Report to Congress

Least Burdensome Training Audit

U.S. Department of Health and Human Services

Food and Drug Administration

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Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Executive Summary

The Food and Drug Administration (FDA or the Agency) is responsible for protecting the public health by (1) ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and (2) ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations of medical products that are safe and effective, and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. The 21st Century Cures Act (Cures Act), Public Law 114-255, signed into law on December 13, 2016, was intended to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently. The Cures Act primarily affects activities of the Department of Health and Human Services (HHS) and its agencies, including FDA.

This report is being issued pursuant to section 513(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Cures Act, which states:

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

''(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

''(1) The Secretary shall—

''(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

''(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

"(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

''(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;
''(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including

with respect to the application of least burdensome concepts to premarket review and decision making;

''(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

''(D) summarize the findings of such audit in a final audit report; and

''(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

''(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

''(ii) on the Internet website of the Food and Drug Administration.''

As required by the Cures Act, FDA implemented mandatory training on the least burdensome requirements for device review staff and supervisors,[1] conducted an audit of such training, and sought input from the medical device industry regarding their experience with respect to the application of least burdensome concepts. All premarket device review staff and supervisors (1,148 Center for Devices and Radiological Health (CDRH) and 267 Center for Biologics Evaluation and Research (CBER); 100 percent) completed the mandatory training. A comparison of pre- and post-training test scores shows a 27.8 percent increase in knowledge gained in CDRH and a 7.7 percent increase in CBER. The audit of the training indicates that the training was effective, knowledge was acquired after completion of the training, that the effort put in place to implement the Cures Act is resulting in improvements towards the appropriate application of the least burdensome concepts and principles, and that perceived trends showed expected results in areas such as requests for additional information.

Perception of how the knowledge gained is being applied varies among different groups (reviewers, their supervisors, and industry). As such, this audit can be used as a baseline to track changes in the perception gap. The data collected from premarket device review staff, supervisors, and the industry during this assessment can serve as baseline for future assessments, including those that serve as part of commitments associated with the Medical Device User Fee Amendments of 2017 (MDUFA IV).[2]

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[1] These review staff and supervisors are in FDA's Center for Devices and Radiological Health (CDRH) or the Center for Biologics Evaluation and Research (CBER), which regulates certain devices.

[2] As part of its commitments associated with MDUFA IV, FDA agreed to implement a quality management system within CDRH and to assess various aspects of CDRH's review program; see the MDUFA IV Commitment Letter, Section III.A.

This report describes the actions taken by FDA to comply with the Cures Act requirements.

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I. Training Provided to Premarket Device Review Staff and Supervisors

A. Cures Act Requirement

The Secretary shall, under section 513(j)(1)(A) of the FD&C Act, as amended by the Cures Act, "ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section [513] and section 515(c)(5)."

B. Summary of Findings

Finding 1. The Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) employees involved in the review of premarket device submissions, including supervisors, received training.

Mandatory Training: Least Burdensome Provisions and Principles: Finding a Balance

Launched September 13, 2017, CDRH's least burdensome training was delivered through an online module. This training requirement was for all CDRH premarket device review personnel and supervisors. CDRH's training included a pre- and post-training test to establish CDRH's baseline and assess knowledge gained.

Launched January 12, 2018, CBER provided least burdensome training to premarket device reviewers and supervisors in person and by Adobe Connect. The session was recorded and was provided online for staff who could not attend the January 12th training. CBER training included a pre- and post-training test to establish CBER's baseline and assess knowledge gained.

The testing for both CDRH and CBER is the same. The learning objectives of this training are to:

- Summarize the least burdensome provisions of the FD&C Act;
- Describe why consistently applying least burdensome principles is essential in the review of medical devices, and for industry and patients; and
- Emphasize the expectation that the least burdensome principles will apply to all activities pertaining to medical device regulation.

Mandatory Training Completion Rate:

- 100 percent of CDRH (1,148) and CBER (267) reviewers and supervisors involved in the review of premarket device submissions successfully completed the training.

- CDRH's and CBER's least burdensome trainings remain in place to facilitate training of future hires.
- CDRH made this training mandatory for all staff, going beyond the premarket reviewer and supervisors training requirement. As of March 2018, 99 percent of all CDRH staff have completed the training.
- While CBER's training was targeted to identified device review personnel and supervisors, it remains open to all CBER personnel, which goes beyond the premarket device reviewer training requirement.

