

**AMENDMENT TO COMMITTEE PRINT**  
**OFFERED BY MR. INSLEE OF WASHINGTON**  
**(MDUFA\_017; June 11, 2007)**

Add at the end of title II the following new section:

1 **SEC. \_\_\_\_ . INSPECTIONS BY ACCREDITED PERSONS.**

2 Section 704(g) (21 U.S.C. 374(g)) is amended—

3 (1) in paragraph (1), by striking “Not later  
4 than one year after the date of enactment of this  
5 subsection, the Secretary” and inserting “The Sec-  
6 retary”;

7 (2) in paragraph (2), by—

8 (A) striking “Not later than 180 days  
9 after the date of enactment of this subsection,  
10 the” and inserting “The Secretary”; and

11 (B) striking the fifth sentence;

12 (3) in paragraph (3), by adding at the end the  
13 following:

14 “(F) Such person shall notify the Sec-  
15 retary of any withdrawal, suspension, restric-  
16 tion, or expiration of certificate of conformance  
17 with the quality systems standard referred to in  
18 paragraph (7) for any device establishment that  
19 such person inspects under this subsection not

1 later than 30 days after such withdrawal, sus-  
2 pension, restriction, or expiration.

3 “(G) Such person may conduct audits to  
4 establish conformance with the quality systems  
5 standard referred to in paragraph (7).”;

6 (4) by amending paragraph (6) to read as fol-  
7 lows:

8 “(6)(A) Subject to subparagraphs (B) and (C),  
9 a device establishment is eligible for inspection by  
10 persons accredited under paragraph (2) if the fol-  
11 lowing conditions are met:

12 “(i) The Secretary classified the results of  
13 the most recent inspection of the establishment  
14 as ‘no action indicated’ or ‘voluntary action in-  
15 dicated’ (delete).

16 “(ii) With respect to inspections of the es-  
17 tablishment to be conducted by an accredited  
18 person, the owner or operator of the establish-  
19 ment submits to the Secretary a notice that—

20 “(I) provides the date of the last in-  
21 spection of the establishment by the Sec-  
22 retary and the classification of that inspec-  
23 tion;

1           “(II) states the intention of the owner  
2           or operator to use an accredited person to  
3           conduct inspections of the establishment;

4           “(III) identifies the particular accred-  
5           ited person the owner or operator intends  
6           to select to conduct such inspections; and

7           “(IV) includes a certification that,  
8           with respect to the devices that are manu-  
9           factured, prepared, propagated, com-  
10          pounded, or processed in the establish-  
11          ment—

12                   “(aa) at least 1 of such devices is  
13                   marketed in the United States; and

14                   “(bb) at least 1 of such devices is  
15                   marketed, or is intended to be mar-  
16                   keted, in 1 or more foreign countries,  
17                   1 of which countries certifies, accred-  
18                   its, or otherwise recognizes the person  
19                   accredited under paragraph (2) and  
20                   identified under subclause (III) as a  
21                   person authorized to conduct inspec-  
22                   tions of device establishments.

23           “(B)(i) Except with respect to the requirement  
24           of subparagraph (A)(i), a device establishment is  
25           deemed to have clearance to participate in the pro-

1       gram and to use the accredited person identified in  
2       the notice under subparagraph (A)(ii) for inspections  
3       of the establishment unless the Secretary, not later  
4       than 30 days after receiving such notice, issues a re-  
5       sponse that—

6               “(I) denies clearance to participate as pro-  
7               vided under subparagraph (C); or

8               “(II) makes a request under clause (ii).

9               “(ii) The Secretary may request from the owner  
10       or operator of a device establishment in response to  
11       the notice under subparagraph (a)(ii) with respect to  
12       the establishment, or from the particular accredited  
13       person identified in such notice—

14               “(I) compliance data for the establishment  
15               in accordance with clause (iii)(I); or

16               “(II) information concerning the relation-  
17               ship between the owner or operator of the es-  
18               tablishment and the accredited person identified  
19               in such notice in accordance with clause  
20               (iii)(II).

21       The owner or operator of the establishment, or such  
22       accredited person, as the case may be, shall respond  
23       to such a request not later than 60 days after receiv-  
24       ing such request.

1           “(iii)(I) The compliance data to be submitted  
2           by the owner or operation of a device establishment  
3           in response to a request under clause (ii)(I) are data  
4           describing whether the quality controls of the estab-  
5           lishment have been sufficient for ensuring consistent  
6           compliance with current good manufacturing prac-  
7           tice within the meaning of section 501(h) and with  
8           other applicable provisions of this Act. Such data  
9           shall include complete reports of inspectional find-  
10          ings regarding good manufacturing practice or other  
11          quality control audits that, during the preceding 2-  
12          year period, were conducted at the establishment by  
13          persons other than the owner or operator of the es-  
14          tablishment, together with all other compliance data  
15          the Secretary deems necessary. Data under the pre-  
16          ceding sentence shall demonstrate to the Secretary  
17          whether the establishment has facilitated consistent  
18          compliance by promptly correcting any compliance  
19          problems identified in such inspections.

