



June 10, 2011

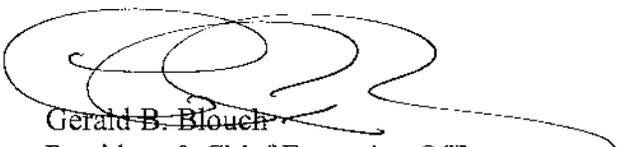
Mr. Ronnie E. Jackson
Director of Compliance
United States Food and Drug Administration
Department of Health and Human Services
District Office
555 Winderley Place, Suite 200
Maitland, FL 32751

Re: Warning Letter; FLA-11-10; Sanford, Florida

Dear Mr. Jackson:

Enclosed please find Invacare's June 10, 2011 update report regarding the FDA Warning Letter relating to our manufacturing facility based in Sanford, Florida.

Sincerely,



Gerald B. Blouch
President & Chief Executive Officer
gblouch@invacare.com

Enclosure

cc: Anthony C. LaPlaca, Sr. Vice President & General Counsel
Douglas J. Newlin, Sr. Vice President, Global Engineering
Jeffrey Craigo, Vice President, Global Quality
Ronald J. Clines, Director, Regulatory Affairs

INVACARE CORPORATION

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June 10, 2011

Mr. Ronnie E. Jackson, Director of Compliance
United States Food and Drug Administration
Maitland, FL

June Update to FDA Warning Letter regarding Invacare Corporation Sanford, FL Facility

Since the issuing of the Warning Letter on December 15, 2010, our team has made the investigation and required corrective action for each of the observations its top priority. The development and further refining of our plan has been communicated through our initial response on January 11, 2011 and in our February and March updates. In reviewing this June update the following should be noted:

- Root causes have been identified for each observation.
- Short term corrective actions have been identified and implemented.
- Those systemic corrective actions which are not involving computer systems deployment have been implemented.
- Implementation plans for those CAPA utilizing computer systems have been developed and scheduled for deployment late 2011 and early 2012.
 - (b) (4) Enhancements
 - (b) (4) Training System
- A third party effectiveness check of our quality system improvements has been established with (b) (4)

Updates regarding our long term corrective action projects specific to the implementation of the (b) (4) system and web based training system will be provided on a (b) (4) basis. The first of these (b) (4) updates will be submitted by September 30th.

Responses to Specific Observations:

For the purpose of keeping our original commitments organized and presented in a clear manner within this follow-up report, we have included the original January 11, 2011 response letter content highlighted in *black italic font*. Updates provided in February and March are indented in regular black font with content of this June update presented in indented regular **blue font**. The attachments in our original response were presented with single letters in red highlighter (e.g. X), the February update attachments were presented with double letters in blue highlighter (e.g. XX), the March attachments were presented with triple letters in yellow highlighter (e.g. XXX), and the attachments in this update are presented with four letters in green highlighter (e.g. XXXX).

Should you have specific questions or need further clarification on any of our actions, please contact Ron Clines, Director Corporate Regulatory Affairs at 440-329-6595 or email: ronclines@invacare.com.

Item 1:

Failure to establish and maintain adequate procedures to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems and to employ appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(1).

The FDA determined that our response was inadequate in that our procedure, Procedure BB14-00, does not clearly identify the requirements for analyzing complaints or discuss what statistical methodology will be utilized to detect recurring problems which is a requirement under 21 CFR

820.100(a)(1). In addition the firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

January Response:

We recognize that our procedure for complaint handling must be improved corporate wide to maintain consistent standards for analyzing complaints which include statistical analysis of complaints from all possible sources and include a process for appropriate and documented corrective action.

Root Cause Determination:

No corporate procedure specific to statistical techniques was used in various areas across the business. Actions need to be risk based, assess all applicable sources and include trigger points for action. While Invacare recognizes that these trigger points may be different from product line to product line, we agree that they need to be defined and statistically based.

Preventative Measures / Systemic Long Term Correction:

1) Create new corporate procedure that defines the statistical methods used. Facility specific procedures, such as BB14-001, will be revised to be in alignment with this new procedure as appropriate. Revised procedures will be provided as part of the February follow-up. Training records on this procedure will be provided as part of the March follow-up.

2) Improve current trending used for Adverse Event complaints and other sources of quality data. Identify improved means to trend Adverse Event complaints especially those involving "key words" such as "fire, smoke, heat, hot and burnt," malfunctions and reportable events. The methods to be employed will be provided as part of the March follow-up. Long term system changes will be reviewed, validated, and audited by (b) (4) and we will update on the expected completion by our June follow-up.

February Update:

1) We created a new corporate Statistical Techniques procedure (CP20-001) and a new Trending and Analysis of Data procedure (CP20-002), copies of both are enclosed (AA). These new corporate procedures address the application of statistical techniques and tools to be utilized in various areas of the business, such as Adverse Events and Returns. Methods include techniques such as:

- (b) (4) studies
- (b) (4) analysis
- Trending of quality complaints, Adverse Events, and Returns
- (b) (4) Analysis
- Month in Service statistical analysis
- Sampling plans

Facility specific procedures Corrective and Preventive Action (BB14-001) and Complaint Handling (BB14-002) are enclosed (AA) has been revised to be in alignment with the new corporate procedure CP20-001. We will provide training records along with the released procedure as part of the March follow-up.

