)(3)(D) of the FD&C Act.

C. Notification of Public Health Authorities

(Comment 7) One comment requested the inclusion of explicit language in the rule directing the investigator to notify or report positive results to public health authorities when appropriate or required by State or Federal law.

(Response) FDA agrees that it is important to report the detection of biologic, chemical, nuclear, or radiological agents to public health authorities and encourages this practice. FDA expects this reporting to occur when appropriate or when required under Federal or State law.

D. Interpretation of the Term "Investigator"

(Comment 8) One comment asked whether the term "investigator" can be interpreted to mean the single entity that deploys the investigational device, in which case it would be possible to use a centralized IRB and have the deploying entity be responsible for the reporting requirements.

(Response) For purposes of this regulation, the Agency interprets the term “investigator” to mean the individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed or used in the diagnosis or treatment of a subject. In the event of an investigation conducted by a team of individuals, we use the term “investigator” to mean the responsible leader of that team. (See 21 CFR 50.3(d)). For purposes of this rule, we anticipate that the investigator will generally be the director of the clinical laboratory using the investigational device. This interpretation does not preclude local IRBs from deferring their review to a centralized IRB, provided that the IRB meets the requirements of 21 CFR part 56.

E. Written Certification Timing

(Comment 9) One comment requested that FDA consider extending the number of days allowed for submitting the written certification for the exception. (Under the rule the investigator has 5 working days after the use of the investigational device to submit the investigator’s determinations and those of the independent physician to the IRB.)

(Response) FDA disagrees with this comment. The requirement that the investigator’s determinations and those of the independent physician be submitted to the IRB within 5 working days, which is similar to the obligations described in other exceptions from the general requirements of informed consent under 21 CFR 50.23, are intended to assure prompt action by the IRB, as needed.

F. Other Public Health Emergency

(Comment 10) Two comments contended that the term “other public health emergency” is vague and should be removed or should be revised to specify in exact terms what constitutes a public health emergency worthy of this extraordinary exception from informed consent.

(Response) For purposes of this rule, the term “other public health emergency” means serious domestic emergencies that have the potential to significantly impact public health such as those caused by deadly weather disasters or by widespread infectious disease such as pandemic influenza.

G. Withdrawal of Previously Collected Data

(Comment 11) One comment requested that the following preamble statement, “subjects or their legally authorized representatives will not be

entitled to withdraw previously collected data from the research database * * *” (71 FR 32827 at 32830), be eliminated because it sets a dangerous precedent by allowing government research to take priority over personal privacy.

(Response) FDA does not agree to eliminate the referenced statement. While a subject may withdraw from a study, FDA reiterates that the withdrawal does not extend to the data already obtained during the time the subject was enrolled. FDA’s longstanding position has been that all data collected up to the point of withdrawal is to be maintained in the database and included in subsequent analyses, as appropriate, in order for the study to be scientifically valid.¹ If a subject withdraws from a study, removal of already collected data would undermine the scientific, and therefore the ethical, integrity of the research.

IV. Applicability of 45 CFR Part 46 and Other Legal Requirements

As described in the IFR, some of the activities described in this rule may also constitute non-exempt human subjects research within the meaning of 45 CFR part 46, according to the Office for Human Research Protection (OHRP) in the Department of Health and Human Services (HHS). In particular, the use of the investigational in vitro diagnostic device on individually identifiable human specimens as described in this rule would not be human subjects research under 45 CFR part 46, while the analysis of the individually identifiable data obtained from the use of the investigational device to determine the safety and effectiveness of the device would be considered human subject research under 45 CFR part 46. If the analysis of individually identifiable data involves non-exempt human subjects research that is conducted or supported by HHS, the institution conducting the analysis must obtain an OHRP-approved assurance. In addition, this means that this research activity, if not exempt, i.e., the analysis of the individually identifiable data, must be reviewed prospectively by an IRB and must be conducted with the informed consent of the subjects unless waived. OHRP expects that IRBs will often find that informed consent may be waived under 45 CFR 46.116(d) for the analysis of the individually identifiable data obtained through the use of the investigational device. OHRP issued

¹ See “Guidance for Sponsors, Clinical Investigators, and IRBs—Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials,” found at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf>.

guidance regarding this issue simultaneously with the publication of the IFR, on June 7, 2006. This guidance can be found at <http://www.hhs.gov/ohrp/policy/invitrodev.html>. Those interested in seeking additional information concerning the application of the regulations at 45 CFR part 46 should contact OHRP. We note that research conducted or supported by another Department or Agency may be subject to other laws and regulations. Sponsors should check to see if they are complying with all applicable requirements.

V. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this action provides an exception from an otherwise applicable requirement for investigators, FDA believes that it does not impose a significant burden. The Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth

in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State or authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain federal requirements applicable to devices. 21 U.S.C. 360k; see *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 128 S. Ct. 999 (2008). This final rule creates requirements for specific medical devices under 21 U.S.C. 360k. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and

recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Devices; Exception From General Requirements for Informed Consent.

Description: The final rule amends FDA’s informed consent regulation to provide an exception from the general requirement to obtain informed consent from the subject of an investigation involving an unapproved or uncleared in vitro diagnostic device intended to identify a chemical, biological, radiological, or nuclear agent. For the exception to apply, it is necessary for the investigator and an independent licensed physician to make the determination and certify in writing certain facts concerning the need for use of the investigational in vitro diagnostic device without informed consent (21 CFR 50.23(e)(1)). When reporting the test results to the subject’s health care provider and, possibly, to the appropriate public health authorities, the investigator must disclose the investigational status of the in vitro diagnostic device (21 CFR 50.23(e)(4)). If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the

determination of the independent licensed physician in advance of using the investigational device, 21 CFR 50.23(e)(2) provides that the determination must be made within 5 working days of use of the device. In either case, the certifications are submitted to the IRB within 5 working days after the use of the device (21 CFR 50.23(e)(3)).

