

Least Burdensome Training Audit: FDA Report to Congress of June 8, 2018 CBER Addendum

As discussed in the final report to Congress¹, to assess the impact of the Least Burdensome training provided to staff at CBER, FDA employed the Kirkpatrick Evaluation Model. This assessment included an evaluation of participant reactions to the training (level 1), level of learning accomplished (level 2), application of the learned behaviors (level 3), and a preliminary assessment of the results of applying the learned behaviors (level 4). This addendum provides an update on the progress of Least Burdensome training provided to CBER staff.

Consistent with the goals of the Cures Least Burdensome training deliverable, CBER continues to provide least burdensome training to new device reviewers and supervisors, as well as to established review staff who are new to the premarket device review process. As of 6/6/18 the number of CBER staff who participated in the focused least burdensome training and associated assessments increased from 267 participants on 4/27/2018² to 311. The data provided in this addendum include updated information from the Level 1 & 2 assessments and new information from the Level 3 & 4 assessments, as well as a supplementary deficiency letter audit conducted five months post-training. The data indicate that the mandatory training was successful and the skills acquired are being applied to the premarket review of CBER devices.

1) Kirkpatrick Level 1

The Level 1 Kirkpatrick evaluation assessed the degree to which participants find the training favorable, engaging and relevant to their jobs.

The following table contains updated percentages for CBER as of 6/6/18. Consistent with the earlier findings, the data appear to indicate that the mandatory training achieved stated learning objectives.

Question	CBER Response
The course content was applicable to the knowledge and skill I need to accomplish my job.	82.5% agree
	16.7% neutral
	0.7% disagree
The course contained useful activities to practice and/or reinforce the learning objectives.	75.8% agree
	22.7% neutral
	1.5% disagree

2) Kirkpatrick Level 2

¹ see <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm122880.htm>

² Data cut-off date for the final report required by Cures.

The Level 2 Kirkpatrick evaluation assessed the degree to which participants acquire the intended knowledge, skills, attitude, confidence and commitment based on their participation in the training.

The following table contains updated percentages for CBER as of 6/6/18. As observed for level 1, the updated data are consistent with previous findings and indicate that knowledge was acquired after completion of the mandatory training. The assessment of additional knowledge gained from the training increased slightly from 7.7 to 8.2 %.

CBER	
Pre-Test Average Score	81.3%
Post-Test Average Score	88.0%
Knowledge Gained	8.2%