Additional Mandatory Training for CDRH: How to Make the Most of Least Burdensome: Case Study Practice

Although not required by the Cures Act, in February 2018, CDRH began requiring a second training for staff involved in all aspects of medical device review to reinforce the least burdensome principles outlined in the September 2017 training. The training focuses on the practical application of least burdensome principles through examination and discussion of case studies that reflect issues throughout the total product lifecycle. As of March 2018, the training was ongoing; therefore, data are not available to assess the effectiveness of this training.

Finding 2. Training and resources are available to support implementation of the least burdensome provisions.

Continuous Education: CDRH and CBER provide continuous education on least burdensome principles through formal, informal, and on-the-job training at the Center, Office, and Division levels.

The following are training actions CDRH is taking to continually support the implementation of the least burdensome provisions:

- How to Make the Most of Least Burdensome: Case Study Practice (Implemented February 2018)
- Basics of Four-Part Harmony in Lead and Consult Reviews (Implemented June 2016; Revised April 2017)[3]
- Master Four-Part Harmony (Implemented June 2016; Revised April 2017)
- Reviewer Certification Program (RCP) (Implemented September 6, 2011; Revised June 2016)

The following are examples of training opportunities that CBER provides to support the implementation of the least burdensome provisions:

[3] For a summary of the four elements that comprise the suggested content and format for deficiencies, also known as four-part harmony, see: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073680.pdf (page 5 *B. Suggested content and format for deficiencies)*

- CBER Medical Device Reviewer Training
- Device Review Updates

Additional Efforts: Access to experts, documented information, and process improvement projects are some of the additional efforts that support the implementation of least burdensome provisions, including:

- CDRH Focal Point Program (FPP) (Biocompatibility implemented November 1, 2016; Electromagnetic Compatibility implemented January 26, 2018)
- Guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (Issued September 29, 2017)
- CDRH SMART Templates (Implemented January 15, 2017; Revised October 2017)
- CDRH Total Product Lifecycle (TPLC) Transformation
- CDRH 2018-2020 Strategic Priority: Simplicity[4]

Additional information and descriptions of the training actions on the continuous education and additional efforts listed above can be found in section V of this report.

II. Measurement Tools

A. Cures Act Requirement

The ombudsman for any organizational unit of FDA responsible for the premarket review of devices shall, under section 513(j)(2)(C) of the FD&C Act, as amended by the Cures Act, "include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements."

B. Summary of Findings

Finding 3. FDA used the Kirkpatrick Evaluation Model to assess the effectiveness of training and actions taken in support of the least burdensome provisions.

Tool Overview: The Kirkpatrick Model[5] is a widely recognized training evaluation framework, and it is the standard of practice used by industry and government agencies worldwide to assess the extent to which training programs contribute to mission accomplishment and meet

[4] 2018-2020 CDRH Strategic Priorities - https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhvisionandmission/ucm592693.pdf

[5] The Kirkpatrick Model - https://www.kirkpatrickpartners.com/Our-Philosophy/The-Kirkpatrick-Model

organizational performance goals. The evaluation framework uses four levels to assess training, described in the table below.

Level	Level Description	Information Collection (Measurement Tools)
Level 1: Reaction	The degree to which participants find the training favorable, engaging, and relevant to their jobs.	CDRH and CBER used a survey instrument to assess the reaction of the participants after completing least burdensome training.
Level 2: Learning	The degree to which participants acquire the intended knowledge, skills, attitude, confidence, and commitment based on their participation in the training.	CDRH and CBER used pre-and post-training tests to evaluate the knowledge acquired.
Level 3: Behavior	The degree to which participants apply what they learned during training when they are back on the job.	CDRH used a survey instrument to evaluate changes in behavior after being exposed to training and supporting activities to implement the least burdensome provisions. CBER's Level 3 post-training analysis is scheduled for June 2018.
Level 4: Results	The degree to which targeted outcomes occur because of the training and the support and accountability package.	CDRH and CBER are in the process of implementing the Kirkpatrick Level 4 evaluation, as agreed to in the MDUFA IV Commitment Letter, by the end of fiscal year 2020. CDRH included questions in the Level 3 survey tool which represent preliminary indicators for Level 4. CBER's preliminary Level 4 analysis is scheduled for June 2018 post-training.

