

this chapter subject to § 864.9, and the following conditions for exemption:

(i) The instrument must not include an indication for sorting and collecting cells for IVD use or other clinical purposes;

(ii) The instrument must not be or include an automated hematology analyzer or include an indication for performing an automated differential cell count;

(iii) Design verification and validation for the instrument must include documenting the appropriate performance of each of the performance aspect mitigations identified in sections 7 through 15 of the FDA document entitled “Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells,” and

(iv) Design verification and validation must include documentation of analysis and non-clinical testing demonstrating performance with either fluorescent beads that have been FDA-cleared, approved, or exempted from the premarket notification requirement, or with fluorescent detection reagents that have been FDA-cleared, approved, or exempted from the premarket notification requirement, coupled with fresh, fixed, or stabilized cells, or some combination of such cells. Documentation shall appropriately demonstrate:

(A) The linearity of all fluorescent detectors covers at least four orders of magnitude with less than 10 percent deviation from expected values across the linear range; and

(B) The total imprecision of the measured fluorescence intensity for each detection channel is less than 10 percent Coefficient of Variation across the linear range of the detectors.

Dated: February 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-105600-18]

RIN 1545-BO62

Guidance Related to the Foreign Tax Credit, Including Guidance Implementing Changes Made by the Tax Cuts and Job Act; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a notice of proposed rulemaking.

SUMMARY: This document contains a correction to a notice of proposed rulemaking that was published in the **Federal Register** on Friday, December 7, 2018. The proposed regulations relate to the determination of the foreign tax credit under the Internal Revenue Code.

DATES: Written or electronic comments and requests for a public hearing were due by February 5, 2019.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG-105600-18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20224. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-105600-18), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations under §§ 1.861-8 through 1.861-13, 1.861-17, and 1.904(b)-3, Jeffrey P. Cowan, (202) 317-4924; concerning the proposed regulations under §§ 1.901(j)-1, 1.904-1 through 1.904-6, 1.904(f)-12, and 1.954-1, Jeffrey L. Parry, (202) 317-4916, and Larry R. Pounders, (202) 317-5465; concerning §§ 1.78-1 and 1.960-1 through 1.960-7, Suzanne M. Walsh, (202) 317-4908; concerning §§ 1.965-5 and 1.965-7, Karen J. Cate, (202) 317-4667.

SUPPLEMENTARY INFORMATION:

Background

This correction to the notice of proposed rulemaking (REG-105600-18) addresses provisions issued under sections 861, 904, and 965 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG-105600-18) contains errors that may prove to be misleading and are in need of clarification.

Correction to Publication

Accordingly, the notice of proposed rulemaking (REG-105600-18), that was the subject of FR Doc. 2018-26322, published December 7, 2018 at 83 FR 63200, is corrected as follows:

§ 1.861-9 [Corrected]

1. On page 63230, second column, the sixth line of amendatory instruction 6, the language “percent foreign owned corporations” is corrected to read “percent owned foreign corporations”.

§ 1.904-5 [Corrected]

2. On page 63251, second column, paragraph (i)(2), the sixth line, the language “together with other any person that” is corrected to read “together with any other person that”.

§ 1.904(f)-12 [Corrected]

3. On page 63254, second column, paragraph (j)(1)(ii), the sixth line, the language “beginning after December 31, 2018.” is corrected to read “beginning after December 31, 2017.”.

§ 1.965-7 [Corrected]

4. On page 63266, second column, paragraph (e)(1)(iv)(B)(1), the eighteenth line, the language “If the amount of the net operating loss carryover or carryback to the taxable year is reduced by reason of the section 965(n) election to an amount less than the U.S. source loss component of the net operating loss, the potential carryovers (or carrybacks) of the separate limitation losses that are part of the net operating loss are proportionately reduced as provided in § 1.904(g)-3(b)(3)(ii).” is corrected to read “Therefore, if the amount of the net operating loss carryover or carryback to the taxable year (as reduced by reason of the section 965(n) election) exceeds the U.S. source loss component of the net operating loss that is carried over under § 1.904(g)-3(b)(3)(i), but such excess is less than the potential carryovers (or carrybacks) of the separate limitation losses that are part of the net operating loss, the potential carryovers (or carrybacks) are proportionately reduced as provided in § 1.904(g)-3(b)(3)(ii) or (iii), as applicable.”.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2019-03942 Filed 3-5-19; 8:45 am]

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