2) We remain on schedule to improve trending for Adverse Event complaints and other sources of quality data, especially those involving "key words", malfunctions and reportable events. We will provide examples of methods to be employed as part of the March follow-up. To demonstrate the progress of our current activities, we (b) (4) from (b) (4) indicating "key words" such as "fire, smoke, heat, hot and burnt," malfunctions and reportable events. (b) (4) consulting will verify the effectiveness of these changes on a timeline to be provided in our June Update report.

3) CAPA process effectiveness has been improved through changes which require:

- Specific techniques for root cause analysis.
- Documentation of decisions and actions related to corrective and preventive actions.

- Ensuring that materials and processes beyond those immediately involved in a quality event are examined and the results documented.

March Update:

1) We released the new corporate Statistical Techniques procedure (CP20-001) and a new Trending and Analysis of Data procedure (CP20-002). Facility specific procedures, Corrective and Preventive Action (BB14-001) and Complaint Handling (BB14-002) have been released to be in alignment with the new corporate procedure CP20-001. The released procedures and training records of affected employees are enclosed (AAA).

2) Adverse Event complaints are evaluated by the Corporate Safety Committee (Management Review) on an ongoing basis. These analyses will now include information involving “key words”, malfunctions, and reportable events. An example of complaint trending using “key word” information is enclosed (BBB). We plan to use statistical trending for this data beginning in our April 2011 meeting.

June Update:

As committed to in March, statistical trending generated from our Trending and Analysis of Data procedure (CP20-001) was used in our April 27th and May 20th Corporate Safety Committee Management Review meetings. It was noted that an increase in MDR reporting has occurred, confirming the effectiveness of the recent changes to our Complaint Handling and Adverse Event Reporting procedure.

Item 2:

Failure to establish and maintain adequate procedures to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3).

Invacare’s response dated September 8, 2010, was determined by the FDA as not adequate. Invacare stated that moving forward it would take actions to increase awareness to customers and users regarding entrapment and is considering adding additional instruction regarding body size as it may relate to increased entrapment. However Invacare’s response did not discuss or provide any evidence of its process for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems. In addition Invacare has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

January Response:

As discussed with the inspectors on site at the Sanford facility, Invacare does recognize that the documentation of our risk assessment activities must be improved. We recognize the need to improve our Corporate risk assessment procedure and apply it consistently throughout our facilities.

Root Cause Determination:

Invacare’s Corporate complaint system does not document that potential user risk was considered, if a formal risk assessment is required or if an existing risk assessment requires review or updating as part of the investigation process. In the current process, risk assessment is performed when a device malfunction or manufacturing process issue is discovered. Risk assessment activities conducted as part of complaint investigation lack specific thresholds that trigger overall product risk update or the potential to update the MDR reporting decision process.

Short Term Corrective Action:

Invacare will revise the procedure "Risk Assessment for Product Malfunctions and Quality Issues" (CP14-013) and the associated form (fm14013a) to ensure risk feed back into the design process. Copies of the revised procedure and form will be provided as part of the March follow-up.

February Update:

1) We revised procedure "Risk Assessment for Product Malfunctions and Quality Issues" CP14-013 and associated form fm14013a to provide for enhanced risk feedback into the design process, enclosed (CC), ahead of the March commitment. The released procedure and relative training records are on schedule to be provided as part of the March follow-up.

March Update:

We released procedure Risk Assessment for Product Malfunctions and Quality Issues CP14-013 and associated form fm14013a. The released documents and training records of affected employees are enclosed (AAA).

June Update:

As indicated in our March update, the occurrence prevention / systemic corrective actions have been implemented.

Occurrence Prevention / Systemic Corrective Action:

Review the (b) (4) complaint system and identify areas for process improvement including risk assessment or other actions that may be required. As indicated in item 1 above, Invacare is creating a Corporate procedure specific to statistical techniques that will address data sources and define trigger points for other action. Summary of this review will be provided as part of the March follow-up. Specific changes to be made to the (b) (4) system and a time line for validation and implementation will be provided as part of the June follow-up. Long term system changes will be reviewed, validated, and audited by (b) (4) and we will update on the expected completion by our June follow-up.

February Update:

We identified a means in (b) (4) to identify whether a complaint risk assessment is necessary and requires verification that a documented review occurs. Once identified, the potential risk is fed back into the design process according to corporate procedure Risk Assessment for Product Malfunctions and Quality Issues (CP14-013). The development of the (b) (4) system and areas for process improvement remains on schedule, and we will update you as part of the March follow-up. To demonstrate the progress of our current activities, we enclosed (BB) prototype screen shots from (b) (4). Specific changes to be made to the (b) (4) process and a time line for verification and implementation are on schedule to be provided as part of the June follow-up. Changes will be reviewed and verified as effective by (b) (4).

As noted above, Invacare created a corporate procedure specific to statistical techniques that addresses data sources and defines trigger points for action, CP20-001, enclosed (AA). The CAPA procedure, CP14-008 (DD), has also been improved to ensure the analysis of quality data occurs and appropriate corrective and preventive actions are taken and documented.