III. Audit Results

A. Cures Act Requirement

The ombudsman for any organizational unit of FDA responsible for the premarket review of devices shall, under section 513(j)(2)(A) of the FD&C Act, as added by the Cures Act, "conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements."

B. Summary of Findings

Finding 4. **Kirkpatrick Level 1 – Reaction:** The Level 1 Kirkpatrick evaluation data indicate that the mandatory training achieved stated learning objectives outlined in Finding 1.

To evaluate the degree to which the mandatory training achieved its learning objectives, CDRH and CBER conducted a Kirkpatrick Level 1 evaluation. CDRH and CBER surveyed employees

who were trained on the least burdensome provisions after they completed training. The results are presented in the table below.

Question	Response
The course content was applicable to the knowledge and skill I need to accomplish my job.	**CDRH:** 87% agree, 10% neutral, 3% disagree **CBER:** 81% agree, 18% neutral, 1% disagree
The course contained useful activities to practice and/or reinforce the learning objectives.	**CDRH:** 90% agree, 7% neutral, 3% disagree **CBER:** 73% agree, 24% neutral, 3% disagree

At Kirkpatrick Level 1—the degree to which participants find the training favorable, engaging, and relevant to their jobs—the training was well-received and contained relevant information.

Finding 5. Kirkpatrick Level 2 – Learning: The Level 2 Kirkpatrick evaluation data indicate that knowledge was acquired after completion of the mandatory training.

To evaluate the degree to which participants acquired the intended knowledge immediately after mandatory training, CDRH and CBER conducted a Kirkpatrick Level 2 evaluation. The online training module required pre- and post-testing. Each test consisted of the same five questions.

	CDRH	CBER
Pre-Test Average Score	71.5%	83.5%
Post-Test Average Score	91.4%	89.9%
Knowledge Gained	27.8%	7.7%

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

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

At Kirkpatrick Level 2, the difference between the pre- and post-test scores indicate that knowledge was acquired during the training. To assess the significance of the CDRH knowledge gained, a Paired t-Test with a confidence interval of 95 percent resulted in a p-value of <0.05, suggesting that the difference between the pre- and post-test scores is significant and knowledge was acquired.

Finding 6. Kirkpatrick Level 3 – Behavior: The Level 3 Kirkpatrick evaluation data appear to indicate that, overall, CDRH efforts in support of the least burdensome provisions have positively impacted the way premarket reviews are conducted.

To evaluate long-term impact of training activities, CDRH conducted a Kirkpatrick Level 3 evaluation. The Level 3 evaluation was performed approximately 6 months after the implementation of the mandatory least burdensome training (Finding 1). A Kirkpatrick Level 3

evaluation incorporates all training and supporting activities executed to implement the least burdensome provisions, as behavioral changes are driven by holistic efforts (Finding 1 and Finding 2). As such, the Level 3 evaluation includes effectiveness from the online module and other activities that transpired during the last year. In addition, supervisors were also asked to assess their teams using the same questions. A summary of findings for CDRH follows:

Questions	CDRH Responses Self-Assessment = All supervisors and reviewers Team Assessment = Supervisors assessed their teams
Q2 and Q10. "I consistently use the Least Burdensome concepts and principles required to perform Premarket review."	**Self-Assessment:** 75% Always, 25% Frequently, 1% Occasionally, 0% Rarely, 0% Never. **Team Assessment:** 41% Always, 53% Frequently, 3% Occasionally, 3% Rarely, 0% Never.
Q3 and Q11. "I consistently work, interactively, with industry to resolve deficiencies using a Least Burdensome approach."	**Self-Assessment:** 69% Always, 29% Frequently, 2% Occasionally, 1% Rarely, 0% Never. **Team Assessment:** 61% Always, 39% Frequently, 0% Occasionally, 0% Rarely, 0% Never.
Q4 and Q12. "I consistently apply the Four-Part Harmony format when writing deficiencies."	**Self-Assessment:** 78% Always, 20% Frequently, 1% Occasionally, 1% Rarely, 0% Never. **Team Assessment:** 47% Always, 47% Frequently, 3% Occasionally, 3% Rarely, 0% Never.
Q5 and Q13. "I consistently consider and/or accept alternate approaches in effort to resolve deficiencies."	**Self-Assessment:** 72% Always, 26% Frequently, 2% Occasionally, 0% Rarely, 0% Never. **Team Assessment:** 52% Always, 48% Frequently, 0% Occasionally, 0% Rarely, 0% Never.
Q6 and Q14. "I consistently consider the balance between Premarket and Postmarket to determine when additional information should be provided to address identified issues."	**Self-Assessment:** 61% Always, 27% Frequently, 9% Occasionally, 4% Rarely, 2% Never. **Team Assessment:** 50% Always, 38% Frequently, 6% Occasionally, 6% Rarely, 0% Never.
Q7 and Q15. "I consistently reference and explain the rationale for the request to the regulatory decision."	**Self-Assessment:** 83% Always, 17% Frequently, 1% Occasionally, 1% Rarely, 0% Never. **Team Assessment:** 55% Always, 45% Frequently, 0% Occasionally, 0% Rarely, 0% Never.
Q8 and Q16. "I consistently explain the relevance to the regulatory decision to industry."	**Self-Assessment:** 75% Always, 21% Frequently, 5% Occasionally, 1% Rarely, 0% Never. **Team Assessment:** 52% Always, 48% Frequently, 0% Occasionally, 0% Rarely, 0% Never.