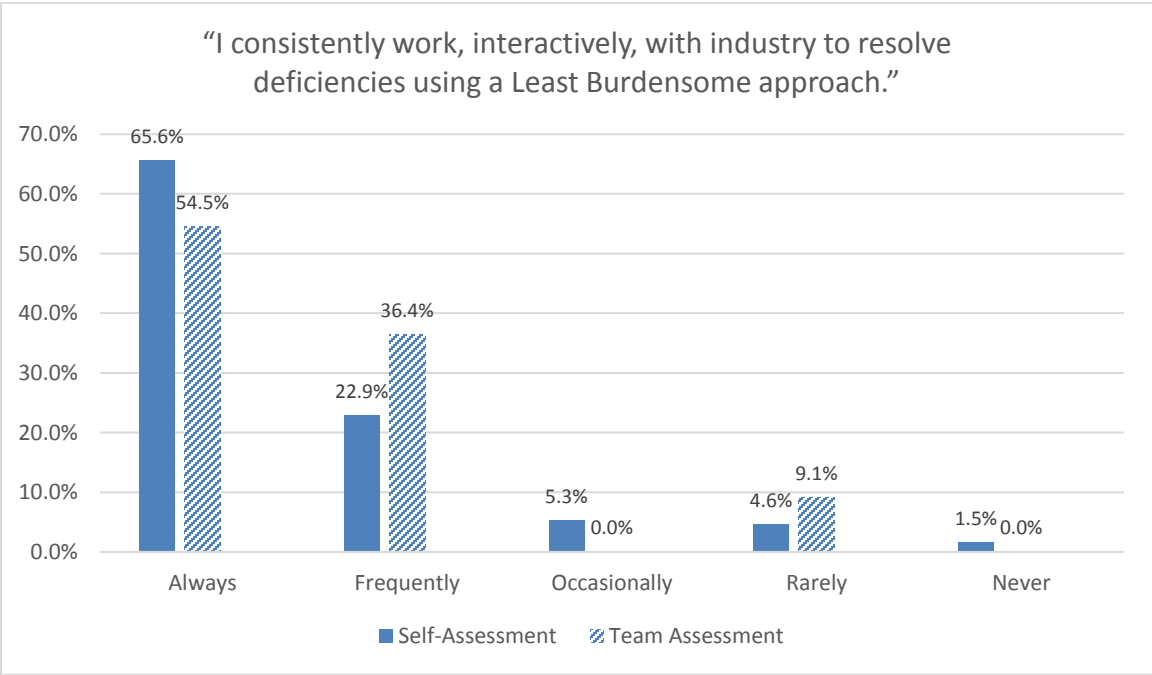
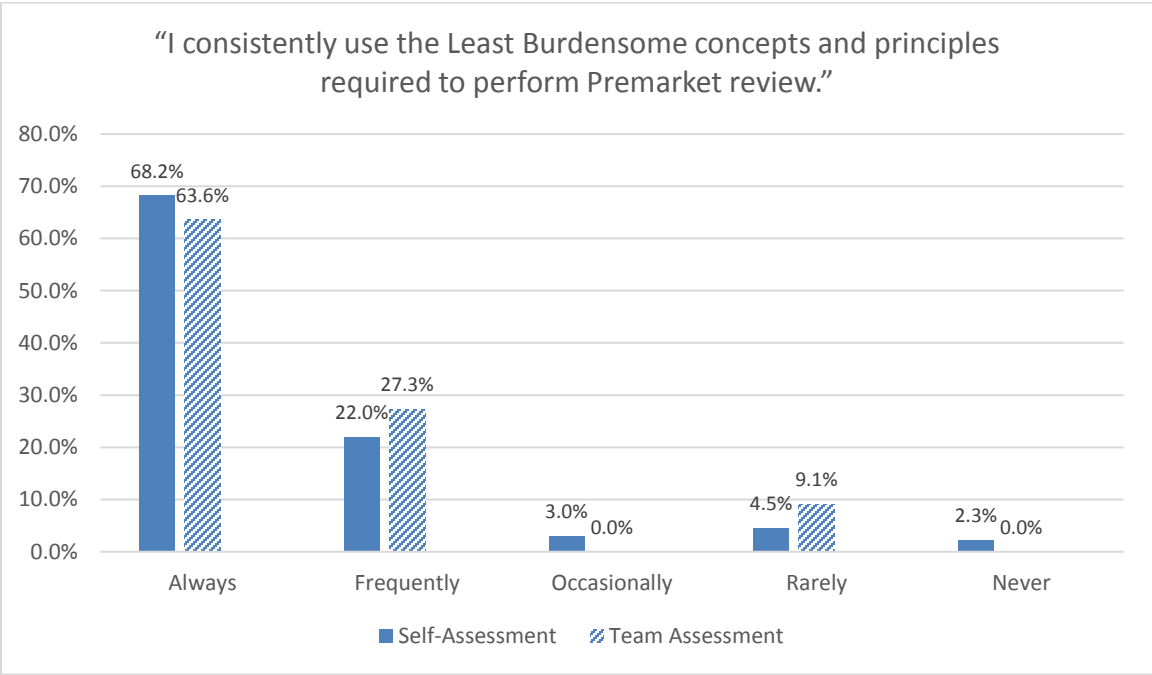
The following formula was used to calculate percent change in knowledge:

$$\% \text{ Knowledge Gained} = \frac{(\text{Post-Test Average} - \text{Pre-Test Average}) \times 100}{\text{Pre-Test Average}}$$