March Update:

In our February update we provided the prototype screen shots from (b) (4) highlighting the use of new data elements added to the system (e.g. "key words", risk assessment, desktop priority, etc.). The timing and events for implementation into the production environment and data field enhancements are enclosed (CCC). This also includes the release of (b) (4) being utilized for e-MDR reporting and relative documents confirming successful transmission / acknowledgement from the FDA Gateway Test Center.

As stated earlier, Invacare released a new corporate procedure specific to statistical techniques that addresses data sources and defines trigger points for appropriate action,

CP20-001. The CAPA procedure, CP14-008, has also been released to ensure the analysis of quality data occurs and appropriate corrective and preventive actions are taken and documented. The released procedures and training records of affected employees are enclosed (AAA).

June Update:

Improvements to our (b) (4) system have been developed and validated in the test environment. Included in these improvements will be the use of e-MDR reporting. We received our e-MDR production account approval from the FDA at the end of May. Migration of our (b) (4) system to our production environment, use of e-MDR filing, and upgrade go-live are planned for completion by September 30, 2011. An updated project plan showing our progress, acknowledgement of our e-MDR production account from the FDA, and approved (b) (4) User Requirements document are enclosed (AAA).

A third party effectiveness check of our quality system improvements has been established with (b) (4). Enclosed is an update letter from (b) (4) (BBB).

Item 3:

Failure to maintain an adequate record of the investigation including the dates and results of the investigation, as required by 21 CFR 820.198(e).

FDA determined that Invacare's response dated September 8, 2010, is not adequate. Invacare stated that it would review the current complaint investigation process and although not specified, is exploring solutions that would document and define "Critical Information" requirements and the attempts to gather this information. Invacare stated that these corrective actions would be completed by October 15, 2010. Invacare has not provided any evidence of implementation of changes to the current investigation process. Invacare also stated that it would document a risk assessment specifically to the potential fire issue and will submit it to FDA by October 15, 2010. Invacare did not mention how it will ensure that the dates and results of complaint investigations are adequate. Additionally, Invacare did not discuss how it will conduct a systemic corrective action that involves re-assessing all complaints to ensure that the investigations were adequately completed and documented.

January Response:

Invacare recognizes the need to improve our complaint handling process. We need to improve the timeliness and documentation of critical information requests and their result.

Root Cause Determination:

Inadequate documentation regarding the minimum information that should be requested / attempted to be obtained as part of the investigation. When information is not available or not provided, there is no documentation indicating that it was requested or that it was not available / or denied. Complaint handling system does not define these data types or require acknowledgement that an attempt was made to obtain the information.

Short Term Corrective Action:

- 1) The consumer incident reporting form, fm14002b, that is used to communicate complaints to Corporate Regulatory Affairs was modified to provide increased visibility of the information required to be obtained as part of the complaint receipt process. A copy of the revised form is enclosed (A).*
- 2) Additionally, we have enclosed a revised risk assessment regarding the "potential fire issue" (B).*

February Update:

Closed in the January response.

Preventative Measures - Systemic Long Term Correction:

- 1) *Invacare will review all risk assessments performed by Regulatory Affairs in response to reportable event complaints or other complaints and determine if other “design considerations” should be added to Invacare’s Product Design Inputs, Risk Assessment and Control Plan, form fm04013c. This will provide for consideration of these identified risks as part of new product development activity. A summary regarding this activity will be provided as part of our March follow-up.*
- 2) *Invacare will review the (b) (4) complaint system and identify areas for improvement. Specific attention will be given to documenting the dates of follow-up attempts, the information requested and the results of that follow-up. A summary of this review will be provided as part of the March follow up. Specific changes to be made to the system including a time line for their validation and implementation will be provided as part of the June follow-up.*
- 3) *Develop an eLearning training module specific to complaint handling. The progress on this activity will be provided as part of the June follow-up.*
- 4) *Invacare will review complaint files received over a two year period that involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. thereby suggesting the potential for fire. Invacare will examine these files to determine if the complaint investigation was adequately investigated and documented. A summary regarding complaints received between July 1, 2010 and December 31, 2010 will be provided as part of our March follow-up. The remaining 18 months will be provided as part of the June follow-up.*

February Update:

- 1) We reviewed all 137 risk assessments performed by Regulatory Affairs in response to Adverse Event complaints or non-Adverse Event complaints and added design considerations to the Product Design Inputs, Risk Assessment and Control Plan form (fm04013c). Based on the initial review activities, this form has been revised ahead of the March commitment, enclosed (EE).
- 2) We remain on schedule with the review of the (b) (4) complaint system to identify areas for improvement. Specific attention has been given to documenting the dates of follow-up attempts, the information requested and the results of that follow-up. A summary of this review will be provided as part of the March follow up. However, to demonstrate the progress of these actions, we (b) (4) that captures the direction of our future changes. Specific changes to be made to the system including a timeline for their verification and implementation remain on schedule and will be provided as part of the June follow-up.
- 3) We remain on schedule in developing an e-learning module prior to our June update, see enclosed prototype screen shots of the e-learning course material (FF), to demonstrate our progress.
- 4) A summary report covering Adverse Event complaints received between July 1, 2010 – December 31, 2010 and copies of any MDRs that resulted in filing as part of this review are enclosed (GG). This includes claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. In summary, 150 Adverse Event complaints were reviewed and we found 17 that contained “entrapment” or “key words” which resulted in filing a MDR. The corresponding MDR numbers are listed in the summary report. We will provide results of our review of the remaining 18 months (January 1, 2009 – June 30, 2010) as part of the March follow-up.