At Kirkpatrick Level 3, the survey results for CDRH indicate that training efforts were effective and positively impacted the way premarket reviews are conducted—specifically, the application of least burdensome concepts and principles. These data, however, show a gap in perception between reviewers and their supervisors, with reviewers consistently assessing changes in behavior in the "Always" category at a higher rate than supervisors. The difference in perception between supervisors and reviewers appears to indicate that, although moving in the right direction, training and supporting activities are yet to be fully embedded into day-to-day operations. The supervisors' assessment of their staff behavior support this observation. Level 3 results should be expected to change as the premarket review program continues to take steps to implement the least burdensome provisions and reviewers continue to apply what they have learned from least burdensome training and supporting activities (Finding 2).

The Kirkpatrick Level 3 assessment for CBER will employ the same questions described above and is scheduled for June 2018.

Finding 7. **Kirkpatrick Level 4 – Results:** Level 4 Kirkpatrick evaluation data—perceived trends for key performance outputs—collected from CDRH supervisors appear to indicate that CDRH efforts are resulting in positive changes. However, there is insufficient data to affirm and quantify perceived trends as of March 2018.

To assess the impact of least burdensome training on the "requests for additional information" process (a key performance indicator), supervisors were presented with four survey questions:

Questions	Responses
Q17. When supervisors were asked "Within my team: Deficiencies have:"	38% decreased, 53% no change and 9% increased
Q18. When supervisors were asked "Within my team: Number of Deficiencies that Require Revisions have:"	27% decreased, 61% no change, 12% increased
Q19. Supervisors were also asked "Within my team: The number of deficiencies that offer an alternative means (rationale) to address the deficiency have:"	6% decreased, 61% no change, 33% increased
Q20. Supervisors were asked "Within my team: The number of applicants that have communicated concerns that deficiencies are not consistent with Least Burdensome principles have:"	33% decreased, 64% no change, 3% increased

At Kirkpatrick Level 4, the survey results for CDRH appear to indicate that training efforts had a positive effect on the premarket review activities typically associated with the effective application of least burdensome concepts and principles, such as the deficiencies included in request for additional information letters. Finding 7 relates to a "perceived trend." Currently, there is insufficient data to affirm and quantify perceived trends.

The Kirkpatrick Level 4 assessment for CBER is scheduled for June 2018 to allow sufficient time for CBER staff to apply the training and supervisors to assess the impact on communications. CBER's Level 4 assessment will employ the same questions described above.

IV. Feedback from Representatives of Device Industry

A. Cures Act Requirement

The ombudsman for any organizational unit of FDA responsible for the premarket review of devices shall, under section 513(j)(2)(B) of the FD&C Act, as added by the Cures Act, "include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decision making."

B. Summary of Findings

Finding 8. Feedback from the device industry appears to indicate that FDA is making progress in the application of least burdensome concepts and principles. It also indicates that there are opportunities for improvement.

Industry Experience Survey: Industry representatives independently collected and submitted the data from 224 respondents to CDRH. In an effort to meet the statutory deadline for submitting this report to Congress, the industry assessment was performed approximately 2 months after implementation of the mandatory training (Finding 1) for CDRH and before implementation of the training for CBER. Therefore, the full benefit of the training conducted may not be reflected in the assessment results.