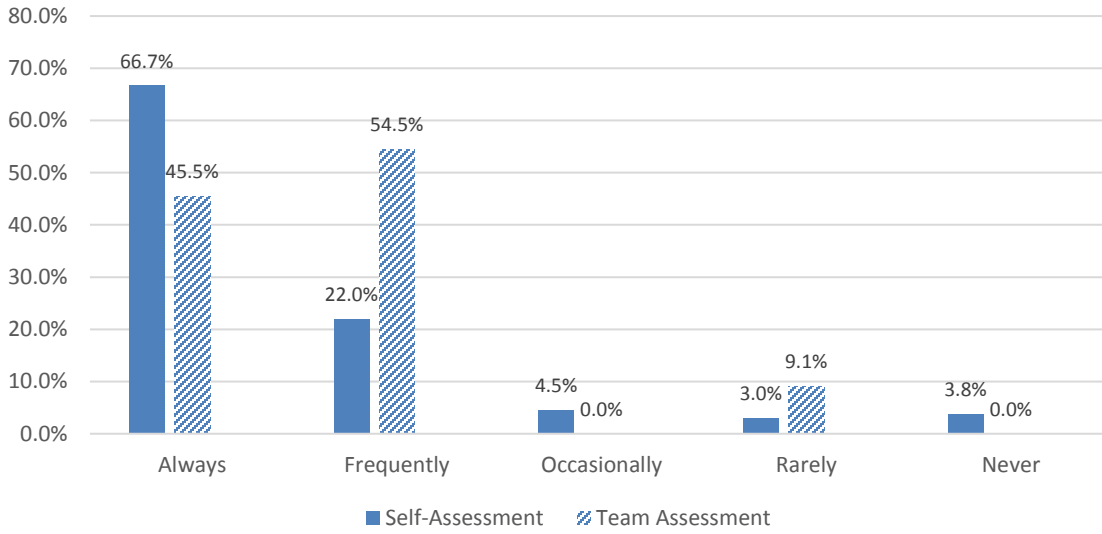
3) Kirkpatrick level 3

The Level 3 Kirkpatrick assessed the degree to which participants apply what they learned during training when they are back on the job.

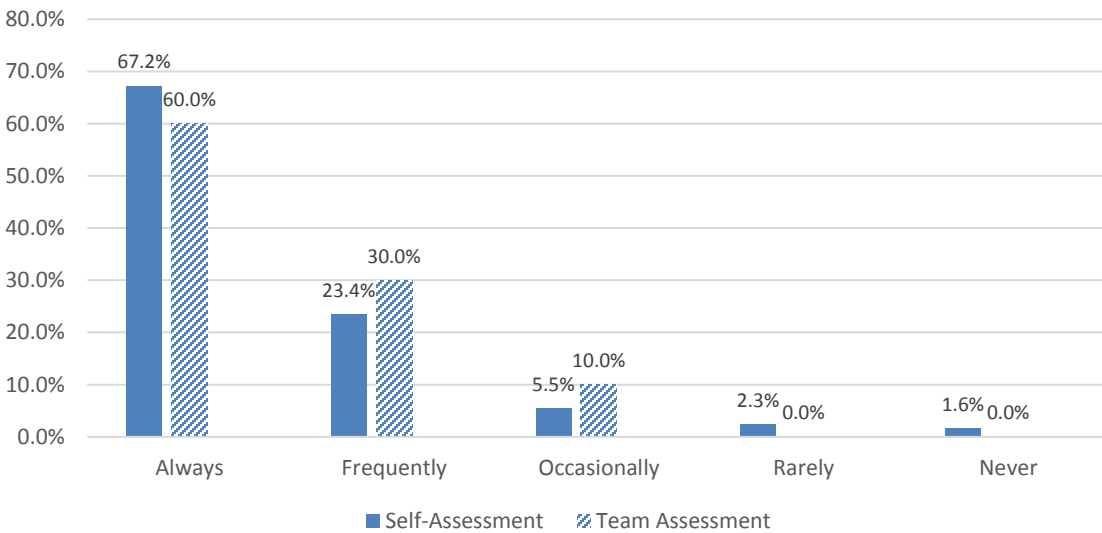
CBER conducted a Kirkpatrick Level 3 evaluation to assess the impact of least burdensome training approximately 5 months after implementation of the mandatory training. Reviewers were asked to provide feedback on how they applied the least burdensome principles to their own review assignments following the training. Supervisors were also asked to assess their own performance as well as that of their teams using the same questions. The data suggest that CBER training efforts appear to have positively impacted reviewer and supervisor awareness of the least burdensome principles and its routine application within the premarket review process. A summary of findings for each question is provided below with data from individual assessments provided in solid blue and from supervisory assessments in striped blue.