March Update:

- 1) In February we reported that we reviewed all 137 risk assessments performed by Regulatory Affairs in response to Adverse Event complaints or non-Adverse Event complaints, and added design considerations to the Product Design Inputs, Risk Assessment and Control Plan form (fm04013c). The released form and training records of affected employees are enclosed (AAA).

- 2) In our February update we provided the prototype screen shots from (b) (4) highlighting the use of new data elements added to the system (e.g. “key words”, risk assessment, desktop priority, etc.). The timing and events for implementation into the production environment and data field enhancements are enclosed (CCC).
- 3) In February we provided the prototype screen shots of e-Learning training material for complaint handling process. We are ahead of our June commitment of developing improved training methods for complaint handling and will implement the e-Learning module in April 2011. This training enables consistent and timely delivery to new employees that have the potential of handling customer complaints, as part of their on boarding process.
- 4) A summary report covering Adverse Event complaints received for the remaining 18 months (January 1, 2009 – June 30, 2010) and copies of any MDRs that resulted in filing as part of this review are enclosed (DDD). This includes claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. In summary, 536 Adverse Event complaints were reviewed and we found 30 that contained “entrapment” or “key words” which resulted in filing a MDR. The corresponding MDR numbers are listed in the summary report.

Additionally, Adverse Event complaints representing six months (July 1, 2010 to December 31, 2010) were examined to determine the adequacy of the investigation. The complaints were reviewed by looking for “cause” and subsequent action. We found that in each case where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.

However, as part of our overall critical review of Adverse Event Complaints, we note deficiencies that existed in past complaint handling. We identified the following deficiencies:

- Lack of complete documentation as relates to specific attempts to contact the complainant.
- Lack of documentation which supports specific details and conclusions within the complaint report.
- Inconsistent detail obtained by different personnel regarding individual complaints.
- Inconsistency among personnel in the timing of obtaining information via telephone and/or the number of attempts, when the complainant was not immediately available.

In February we made, or initiated the following changes as Corrective and Preventive action:

1. Implementation of new work instructions within Customer Service (CSWI 18-001) and Quality Complaint Form (fm14002e) along with revision of Consumer Incident Reporting Form fm14002b, which will assist in providing consistent and complete information in documentation of new complaints.
2. Initiation of changes to the complaint handling computer system, (b) (4) which will mandate the minimum number of attempts to gather information, and the associated timing of information gathering.
3. Revised Complaint Handling work instructions (RAWI-14-003 and fm14002e) to require specific details consistently by all customer service personnel, and ensure the detail is recorded and placed into the complaint file.
4. Training of changes to the complaint handling process was conducted and documented.

In the interim prior to (b) (4) deployment, we have included in our audit schedule routine audits of Complaint Files to confirm the presence of consistent and complete

information. The results of these audits will be maintained and used for training purposes, as necessary.

The remaining 18 months (January 1, 2009 to June 30, 2010) will be provided within the June update as originally committed in the January response.

June Update:

- 1) As reported in March, our review of Adverse Event and non-Adverse event complaints for added design considerations is complete.
- 2) As reported in our above response to observation 2, our (b) (4) project is on schedule with an updated project plan enclosed (b)(4).
- 3) As reported in March, the complaint handling training module for customer facing associates was developed, reviewed, and approved. Automation of Invacare's training program will be managed through the implementation of a web based training system. A summary of the project plan is enclosed (b)(4).
- 4) Prior complaint files (January 1, 2009 to June 30, 2010) with claims of possible bed rail entrapment as well as files where malfunctions were suggested with keywords such as "smoke", "fire", "heat", "hot" and "burnt", were reviewed for investigation and documentation adequacy. Results were as follows:
 - Twelve (12) files that involved claims of possible bed rail entrapment were opened between January 1, 2009 and June 30, 2010. Each file was examined to *determine if the* complaint investigation was adequately investigated and documented. In all twelve cases where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.
 - One hundred forty six (146) files that involved claims with keywords such as fire, smoke, flame, etc., were opened between January 1, 2009 and June 30, 2010. Each file was examined to determine if the complaint investigation was adequately investigated and documented. All 146 files where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.

As we have previously reported in our March update, we have taken preventive action to ensure new complaint files are adequately investigated and documented (see March update to Item 3, bullet #4).

Item 4:

Failure to establish and maintain adequate procedures for validating the device design in order to ensure that devices conform to defined user needs and intended uses, and perform risk analysis where appropriate, as required by 21 CFR 820.30(g).

The FDA determined that Invacare's response dated September 8, 2010, was not adequate. Invacare stated that it would conduct a risk assessment regarding bed rail entrapment with the intent of determining if the areas of concern that are not currently addressed, such as patient size, or if existing labeling can be augmented in some way. Invacare stated that these activities will be completed by October 30, 2010; however, it has not provided any evidence of implementation of this corrective action. Invacare's response did not address other issues associated with the mattresses or bed rails or how, according to its procedure, CPO4- 013, information obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information will be assessed to determine if a need exists to modify the existing risk assessment. Additionally, Invacare did not discuss how it will conduct a systemic corrective action that includes a retrospective review and

reevaluation of other types of complaints to ensure that the risk analysis has been appropriately updated.