The information collection requirements in 21 CFR 50.23(e)(1), (e)(2), and (e)(4) in the IFR have been approved under OMB control number 0910–0586. The information collection requirement in 21 CFR 50.23(e)(3) (submitting the certifications to the IRB) was considered part of the burden for 21 CFR 50.23(e)(1) and (e)(2).

This final rule makes one change to the regulatory requirements established by the IFR. This change requires the investigator to submit the documentation required in 21 CFR 50.23(e)(1) and (e)(2) to FDA, in addition to the reviewing IRB. The documentation the investigator must submit to FDA is identical to the documentation the investigator must submit to the IRB.

Description of Respondents: Clinical laboratory directors, physicians who are investigators.

FDA estimates the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours	Total operating & maintenance costs
50.23(e)(3)	150	3	450	15/60	113	\$100

¹ There are no capital costs associated with this collection of information.

From its knowledge of in vitro diagnostic device investigations, FDA estimates that there are approximately 150 laboratory directors or physicians who could perform this type of testing and, as investigators, are required to comply with information collection and recordkeeping. FDA estimates that there are approximately 450 naturally occurring cases of this type each year. Based on its knowledge of similar types of submissions, FDA estimates that it will take about .25 hour or 15 minutes to prepare each written documentation to be submitted to FDA as required by 21 CFR 50.23(e)(3). The estimated 112.5 total hours was calculated by multiplying the estimated total annual response by the hours per response.

In compliance with the Paperwork Reduction Act of 1995, the collection of

information in this final rule has been submitted to OMB for review. The new information has been submitted as a revision to the previously approved collection OMB control number 0910–0586.

This final rule also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995. The collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR 50.23(e)(1), (e)(2), and (e)(4) have been approved under OMB control number 0910–0586.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

Accordingly, the interim final rule amending 21 CFR part 50 which was published at 71 FR 32827 on June 7, 2006, is adopted as a final rule with the following change:

PART 50—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for 21 CFR part 50 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 2. Revise § 50.23(e)(3) to read as follows:

§ 50.23 Exception from general requirements.

* * * * *

(e) * * *
(3) The investigator must submit the written certification of the determinations made by the investigator and an independent physician required in paragraph (e)(1) or (e)(2) of this section to the IRB and FDA within 5 working days after the use of the device.

* * * * *

Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15816 Filed 6–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 882**

[Docket No. FDA–1997–N–0040] (formerly Docket No. 1997N–0484P)

Medical Devices; Neurological Devices; Clarification of Classification for Human Dura Mater; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the device regulations to clarify the applicability of the device classification for human dura mater. This action is being taken to improve the accuracy of the regulations.

DATES: This final rule is effective June 24, 2011.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is clarifying the regulatory authority for human dura mater in the Agency's

codified regulations for part 882 (21 CFR part 882). In the **Federal Register** of November 24, 2004 (69 FR 68612), FDA published a final rule regarding current good tissue practice for establishments that manufacture human cell, tissue, and cellular and tissue-based products (HCT/Ps). That rule became effective on May 25, 2005. Prior to the effective date of the final rule, human dura mater was regulated as a medical device under § 882.5975. As stated in the final rule, human dura mater is now defined under 21 CFR 1271.3(d) as a HCT/P. As such, it is regulated under section 361 of the Public Health Service Act (42 U.S.C. 264) and the requirements of 21 CFR part 1271, including requirements related to registration and listing, donor eligibility determinations, and current good tissue practice. Accordingly, the device classification contained in § 882.5975 is only applicable for human dura mater recovered prior to the effective date of the final rule, May 25, 2005. The final rule omitted a corresponding annotation to § 882.5975 to clarify that the device classification is only applicable for human dura mater recovered prior to the effective date of the final rule. This document clarifies the regulatory authority for human dura mater. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.5975 is amended by adding paragraph (c) to read as follows:

§ 882.5975 Human dura mater.

* * * * *

(c) *Scope.* The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15817 Filed 6–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9530]

RIN 1545–BH56

Guidance Under Section 956 for Determining the Basis of Property Acquired in Certain Nonrecognition Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations under section 956 of the Internal Revenue Code (Code) regarding the determination of basis in certain United States property acquired by a controlled foreign corporation in certain nonrecognition transactions that are intended to repatriate earnings and profits of the controlled foreign corporation without U.S. income taxation. The regulations affect United States shareholders of a controlled foreign corporation that acquires United States property in certain nonrecognition transactions.

DATES: *Effective Date:* These regulations are effective on June 24, 2011.

Applicability Date: For dates of applicability, see § 1.956–1(e)(6)(vii).

FOR FURTHER INFORMATION CONTACT: Kristine A. Crabtree at (202) 622–3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background and Explanation of Provisions**

On June 24, 2008, the IRS published final and temporary regulations under section 956 (TD 9402) in the **Federal Register** (73 FR 35580). On the same date, the IRS published a notice of proposed rulemaking (REG–102122–08) (the proposed regulations) in the **Federal Register** (73 FR 35606) cross-referencing the temporary regulations. The temporary and proposed regulations provided guidance regarding the determination of basis in certain United States property (as defined in section 956(c)) acquired by a controlled foreign corporation (as defined in section 957(a)) in certain nonrecognition