Survey Question	Summary of Responses
Q1. FDA considers the least burdensome approach during the premarket review process.	4% Always, 33% Frequently, 47% Occasionally, 15% Rarely, 1% Never.
Q2. To make informed regulatory decisions during the premarket review process, FDA only requests information to resolve "need to know" deficiencies or questions rather than "nice to know" deficiencies or questions.	4% Always, 35% Frequently, 47% Occasionally, 12% Rarely, 1% Never.
Q3. When requesting additional information, FDA: - Acknowledges the information submitted; - Explains why it is deficient; - Explains the relevance of the request to the regulatory decision; and - Explicitly requests the information necessary and proposes alternatives, if applicable.	9% Always, 43% Frequently, 31% Occasionally, 13% Rarely, 2% Never.
Q4. When requesting additional information, FDA requests the minimum required information for a decision.	0% Always, 31% Frequently, 49% Occasionally, 19% Rarely, 1% Never.
Q5. FDA remains open-minded and considers alternative approaches to efficiently respond to requests for additional information during the premarket review process.	13% Always, 33% Frequently, 42% Occasionally, 11% Rarely, 1% Never.

Survey Question	Summary of Responses
Q6. In areas other than premarket, to make informed regulatory decisions, FDA only requests information to resolve "need to know" questions rather than "nice to know" questions.	3% Always, 45% Frequently, 37% Occasionally, 13% Rarely, 2% Never.

As part of the survey responses, respondents provided additional feedback through comments. CDRH conducted an analysis of the survey responses and comments to identify areas of strength and opportunities for improvements:

Strengths	Opportunities for Improvements
Progress applying least burdensome principles during premarket review	Provide more clarity when explaining the relevance of an FDA action to regulatory decision-making
Improvements with the processes used to request additional information, including interactive review	Promote consistency of the review process across branches

As shown in the tables above, industry feedback appears to indicate that FDA is moving in the right direction regarding the application of least burdensome provisions. However, perception of how the knowledge gained is being applied varies between FDA and industry and appears to indicate that there are opportunities to improve the consistency of the premarket review process.[6]

V. Ongoing Implementation of the Least Burdensome Provisions

FDA continues to act to reinforce implementation of the least burdensome provisions. Actions include:

A. How to Make the Most of Least Burdensome: Case Study Practice (CDRH)

Implemented February 2018
Intended to reinforce the least burdensome principles outlined in the September 2017 training. The required training focuses on the practical application of least burdensome principles through examination and discussion of case studies that reflect issues throughout the total product lifecycle.

[6] Note that the industry survey was conducted 2 months after mandatory training implementation, while the Kirkpatrick Levels 3 and 4 evaluations were conducted 6 months after mandatory training.

B. Basics of Four-Part Harmony in Lead and Consult Reviews (CDRH)

Implemented June 2016; Revised April 2017
Intended to improve a reviewer's ability to write deficiencies, the course teaches the components of four-part harmony[7], their purpose, and explains how to apply them in premarket reviews. This course targets new and experienced reviewers.

C. Master Four-Part Harmony (CDRH)

Implemented June 2016; Revised April 2017
Intended to further improve a reviewer's ability to write deficiencies that are clear, concise, and in the appropriate format. The course also emphasizes best practices for writing deficiencies in four-part harmony.

D. Reviewer Certification Program (CDRH)

Implemented September 6, 2011; Revised June 2016
Designed for new reviewers and medical officers, the Reviewer Certification Program develops baseline knowledge, skills, and abilities required to evaluate premarket medical device submissions. To ensure Center-wide consistency and review quality, this program introduces new reviewers and medical officers across the Center to device law, device regulations, and the Center's premarket processes and policies.

E. CBER Medical Device Reviewer Training

Intended to provide CBER regulatory staff with a general knowledge of the overall medical device regulatory process, including the least burdensome provisions, this training provides: a description of the different medical device types regulated by CDRH and CBER; the review life cycle of medical devices; key legislation, regulations, guidance, and policies applicable to various phases of device review; the differences in regulatory/scientific requirements among investigational new drugs (IND), biologic license applications (BLA), and device premarket submissions (investigational device exemptions (IDE), premarket approvals (PMA), and 510(k) and De Novo submissions); how to identify special considerations associated with accessories to CBER devices; the categories of medical device submissions that are inspected by CBER; and the regulatory steps for post-approval inspections.