January Response:

As indicated in item 2 above, Invacare recognizes that our Corporate complaint system does not document that potential user risk was considered, if a formal risk assessment is required or if an existing risk assessment requires review or updating as part of the investigation process. In the current process, risk assessment is performed when a device malfunction or manufacturing process issue is discovered. Risk assessment activities conducted as part of complaint investigation lack specific thresholds that trigger overall product risk update at the design level or the potential to update the MDR reporting decision process.

Related Product / System Containment:

1) Invacare will review all risk assessments performed by Regulatory Affairs over the past two years in response to complaints and determine if other design considerations should be added to Invacare's Product Design Inputs, Risk Assessment and Control Plan, fm04013c. This will provide for consideration of these identified risks as part of new product development activity. A summary of this activity will be provided as part of the March follow-up.

2) Review procedure "Risk Assessment for Product Malfunctions and Quality Issues" (CP14-013) and associated form (fm14013a) to provide for enhanced risk feed back into the design process. Copies of revised procedures and forms will be provided as part of the March follow-up.

*3) Invacare will review complaint files received over a two year period that involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. thereby suggesting the potential for fire. Invacare will examine these files to determine if the complaint investigation was adequately investigated and documented. A summary regarding complaints received between July 1, 2010 and December 31, 2010 will be provided as part of our March follow-up. The remaining 18 months will be provided as part of the **June** follow-up.*

February Update:

1) We reviewed all 137 risk assessments performed by Regulatory Affairs in response to Adverse Event complaints or non-Adverse Event complaints and added design considerations to the Product Design Inputs, Risk Assessment and Control Plan form (fm04013c). Based on the review activities, this form has been revised ahead of the March commitment, enclosed **(EE)**.

2) We revised procedure CP14-013, "Risk Assessment for Product Malfunctions and Quality Issues" and the associated Risk Analysis Record form (fm14013a) to provide for enhanced risk feedback into the design process. Copies of the revised procedure and associated form are enclosed **(CC)**, ahead of our March commitment. The released procedure and relative training records are on schedule to be provided as part of the March follow-up.

3) A summary report covering Adverse Event complaints received between July 1, 2010 – December 31, 2010 and copies of any MDRs that resulted in filing as part of this review are enclosed **(GG)**. These involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of "key words" such as fire, smoke, flame, etc., thereby suggesting the potential for fire. Of the 150 examined in this review, 17 have been identified as requiring a MDR under these additional criteria. The corresponding MDR numbers are listed in the summary report.

We are ahead of our **June** commitment to provide results of the review of the remaining 18 months (January 1, 2009 – June 30, 2010) and will report the results in our March update.

March Update:

1) In February we reported that we reviewed all 137 risk assessments performed by Regulatory Affairs in response to Adverse Event complaints or non-Adverse Event complaints and added design considerations to the Product Design Inputs, Risk Assessment and Control

Plan form (fm04013c). The released form and training records of affected employees are enclosed (AAA).

2) We released procedure CP14-013, "Risk Assessment for Product Malfunctions and Quality Issues" and the associated Risk Analysis Record form (fm14013a) to provide for enhanced risk feedback into the design process. The released procedure and training records of affected employees are enclosed (AAA).

3) A summary report covering Adverse Event complaints for the remaining 18 months (January 1, 2009 – June 30, 2010), and copies of any MDRs that resulted in filing as part of this review are enclosed (DDD). These involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of "key words" such as fire, smoke, flame, etc., thereby suggesting the potential for fire. Of the 536 examined in this review, 30 have been identified as requiring a MDR under these additional criteria. The corresponding MDR numbers are listed in the summary report. Additionally, Adverse Event complaints representing six months (July 1, 2010 to December 31, 2010) were examined to determine the adequacy of the investigation. The complaints were reviewed by looking for "cause" and subsequent action. We found that in each case where the product was available, or sufficient information was provided without the product, the complaint was investigated and documented.

Additionally, Adverse Event complaints representing six months (July 1, 2010 to December 31, 2010) were examined to determine the adequacy of the investigation. The complaints were reviewed by looking for "cause" and subsequent action. We found that in each case where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.

However, as part of our overall critical review of Adverse Event Complaints, we note deficiencies that existed in past complaint handling. We identified the following deficiencies:

- Lack of complete documentation as relates to specific attempts to contact the complainant.
- Lack of documentation which supports specific details and conclusions within the complaint report.
- Inconsistent detail obtained by different personnel regarding individual complaints.
- Inconsistency among personnel in the timing of obtaining information via telephone and/or the number of attempts, when the complainant was not immediately available.

In February we made, or initiated the following changes as Corrective and Preventive action:

1. Implementation of new work instructions within Customer Service (CSWI 18-001) and Quality Complaint Form (fm14002e) along with revision of Consumer Incident Reporting Form fm14002b, which will assist in providing consistent and complete information in documentation of new complaints.
2. Initiation of changes to the complaint handling computer system, (b) (4) which will mandate the minimum number of attempts to gather information, and the associated timing of information gathering.
3. Revised Complaint Handling work instructions (RAWI-14-003 and fm14002e) to require specific details consistently by all customer service personnel, and ensure the detail is recorded and placed into the complaint file.
4. Training of changes to the complaint handling process was conducted and documented.