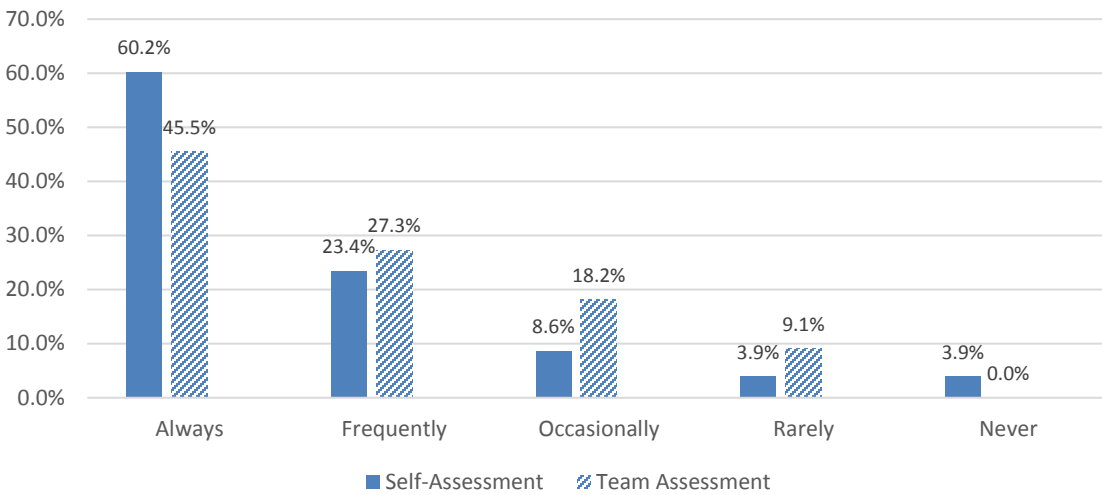
“I consistently apply the Four-Part Harmony (previously known in CBER as Least Burdensome) format when writing deficiencies.”



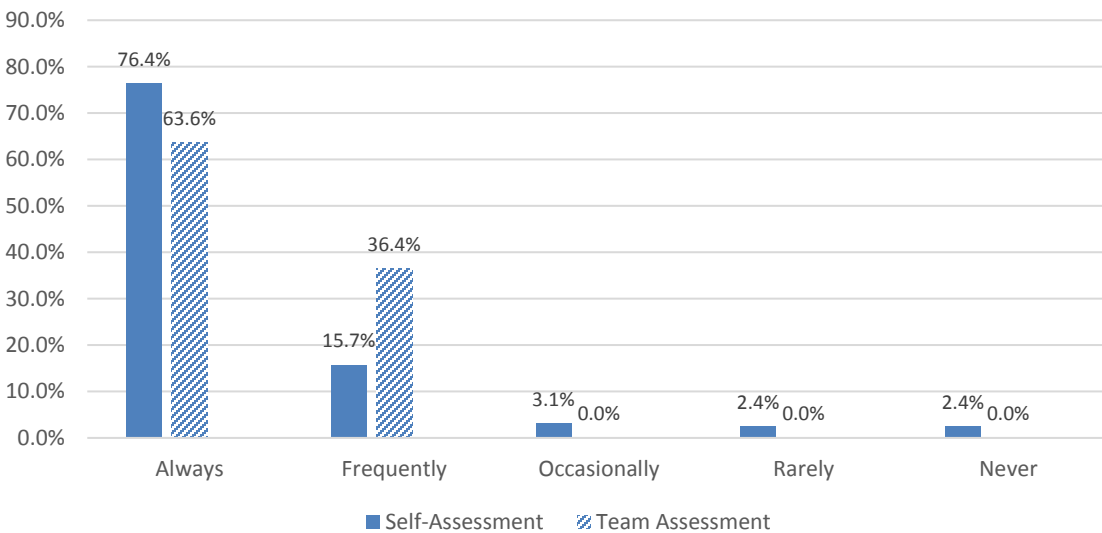
“I consistently consider and/or accept alternate approaches in effort to resolve deficiencies.”