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[7] For a summary of the four elements that comprise the suggested content and format for deficiencies, also known as four-part harmony, see:
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073680.pdf (page 5 *B. Suggested content and format for deficiencies).*

F. CBER Device Review Updates

These sessions are intended to provide training on both new and existing review management/regulatory processes including Standard Operating Policy and Procedures (SOPPs), guidance documents, and regulations related to the regulation of medical devices. These sessions focus on relevant and supporting issues with the overall goal to assure consistent and accurate application of these processes.

G. CBER Training

Based on the results of the training audit, CBER plans to provide additional training on areas of confusion identified in the post-test in order to improve the understanding of those concepts, including when and how to request some information postmarket rather than premarket; writing deficiencies in four-part harmony; and categorizing deficiencies as major or minor. CBER also plans to provide additional training on the deficiency writing and the supervisor's role in ensuring staff are adhering to least burdensome principles.

H. CDRH Focal Point Program (FPP)

Implemented November 1, 2016 (Biocompatibility); Implemented January 26, 2018 (Electromagnetic Compatibility)
Intended to provide greater consistency in the review of specialty topics, this new program currently focuses on Biocompatibility and Electromagnetic Compatibility (EMC) review topics. Under the program, topic area experts help mitigate issues that arise during the review process and promote consistent interpretation within the specialty area.

I. Guidance Documents

"Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (final guidance issued September 2017)[8]: this guidance document is intended to help FDA staff develop a request for additional information needed to decide on a medical device marketing application in accordance with the least burdensome provisions of the FD&C Act. Such an FDA request for additional information is known as a "deficiency." The guidance:

- Describes suggested formats for FDA staff to communicate deficiencies, and for industry to use for responses to such requests, to make efficient use of industry and FDA's time;
- Includes examples of well-constructed deficiencies and industry responses to facilitate an efficient review process; and

[8] Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (final guidance issued September 2017
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf

- Details supervisory review, major/minor deficiencies, additional considerations, and prioritization of deficiencies in FDA deficiency letters.

In addition, the guidance document describes the guiding principles FDA review staff should follow regarding the development of deficiency letters.

Least Burdensome Provisions: Concept and Principles (Draft Guidance issued December 2017): Although not required by the Cures Act, the draft guidance notes that least burdensome principles should be widely applied to all activities in the premarket and postmarket settings to remove or reduce unnecessary burdens so that patients can have earlier and continued access to high quality, safe, and effective devices. When this guidance is finalized, it will represent the Agency's current thinking on this topic. This draft guidance describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to medical devices. The guidance includes both premarket and postmarket examples to demonstrate approaches that FDA and industry can take to ensure that least burdensome principles are implemented for all device-related applications and interactions with FDA.

J. CDRH SMART Templates

Implemented January 15, 2017; Revised October 2017

SMART templates were created to help and guide CDRH premarket staff through their reviews. The SMART templates are intended to enhance consistency in the review of premarket submissions and facilitate adherence to the least burdensome principles by offering deficiency language for common issues that adheres to the four-part harmony principles for deficiency writing. To date, separate SMART templates are available for 510(k), De Novo, and Pre-Submission premarket submissions. The templates use software (Visual Basic for Applications, or VBA) embedded in a Microsoft Word document to guide reviewers through review and documentation of the various sections of a premarket submission (e.g., sterility, software, biocompatibility, battery, EMC). The templates were updated to require self-certification (electronic signature) of the application of the least burdensome provisions or principles.[9]

[9] An example of the self-certification statement added to the SMART template for 510(k)s is as follows: "This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence."

K. CDRH Total Product Lifecycle (TPLC) Transformation

The TPLC transformation, a new approach to how CDRH conducts business and the way it is structured, is an opportunity to increase information-sharing across the Center, enhance collective decision-making, improve work-life balance, and increase professional opportunities for employees. TPLC's holistic approach considers all the steps and processes that lead to the design, production, use, and impact of safe, effective, and high-quality medical devices. Work will be conducted in teams—primarily within Offices and Divisions, but also with assistance from individuals from across the Center—and will promote consistency and predictability across the organization.

L. CDRH 2018-2020 Strategic Priority: Simplicity[10]

CDRH's "Simplicity" strategic priority aims at improving decision-making and better use of our resources to achieve the Center's public health mission and vision. CDRH states that:

> *The medical device ecosystem has become increasingly varied and complex, and we keep building on our existing policies and processes based on experiences and theory rather than redesigning them to better meet the changing needs of our customers today and reduce the additional workload unnecessary complexity creates for our employees and our customers. Although well intentioned, by adding new layers of requirements and processes without revisiting the value of these modifications in the aggregate, we may unintentionally create unnecessary hurdles and policies and processes that are so complex that there is a risk of incorrect and inconsistent implementation and adherence.*

Simplicity is consistent with, but is more than, the least burdensome provisions. Under this strategic priority, CDRH intends to simplify policies and processes and focus on what has the biggest positive impact on public health.