In the interim prior to (b) (4) deployment, we have included in our audit schedule routine audits of Complaint Files to confirm the presence of consistent and complete information. The results of these audits will be maintained and used for training purposes, as necessary.

The remaining 18 months (January 1, 2009 to June 30, 2010) will be provided within the June update as originally committed in the January response.

June Update:

As reported in our June response to observation 2, our (b) (4) project is on schedule with an updated project plan enclosed (HH).

Prior complaint files (January 1, 2009 to June 30, 2010) with claims of possible bed rail entrapment as well as files where malfunctions were suggested with keywords such as "smoke", "fire", "heat", "hot" and "burnt", were reviewed for investigation and documentation adequacy. Results were as follows:

- Twelve (12) files that involved claims of possible bed rail entrapment were opened between January 1, 2009 and June 30, 2010. Each file was examined to *determine if the complaint investigation was adequately investigated and documented*. In all twelve cases where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.
- One hundred forty six (146) files that involved claims with keywords such as fire, smoke, flame, etc., were opened between January 1, 2009 and June 30, 2010. Each file was examined to determine if the complaint investigation was adequately investigated and documented. All 146 files where the product was available, or sufficient information was provided without the product, the complaint was adequately investigated and documented.

As we have previously reported in our March update, we have taken preventive action to ensure new complaint files are adequately investigated and documented.

Invacare continues to support the FDA's position as stated within the "Practice Hospital Bed Safety" publication that was published in June 2009 that stated that "not all patients are at risk for entrapment, and not all hospital beds pose an entrapment risk" and that "...health care facilities, as well as patient caregivers, are urged to take a careful look at hospital beds. They need to determine if there are large openings that present an entrapment risk" for particular patients and "to take steps to minimize this risk".

Recognizing that manufacturers must provide adequate instructions for use, which may include patient use that may be contraindicated, Invacare has conducted a risk assessment regarding patient size or other factors that may impact a patient's risk of entrapment. A copy of that assessment is enclosed (C). As a result of that assessment, Invacare has developed language specific to "body size" and other conditions where the use of the product may be contraindicated. Enclosed is a copy of the approved language that will be added to all of Invacare's bed product lines moving forward (D). We will make this available on our corporate web site and explore other ways of sharing this information with our existing customers.

February Update:

In addition to the assessment provided in our January Response that resulted in the development of language specific to "body size" and other conditions where the use of the product may be contraindicated, Invacare has developed a pamphlet "Bedrail Entrapment Risk Notification Guide" which has been posted on our corporate web site, screen shot enclosed. ECN# 1145004 created and released the new corporate guidelines. The ECN, pamphlet, and website screenshots are enclosed (HH). The pamphlet will also be included in bedrail packages and bed systems captured as part of the bill of material. A separate ECN will be released to incorporate the Pamphlet into the bill of material and will be provided in our March update.

March Update:

ECN# 1145004, pamphlet, and website screenshots relative to the “Bedrail Entrapment Risk Notification Guide” were included in the February update, as stated above. The pamphlet will also be included in bedrail packages and bed systems captured as part of the bill of material. A separate ECN (no. 1145010) was approved and will be released to incorporate the Pamphlet into the bill of material of approximately 190 products, see enclosed approval (EEE).

June Update:

ECN (no. 1145010) has been released and a copy of the ECN is enclosed (DDDD).

Occurrence Prevention / Systemic Corrective Action:

We will review the (b) (4) complaint system and identify areas for process improvement including risk assessment or other actions that may be required. As indicated in item 1 above, Invacare is creating a Corporate procedure specific to statistical techniques that will address data sources and define trigger points for other action. Summary of this review will be provided as part of the March follow-up. Specific changes to be made to the (b) (4) system and a time line for validation and implementation will be provided as part of the June follow-up. Long term system changes will be reviewed, validated and audited by (b) (4). This will be supplied as part of our March follow-up.

In addition we will update the corporate Product Design Input, Risk Assessment and Control plan, form fm04013c, to add “small patient body size” as a specific design consideration. This will provide for consideration of this potential risk as part of any new product development activity. A copy of the revised form will be part of the March follow-up.

February Update:

We remain on schedule with the review of the (b) (4) complaint system to identify areas for improvement including risk assessment or other actions that may be required. A summary of this review will be provided as part of the March follow up. However, to demonstrate the progress of these activities, we (b) (4) that captures the direction of our future changes. Specific changes to be made to the system including a timeline for their verification and implementation remain on schedule and will be provided as part of the June follow-up.

1) We created a new corporate Statistical Techniques procedure (CP20-001) and a new Trending and Analysis of Data procedure (CP20-002), copies of both are enclosed (AA). These new corporate procedures address the application of statistical techniques and tools to be utilized in various areas of the business, such as Adverse Events and Returns. Methods include techniques such as:

- (b) (4) studies
- (b) (4) analysis
- Trending of quality complaints, Adverse Events, and Returns
- (b) (4) Analysis
- Month in Service statistical analysis
- Sampling plans

Facility specific procedure BB14-001, Statistical Techniques, enclosed (AA) has been revised to be in alignment with the new corporate procedure CP20-001. We will provide training records along with the released procedure as part of the March follow-up.