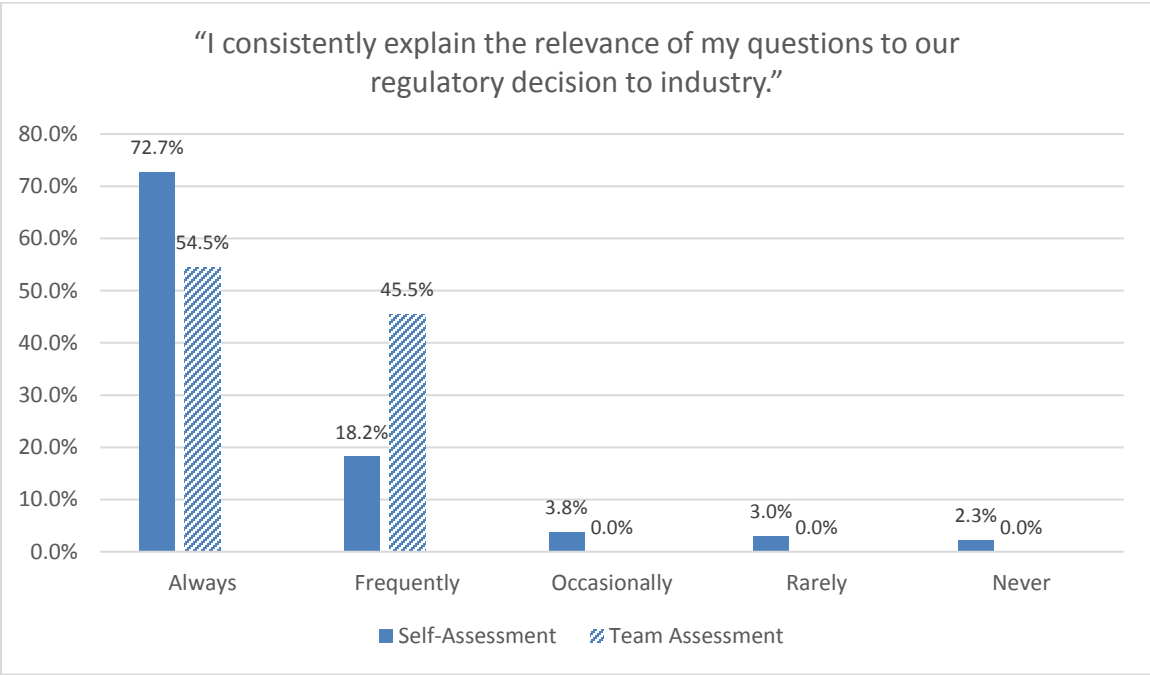


“I consistently consider the balance between Premarket and Postmarket to determine when additional information should be provided to address identified issues.”



“I consistently reference and explain the rationale for the request to the regulatory decision.”