M. CBER Communications with the Device Industry

In support of the Kirkpatrick Level 4 assessment, CBER is considering a study on the application of least burdensome provisions in CBER communications. Given the low volume of device submissions in the Center, CBER is planning a preliminary assessment to determine the feasibility of such a study in May 2018. The preliminary assessment will focus on volume and distribution of CBER device premarket communications.

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[10] 2018-2020 CDRH Strategic Priorities - https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhvisionandmission/ucm592693.pdf

N. Deficiency Letters Audit

Commitments outlined in the MDUFA IV Commitment Letter relating to the audit of deficiency letters will support further implementation and future assessments of the effectiveness of the implementation of the least burdensome provisions.[11] Specifically, the MDUFA IV Commitment Letter[12] states: "As part of these ongoing audits, high-performing premarket review processes utilized in one division will be identified and shared accordingly with other divisions to improve efficiencies and effectiveness. At a minimum, FDA audits in the following areas will be completed by the end of FY 2020: Deficiency Letters and Pre-Submissions."

O. Kirkpatrick Level 4 Implementation

FDA will continue to improve training for new and current reviewers. As stated in the MDUFA IV Commitment Letter, further evaluations of the impact of training activities relevant to premarket device review (using Kirkpatrick Level 4) will be performed by the end of FY 2020.

VI. Conclusion

As required by the Cures Act, FDA implemented mandatory training on the least burdensome requirements for medical device premarket reviewers, supervisors, and associated staff; conducted an audit of such training; and sought input from the medical device industry regarding their experience with respect to the application of least burdensome concepts.

All premarket device review staff and supervisors (100 percent) completed the mandatory training (Finding 1). Training data show a 27.8 percent knowledge gain for CDRH and a 7.7 percent knowledge gain for CBER (Finding 5). The audit of the effectiveness indicates that:

- the training was well received and adequate (Finding 4);
- knowledge was acquired after completion of the training (Finding 5);
- the effort put in place to implement the Cures Act is resulting in improvements towards the appropriate application of the least burdensome concepts and principles (Finding 6); and
- perceived trends showed improved results in expected areas such as requests for additional information for CDRH (Finding 7).

The overall audit results indicate that the audited training efforts and supporting activities were

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[11] See the guidance entitled "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions." For a description of the guidance, see Finding 2.

[12] MDUFA IV Commitment Letter
https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf

effective—i.e., that they positively impacted the implementation of the least burdensome provisions. These data, however, show a gap in perception between reviewers and their supervisors, with reviewers consistently assessing changes in behavior in the "Always" category at a higher rate than supervisors (Finding 6). A difference is also observed when comparing CDRH's perception to industry's perception (Findings 6 and 8). The differences in perception appear to indicate that, although moving in the right direction, training and supporting activities are yet to be fully embedded into day-to-day operations. As of March 2018, the premarket device review program continues to take steps to implement the least burdensome provisions and reviewers continue to apply what they have learned from least burdensome training and supporting activities (Finding 2 and section V).

The data collected for this audit may serve as a baseline to track changes in the perception gap and for future assessments, including those that serve as part of commitments associated with MDUFA IV. Results are expected to change as the premarket device review program continues to take steps to implement the least burdensome provisions and reviewers continue to apply what they have learned from least burdensome training and supporting activities. FDA is committed to continuing its efforts to effectively and consistently implement the least burdensome provisions of the statute.

Appendix: Food and Drug Administration Acronyms

510(k)	Premarket Notifications
BLA	Biologic License Application
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
Cures Act	21st Century Cures Act
EMC	Electromagnetic Compatibility
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FFP	Focal Point Program
HHS	Department of Health and Human Services
IDE	Investigational Device Exemption
IND	Investigational New Drug
MDUFA	Medical Device User Fee Amendments
NSE	Not Substantially Equivalent
PMA	Premarket Approval Application
RCP	Reviewer Certification Program
TPLC	Total Product Lifecycle
VBA	Visual Basic for Applications