In addition, we updated the corporate Product Design Input, Risk Assessment and Control plan, form fm04013c, to add “small patient body size” as a specific design consideration. This will provide for consideration of this potential risk as part of any new product development. We provided a copy of the revised form enclosed (EE) ahead of schedule. The released procedure with associated training records of affected employees will be part of the March follow-up.

March Update:

In our February update we provided the prototype screen shots from (b) (4) to identify whether a complaint risk assessment is necessary and requires verification that a documented review occurs. The timing and events for implementation into the production environment and data field enhancements are enclosed (CCC).

We released a new corporate Statistical Techniques procedure (CP20-001) and a new Trending and Analysis of Data procedure (CP20-002). Copies of the released procedures and associated training records are enclosed (AAA).

We also released facility specific procedure BB14-001, Statistical Techniques. This procedure has been revised to be in alignment with the new corporate procedure, CP20-001. The released procedure and training records of affected employees are enclosed (AAA).

We released the updated corporate Product Design Input, Risk Assessment and Control Plan, form fm04013c, to add "small patient body size" as a specific design consideration. The released procedure with training records of affected employees are enclosed (AAA).

June Update:

As reported in our June response to observation 2, our (b) (4) project is on schedule with an updated project plan enclosed (AAA).

A third party effectiveness check of our quality system improvements has been established with (b) (4). Enclosed is an update letter from (b) (4) (BBB).

Item 5:

Failure to establish adequate procedures for identifying training needs for ensuring that all personnel are trained to adequately perform their assigned responsibilities and for documenting training, as required by 21 CFR 820.25(b).

FDA determined that the adequacy of Invacare's response could not be determined at the time of the issuance of the warning letter. Invacare stated that it was reviewing the training of the current Customer Service Staff and was providing additional training as needed. Additionally, the on-boarding process for new customer service staff was reviewed to ensure that new associates in the future have documented training in place prior to processing calls of this type. These activities were expected to be completed by October 15, 2010; however, Invacare has not provided any evidence of implementation of these corrective actions. FDA also indicated that Invacare failed to review previous complaint history or FDA MDR databases in accordance with Invacare procedures with the intention of identifying possibly related incident and trends.

January Response:

The training issue identified involved a Customer Service employee located at the corporate office. While Invacare did complete training of the Customer Service employees, Invacare concurs that those activities were not documented.

Short Term Containment:

Training was completed for all Customer Service Staff. Those training records are enclosed (E).

February Update:

Additional Customer Service staff functioning as part of our Long Term Care business unit has now been included in the training, as well as staff who were unavailable at the time of our earlier training session. Evidence of this training is enclosed (JJ). This training will continue as

new employees are on-boarded. Record of any ongoing training will be provided within the March update.

March Update:

There have been no additional new employees into the Long Term Care business unit and, therefore, no additional training has occurred since our February Update. While new employee training will continue as necessary, we consider this action closed.

Root Cause Determination:

Employee on-boarding process at the corporate level is poorly defined regarding training requirements and those documentation requirements.

Occurrence Prevention / Systemic Corrective Action:

Identify and implement a web based training system corporate wide with initial focus on customer facing employees. This will ensure that training requirements for new employees are properly identified and that training activities are completed prior to the employee performing the activity. Results of initial solution search and proposed plan will be part of the March follow-up. A specific solution and time line will be provided as part of the June follow-up.

In addition we will conduct a review of previous complaint history and existing FDA databases and provide an update as part of our March follow-up.

February Update:

We remain on schedule to identify and implement a web based training system corporate wide with initial focus on training for employees whose job duties include customer complaint handling. We will modify CP18-003, "Functional Department Training" to address changes to the training system. We will provide the results of the initial solution search and proposed plan, as part of the March follow-up. A specific solution and timeline will be provided as part of the June follow-up.

In addition, we are currently conducting a review of our previous complaint history and existing FDA database (MAUDE) from which to make any further training improvements. We will provide an update as part of our March follow-up.

March Update:

We remain on schedule to identify and implement a web based training system corporate wide that tracks employee specific training requirements, activities, effectiveness, and record storage. We will modify procedure CP18-003, "Functional Department Training" to address changes to the training system. A specific solution and time line will be provided as part of the June follow-up.

We have reviewed recent changes made to procedure CP14-002, "Complaint Handling and Medical Device/Vigilance Reporting" (FFF) and have confirmed that the updated procedure will provide for the review of previous complaint history including FDA MAUDE data when appropriate. When performed as part of a complaint investigation, these reviews will be documented.

June Update:

Automation of Invacare's training program will be managed through the implementation of a web based training system. Invacare is currently finalizing contract negotiations with our training systems provider on their Learning Management product. A project plan for implementation has been established. A high level summary of the project plan is enclosed (CCC). Invacare will also provide a more specific requirements document during the next quarterly update.

Item 6:

Failure to report to the FDA no later than 30 calendar days after the day that you become aware of information, from any source, that reasonably suggests that a device that you market has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). Invacare's response dated September 8, 2010, did not address this charge because it was not on the FDA 483 issued to you at the end of the inspection.