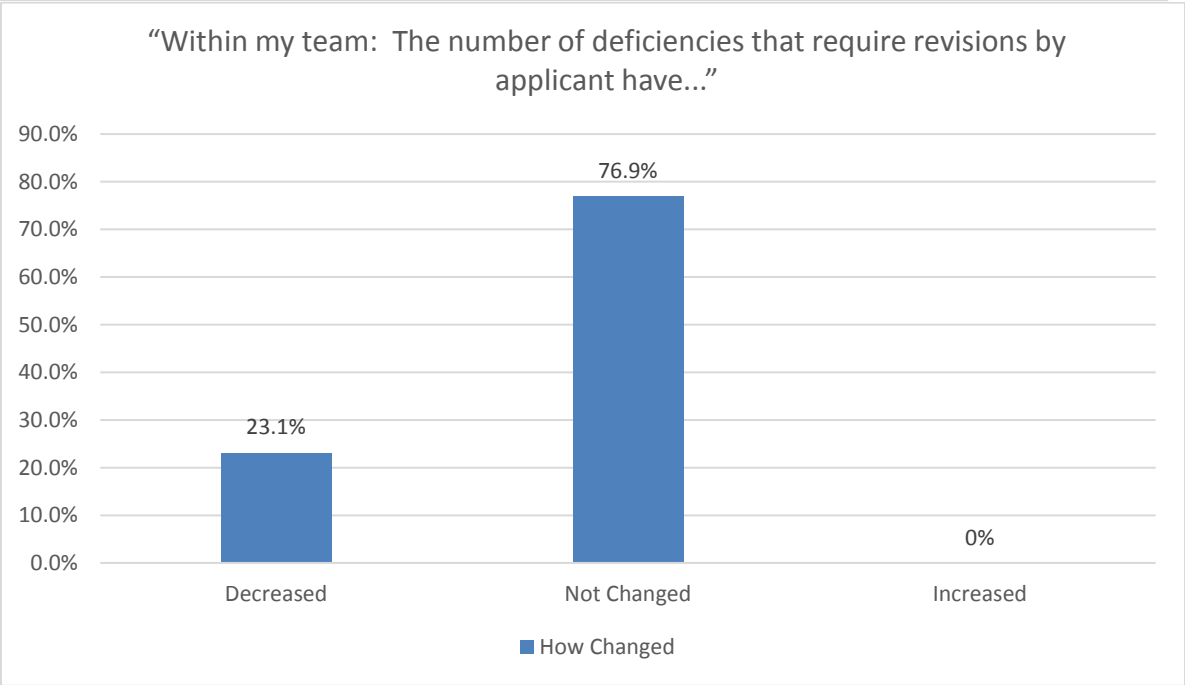
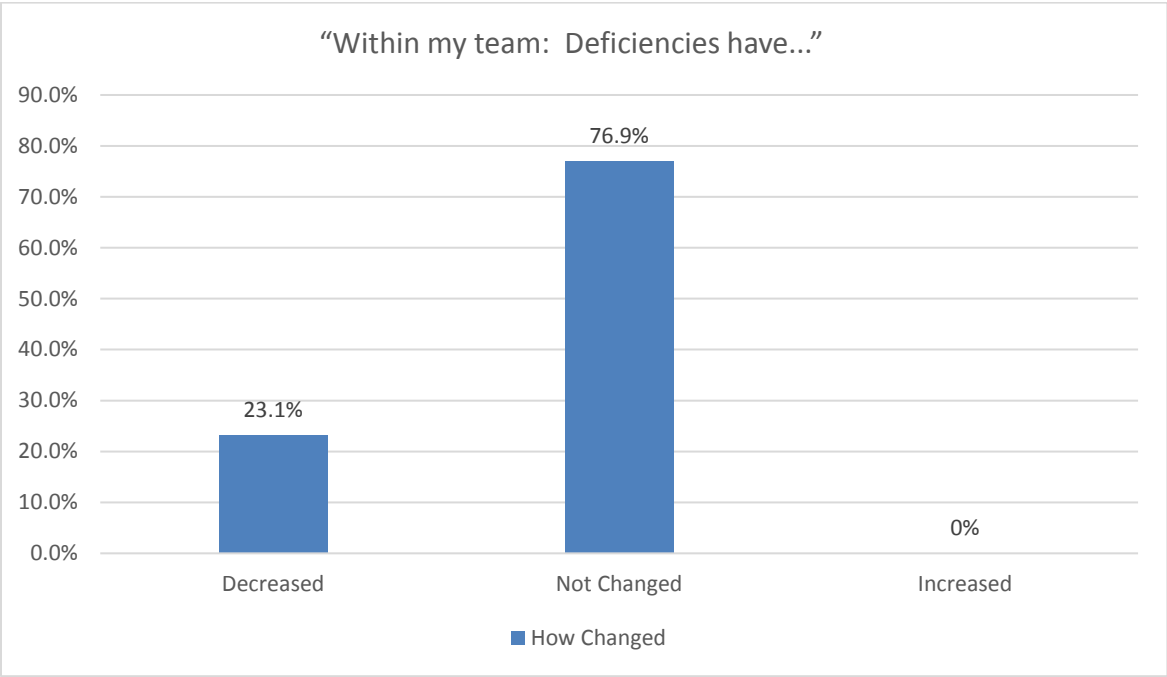


