**Summary of the changes to the FDG-PET/CT Profile from the Stage 2 'Publicly Reviewed' version are as follows:**  
  
**1. An addition to the Claim**  
While the claim still states "... maximum standardized uptake value (SUVmax) is measurable from FDG-PET/CT with a within-subject coefficient of variation of 10-12%" This statement is labelled as 'Claim 1', and new added claim states: "Claim 2: A measured increase in SUVmax of 39% or more, or a decrease of -28% or more, indicates that a true change has occurred with 95% confidence." This added claim is based on the Velasquez 2009 and newer Weber 2015 publications. The consideration #3 has been modified to include an explanation of where these asymmetric repeatability coefficients arise from, and to demonstrate that these limits are consistent with Claim 1. The discussion and references of Appendix B have been updated to include the recent Weber 2015 publication.  
  
**2. Field Tests**  
The Publicly Reviewed version of the Profile was reviewed in two series of 'Field tests' where the Normative statements were reviewed in detail for feasibility. In the first phase, all normative statement were reviewed in detail at three sites using GE, Philips, and Siemens PET/ CT scanners (prior to the availability of Toshiba PET/CT scanners). As a result a simplified and reduced set of normative statements was proposed. In phase 2, the reduced set of normative statements were evaluated for feasibility at 12 sites with varying systems, as well as an in detail review by four manufactures: GE, Philips, Siemens, and Toshiba.   
  
**3. Modifications to the Profile**  
As a result of the Field Tests, several redundant or infeasible normative statements were removed from the Profile, and minor changes to the descriptive text were made. These occurred over a roughly 1-year period at Biomarker Committee meetings using a consensus approach.  
  
**4. Addition of Imaging Site and Scanner Checklists**The final list of normative statements that applied to imaging sites were collected as concise "YES/NO" compliance checklist and added as Appendix I. A similar checklist for normative statements applicable to PET scanner manufacturers was compiled and appended to imaging sites and appended to Appendix I.  
  
**5. Numerous small corrections were made**