

machinery, automated or powered systems. General purpose reagents include cytological preservatives, decalcifying reagents, fixatives and adhesives, tissue processing reagents, isotonic solutions and pH buffers. Reagents used in tests for more than one individual chemical substance or ligand are general purpose reagents (e.g., TAQ polymerase, substrates for enzyme immunoassay (EIA)).

\* \* \* \* \*

6. New § 864.4020 is added to subpart E to read as follows:

**§ 864.4020 Analyte specific reagents.**

(a) *Identification.* Analyte specific reagents are antibodies, both polyclonal and monoclonal, specific receptor proteins, nucleic acid sequences, and similar biological reagents which, through chemical binding or reaction with substances in a specimen, are intended for identification and quantification of an individual chemical substance or ligand in biological specimens.

(b) *Classification.*

(1) Class I (General Controls), except as described in paragraph (b)(2) of this section. These devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter.

(2) These devices are in Class III (Premarket Approval), when:

(i) The analyte is used to develop a test intended to diagnose a contagious condition and the condition is highly likely to result in a fatal outcome and prompt accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV) or tuberculosis); or

(ii) The analyte is used to develop a test intended to diagnose a condition for which FDA has established a recommendation or requirement for the use of the test in safeguarding the blood supply or establishing the safe use of blood and blood products (e.g., hepatitis, syphilis, or blood grouping antisera).

(3) ASR's that meet the criteria in paragraph (b)(2) of this section but are used to develop tests that have been classified by FDA into class I or class II are classified into the same class as the test for which they are being used.

(c) Date PMA or notice of completion of a PDP is required:

(1) Preamendments ASR's; No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(2) of this section. See § 864.3.

(2) For postamendments ASR's; (effective date of the final rule).

Dated: March 8, 1996.  
William B. Schultz,  
Deputy Commissioner for Policy.  
[FR Doc. 96-6160 Filed 3-11-96; 4:01 pm]  
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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[EE-35-95]

RIN 1545-AT82

**Allocation of Accrued Benefits Between Employer and Employee Contributions; Correction**

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Correction to notice of proposed rulemaking.

**SUMMARY:** This document contains corrections to the notice of proposed rulemaking (EE-35-95) which was published in the Federal Register on Friday, December 22, 1995 (60 FR 66532), relating to proposed regulations that provide guidance on calculation of an employee's accrued benefit derived from the employee's contributions to a qualified defined pension plan.

**FOR FURTHER INFORMATION CONTACT:** Janet A. Laufer, (202) 622-4606, (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

The notice of proposed rulemaking that is the subject of this correction proposes amendments that reflect changes made to section 411(c)(2) by the Omnibus Budget Reconciliation Act of 1987 and the Omnibus Budget Reconciliation Act of 1989.

**Need for Correction**

As published, the notice of proposed rulemaking (EE-35-95) contains errors which may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the publication of the notice of proposed rulemaking (EE-35-95), which was the subject of FR Doc. 95-31006, is corrected as follows:

**§ 1.411(c)-1 [Corrected]**

1. On page 66535, column 1, § 1.411(c)-1 (c)(6)(ii), paragraphs (1) through (8) of *Example 1.*, are correctly designated as paragraphs (A) through (H) of *Example 1.*

2. On page 66535, column 1, § 1.411(c)-1 (c)(6)(ii), newly designated

paragraph (D) of *Example 1.*, line 4, the language "determined in paragraph (3) of this *Example*" is corrected to read "determined in paragraph (C) of this *Example*".

3. On page 66535, column 1, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (D) of *Example 1.*, the last line, the language "\$11,913 - 9.196 = \$1,295." is corrected to read "\$11,913 ÷ 9.196 = \$1,295.".

4. On page 66535, column 1, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (H) of *Example 1.*, second and third lines from the bottom of the column, the language "contributions, the sum of paragraphs (4) and (7) of this *Example 1.* (\$1,295 + \$1,654 = " is corrected to read "contributions, the sum of paragraphs (D) and (G) of this *Example 1.* (\$1,295 + \$1,654 = ".

5. On page 66535, column 2, § 1.411(c)-1 (c)(6)(ii), paragraphs (1) through (5) of *Example 2.* are correctly designated as paragraphs (A) through (E) of *Example 2.*

6. On page 66535, column 2, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (B) of *Example 2.*, last line, the language "(\$6,480 from paragraph 2 of *Example 1.*." is corrected to read "(\$6,480 from paragraph (B) of *Example 1.*.".

7. On page 66535, column 2, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (C) of *Example 2.*, last line, the language "from paragraph 3 of *Example 1.*." is corrected to read "from paragraph (C) of *Example 1.*.".

8. On page 66535, column 2, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (D) of *Example 2.*, line 4, the language "determined in paragraph (3) of this *Example*" is corrected to read "determined in paragraph (C) of this *Example*".

9. On page 66535, column 2, § 1.411(c)-1 (c)(6)(ii), newly designated paragraph (D) of *Example 2.*, last line, the language "(\$1,295 from paragraph 4 of *Example 1.*)" is corrected to read "(\$1,295 from paragraph (D) of *Example 1.*)".

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 96-5675 Filed 3-13-96; 8:45 am]

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