While the Kirkpatrick level 3 data show a positive trend in awareness and perceived application of the least burdensome principles, the survey results for CBER show some differences in the perception of consistency (i.e., always vs frequently), between reviewers and their supervisors. We expect that the differences noted in the level 3 results will decrease over time as reviewers and their supervisors become more proficient with the application of the least burdensome provisions, including more routine application of all four elements of the four-part harmony approach.

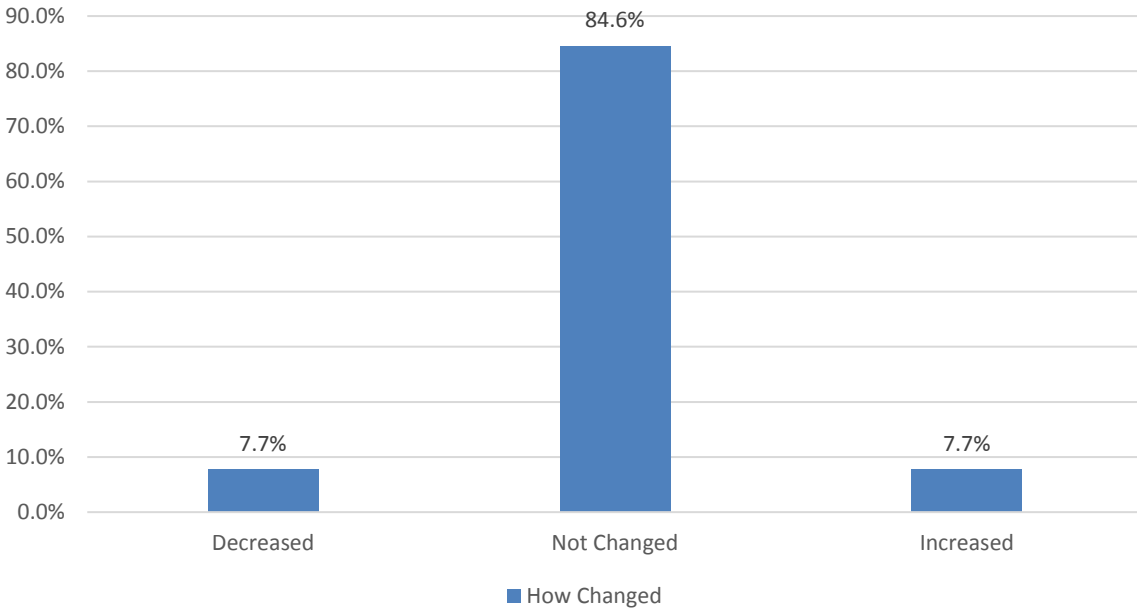
4) Kirkpatrick Level 4

The Level 4 Kirkpatrick evaluation assessed the degree to which targeted outcomes occur because of the training.