January Response:

The FDA's position is that any complaint that contains a "key word", by its very nature regardless of the product involved, suggests that potential and therefore meets the "may cause" element within the regulation. Invacare understands the FDA's position and its justification. As such, going forward Invacare will take "key word" usage into consideration when making MDR decisions.

Related Product / System Containment: Invacare has reviewed the two complaint files referenced in the warning letter, 2850 and 4470, and has filed MDRs. Copies are enclosed (F). Invacare will also review all complaints over the past 2 years which reference a "key word" for an MDR decision that is in line with the "may have caused..." requirement. Invacare will provide a summary report covering complaints received between July 1, 2010 – December 31, 2010 and copies of any MDRs that resulted in filing as part of this review in the February follow-up. We will follow with the remaining 18 months (January 1, 2009 – June 30, 2010) in the March follow-up.

February Update: See enclosed summary report (GG) covering our review of Adverse Event complaints received between July 1, 2010 – December 31, 2010 and copies of MDRs that resulted in filing as part of this review. In summary, 150 complaint files were reviewed and we found 17 that were not in line with the "may have caused injury..." requirement that resulted in the filing of MDRs. The corresponding MDR manufacturer report numbers are listed in the summary report and copies of the MDRs are enclosed.

We will provide in March a report of our review of the remaining 18 months (January 1, 2009 – May 31, 2010).

March Update:

See enclosed summary report (DDD) of Adverse Events complaints covering the remaining 18 months (January 1, 2009 – June 30, 2010) and copies of MDRs that resulted in filing as part of this review. In summary, 536 complaint files were reviewed and we found one (1) that was not in line with the "may have caused injury..." requirement that resulted in the filing of a MDR. The corresponding MDR manufacturer report number is listed in the summary report and copy of the MDR is enclosed.

June Update:

As reported in our March update, our review of Adverse Event complaints is complete.

Root Cause Determination: Risk of malfunction is not presumed until confirmed during analysis. Invacare should report based on the claim as received (including any analysis performed within the 30 days of complaint notification) and provide follow up MDRs if additional information or analysis indicates that that the original assessment was inaccurate or incomplete.

Short Term Corrective Action: Review "Adverse Event File Handling and MDR Reporting" (RAWI-14-003) as well as the Complaint Handling and Medical Device Reporting / Vigilance Reporting procedure (CP14-002) and the "Preliminary Product Evaluation" procedure (CP14-011) and update with training as appropriate. Revised procedures will be provided as part of the February follow-up.

February Update:

We revised our work instruction "Adverse Event File Handling and MDR Reporting" (RAWI-14-003), the corporate procedure "Complaint Handling and Medical Device Reporting / Vigilance

Reporting" (CP14-002), and the "Preliminary Product Evaluation" procedure (CP14-011), all of which are enclosed (II). Invacare has modified its procedures to provide, among other things, that an allegation or claim of Invacare product involvement is sufficient information to "reasonably suggest" and that serious injuries or death that may have been attributed to an Invacare device will be reported within 30 days.

We will provide released documents and include the relative training records of affected employees in the March update report.

March Update:

We released work instruction Adverse Event File Handling and MDR Reporting (RAWI-14-003), the corporate procedure Complaint Handling and Medical Device Reporting / Vigilance Reporting (CP14-002), and the Preliminary Product Evaluation procedure (CP14-011). The released documents and training records of affected employees are enclosed (AAA).

June Update:

As indicated in our March update, all short term corrective actions have been implemented.

Occurrence Prevention / Systemic Corrective Action: 1) Investigate potential to update (b) (4) workflow to identify "critical" or "key word" complaints on entry in a manner that would prioritize complaint review and filing decisions. 2) Review (b) (4) complaint handling process with regard to how risk analysis ties back into the MDR decision and other areas. Summary of initial reviews of these activities will be provided as part of the March follow up. Specific changes identified for the (b) (4) system and a time line for validation and go-live will be provided as part of the June follow-up. Long term system changes will be reviewed and audited by (b) (4)

February Update:

We remain on schedule with the development of our complaint handling system named (b) (4). To demonstrate the progress of our current activity to date, enclosed are (b) (4), highlighting the use of new data elements added to the system (e.g. "key words", risk assessment, desktop priority, etc.) and how risk analysis ties back into the MDR decision.

March Update:

In our February update we provided the prototype screen shots from (b) (4) highlighting the use of new data elements added to the system (e.g. "key words", risk assessment, desktop priority, etc.). The timing and events for implementation into the production environment and data field enhancements are enclosed (CCC). This also includes the release of (b) (4) being utilized for e-MDR reporting and relative documents confirming successful transmission / acknowledgement from the FDA Gateway Test Center.

In February we provided the prototype screen shots of e-Learning training material for complaint handling process. We are ahead of our June commitment of developing improved training methods for complaint handling and will implement the e-Learning module in April 2011. This training enables consistent and timely delivery to new employees that have the potential of handling customer complaints, as part of their on boarding process.

June Update:

As detailed in our response to Item 5, a summary project plan of web based training system the project plan is enclosed (CCCC).

A third party effectiveness check of our quality system improvements has been established with (b) (4). Enclosed is an update letter from (b) (4) (CCCC).