20           “(II) A request to an accredited person under  
21          clause (ii)(II) may not seek any information that is  
22          not required to be maintained by such person in  
23          records under subsection (f)(1).

24           “(iv) A device establishment is deemed to have  
25          clearance to participate in the program and to use

1 the accredited person identified in the notice under  
2 subparagraph (A)(ii) for inspections of the establish-  
3 ment unless the Secretary, not later than 60 days  
4 after receiving the information requested under  
5 clause (ii), issues a response that denies clearance to  
6 participate as provided under subparagraph (C).

7 “(C)(i) The Secretary may deny clearance to a  
8 device establishment if the Secretary has evidence  
9 that the certification under subparagraph (A)(ii)(IV)  
10 is untrue and the Secretary provides to the owner or  
11 operator of the establishment a statement summa-  
12 rizing such evidence.

13 “(ii) The Secretary may deny clearance to a de-  
14 vice establishment if the Secretary determines that  
15 the establishment has failed to demonstrate con-  
16 sistent compliance for purposes of subparagraph  
17 (B)(iii)(I) and the Secretary provides to the owner  
18 or operator of the establishment a statement of the  
19 reasons for such determination.

20 “(iii)(I) The Secretary may reject the selection  
21 of the accredited person identified in the notice  
22 under subparagraph (A)(ii) if the Secretary provides  
23 to the owner or operator of the establishment a  
24 statement of the reasons for such rejection. Reasons  
25 for the rejection may include that the establishment

1 or the accredited person, as the case may be, has  
2 failed to fully respond to the request, or that the  
3 Secretary has concerns regarding the relationship  
4 between the establishment and such accredited per-  
5 son.

6 “(II) If the Secretary rejects the selection of an  
7 accredited person by the owner or operator of a de-  
8 vice establishment, the owner or operator may make  
9 an additional selection of an accredited person by  
10 submitting to the Secretary a notice that identifies  
11 the additional selection. Clauses (i) and (ii) of sub-  
12 paragraph (B), and subclause (I) of this clause,  
13 apply to the selection of an accredited person  
14 through a notice under the preceding sentence in the  
15 same manner and to the same extent as such provi-  
16 sions apply to a selection of an accredited person  
17 through a notice under subparagraph (A)(ii).

18 “(iv) In the case of a device establishment that  
19 is denied clearance under clause (i) or (ii) or with  
20 respect to which the selection of the accredited per-  
21 son is rejected under clause (iii), the Secretary shall  
22 designate a person to review the statement of rea-  
23 sons, or statement summarizing such evidence, as  
24 the case may be, of the Secretary under such clause  
25 if, during the 30-day period beginning on the date

1 on which the owner or operator of the establishment  
2 receives such statement, the owner or operator re-  
3 quests the review. The review shall commence not  
4 later than 30 days after the owner or operator re-  
5 quests the review, unless the Secretary and the  
6 owner or operator otherwise agree.”;

7 (5) in paragraph (7)—

8 (A) by amending subparagraph (A) to read  
9 as follows:

10 “(A) Persons accredited under paragraph  
11 (2) to conduct inspections shall record in writ-  
12 ing their inspection observations and shall  
13 present the observations to the device  
14 establishment’s designated representative and  
15 describe each observation. Additionally, such ac-  
16 credited person shall prepare an inspection re-  
17 port in a form and manner designated by the  
18 Secretary to conduct inspections, taking into  
19 consideration the goals of international harmo-  
20 nization of quality systems standards. Any offi-  
21 cial classification of the inspection shall be de-  
22 termined by the Secretary.”; and

23 (B) by adding at the end the following:

24 “(F) For the purpose of setting risk-based  
25 inspectional priorities, the Secretary shall ac-

1           cept voluntary submissions of reports of audits  
2           assessing conformance with appropriate quality  
3           systems standards set by the International Or-  
4           ganization for Standardization (ISO) and iden-  
5           tified by the Secretary in public notice. If the  
6           owner or operator of an establishment elects to  
7           submit audit reports under this subparagraph,  
8           the owner or operator shall submit all such  
9           audit reports with respect to the establishment  
10          during the preceding 2-year periods.”; and  
11          (6) in paragraphs (10)(C)(iii), by striking  
12          “based” and inserting “base”.