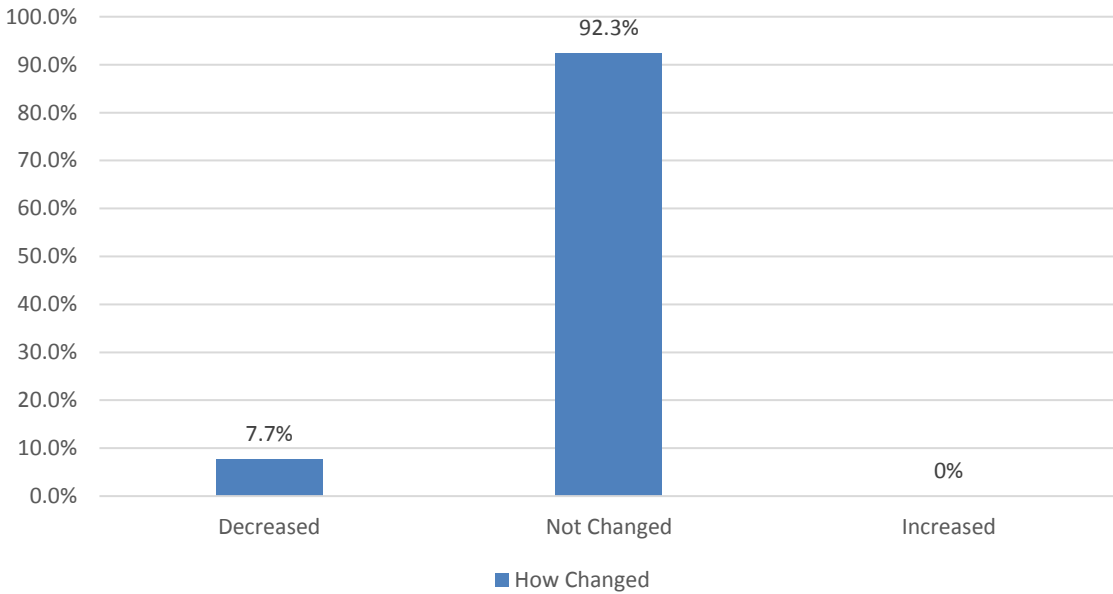
To assess the impact of least burdensome training on “requests for additional information” (a key performance indicator for application of least burdensome principles), CBER supervisors were asked to respond to four survey questions. As illustrated below, supervisor responses suggest that training efforts produced a positive trend in identification and communication of deficiencies to sponsors. Supervisors reported observing a modest decrease in the number of deficiencies identified and an increase in the quality of CBER communications regarding the remaining deficiencies. More effective communication with sponsors has the potential to help reduce regulatory burden both for sponsors and FDA review staff.



“Within my team: The number of deficiencies for which applicants offer an alternative means (rationale) to address the deficiency have...”



“Within my team: The number of applicants that have communicated concerns that deficiencies are not consistent with Least Burdensome principles have...”



5) CBER Device Deficiency Letter Audit: For Compliance with the Four-Part Harmony Approach

In 2017, the agency issued a Guidance for Industry and Food and Drug Administration Staff on “Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions”. This guidance provided a suggested format for effectively writing a deficiency that includes four key elements: 1) “Acknowledgement of information provided,” 2) “Explanation of deficiencies noted,” 3) “Statement of requested information,” and 4) “Statement of why we want it.” This approach is collectively referred to as ‘four-part harmony.’

To more fully assess the impact of CBER’s least burdensome training efforts, 510(k) and PMA deficiency letters issued by CBER offices prior to and after formal training were audited for compliance with the four-part harmony approach. The degree to which each of the four elements were addressed in letters issued during the six months immediately prior to training was assessed and compared to the frequency of application of each element in letters issued in the first five months after training.

As illustrated below, CBER review staff were already applying the first three elements of four-part harmony to a significant degree during the six months prior to the least burdensome training. The post-training results indicate that CBER staff continued to consistently apply these elements, with elements 1 and 3 being applied greater than 90% of the time post-training. Element four is a recent addition to CBER letters and was more fully defined in the training, which resulted in a substantial increase in awareness and application of this element to CBER deficiency letters.

Future training on the four-part harmony approach will initially focus on elements 2 and 4 to help enhance their routine application in CBER letters. This training will include examples of well-crafted deficiency letters to demonstrate effective application of the four-part harmony approach and may include case studies from recent applications.

	Total Number of Individual Deficiencies Assessed	Contain 1) Statement of Relevant Information	Contain 2) Statement of Deficiency	Contain 3) Statement of What is Wanted	Contain 4) Statement of Why It is Wanted
All Letters					
Pre-LB Training	197	163	139	186	45
% of Total		82.7%	70.6%	94.4%	22.8%
Post-LB Training	110	99	84	102	51
% of Total		90.0%	76.4%	92.7%	46.4%