

Review and Update of Device Establishment Inspection Processes and Standards

Draft Guidance for Industry

DRAFT GUIDANCE

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For questions about this document contact the ORA Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov.



**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**

Preface

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63 **and Standards**

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66 **Draft Guidance for Industry**
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68 *This draft guidance, when finalized, will represent the current thinking of the Food and Drug*
69 *Administration (FDA or Agency) on this topic. It does not establish any rights for any person*
70 *and is not binding on FDA or the public. You can use an alternative approach if it satisfies*
71 *the requirements of the applicable statutes and regulations. To discuss an alternative*
72 *approach, contact the FDA staff or Office responsible for this guidance as listed on the title*
73 *page.*

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75 **I. INTRODUCTION**
76

77 FDA is issuing this draft guidance to comply with section 702(b)(1) of the FDA Reauthorization
78 Act of 2017 (FDARA) (Public Law 115-52), which directs FDA to issue draft guidance that
79 specifies how the Agency will implement uniform processes and standards¹ that are applicable to
80 inspections² (other than for-cause) of foreign and domestic medical device establishments. FDA
81 updated processes and standards as needed, to address the new provisions in section 704(h)(1) of
82 the Federal Food, Drug, and Cosmetic Act (FD&C Act) that were added by FDARA section
83 702(a), and to establish a standard timeframe for inspections. This draft guidance also describes
84 standardized methods of communication during the inspection process, and identifies practices
85 for investigators and device establishments to facilitate the continuity of inspections of such
86 establishments.
87

88 FDA’s guidance documents, including this draft guidance, do not establish legally enforceable
89 responsibilities. Instead, guidance describes the Agency’s current thinking on a topic and should
90 be viewed only as recommendations, unless specific regulatory or statutory requirements are
91 cited. The use of the word *should* in Agency guidance means that something is suggested or
92 recommended, but not required.
93

¹ As used in this guidance, the term “standards” refers to “a level of quality or attainment” and does not refer to a “voluntary consensus standard” as described in Office of Management and Budget Circular No. A-119 at https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf.

² Section 704(h)(1) of the FD&C Act applies to “other than for-cause inspections” only. Therefore, as used in this draft guidance, “inspection” does not include for-cause inspections.

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94 **II. BACKGROUND**

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96 On August 18, 2017, FDARA was signed into law. Among other things, FDARA added section
97 704(h)(1) to the FD&C Act. This provision requires FDA to review processes and standards
98 applicable to inspections of domestic and foreign device establishments and update such
99 processes and standards, as necessary, through the adoption of uniform processes and standards
100 applicable to such inspections. Section 704(h)(1) specifies that the updated uniform processes
101 and standards will describe how FDA should, among other things, pre-announce inspections of
102 device establishments within a reasonable time before the inspection begins, provide a
103 reasonable estimated timeframe for inspections, and ensure regular communication with the
104 establishment owner, operator, or agent in charge during inspections.

105
106 Section 702(b) of FDARA instructs FDA to issue this draft guidance to describe how it is
107 implementing section 704(h)(1), provide for standardized methods of communication when
108 communication is required under 704(h)(1), establish a standard timeframe for inspections, and
109 identify practices for investigators and device establishments to facilitate the continuity of
110 inspections of such establishments.

111
112 **III. DISCUSSION**

113
114 Pursuant to section 704(h)(1) of the FD&C Act, as added by FDARA, FDA reviewed the
115 processes and standards applicable to inspections of foreign and domestic medical device
116 establishments that were in place as of August 18, 2017. The review encompassed FDA
117 guidances, manuals, programs, and internal standard operating procedures related to medical
118 device establishment inspections. As a result of this review, FDA identified uniform processes
119 and standards and drafted revisions to procedural documents, including the Investigations
120 Operations Manual and training materials, where necessary, to align with these processes and
121 standards.

122
123 FDA believes that uniformity in investigators' approaches to inspections, both before and during,
124 may inform firms' preparation for the inspection and set baseline communication and timing
125 expectations for each party. The processes and standards identified below should facilitate
126 practices that encourage continuity within an inspection and across inspections. Section
127 704(h)(1)(A) allows FDA to establish exceptions to the updated processes and standards, as
128 appropriate.

129
130 **Pre-announcement Notice and Communication**

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132 Under the uniform processes and standards, an FDA investigator notifies the owner, operator, or
133 agent in charge of a medical device establishment by telephone before their facility undergoes an
134 FDA surveillance and/or pre-approval inspection. Under the statute, this notice will be provided
135 within a reasonable time before the inspection is scheduled to occur. For domestic inspections,
136 the pre-announcement should generally be no less than five calendar days in advance of the
137 inspection. The pre-announcement for foreign inspections may be more than five days due to

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138 requirements of particular country clearances. For both domestic and foreign inspections, the
139 notification should include information about the type and nature of the inspection, such as
140 whether the inspection is scheduled as abbreviated, comprehensive, or pre-approval.
141

142 Updated processes specify that during pre-announcement, investigators may communicate with
143 the firm regarding the appropriate working hours during which the inspection is likely to take
144 place. To the extent possible, FDA should also provide advance notice of some records that may
145 be requested during the inspection. Under 704(h)(1), FDA retains authority to conduct
146 unannounced, for-cause inspections.
147

Standard Inspection Timeframe

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149
150 FDA standards for reasonable estimated timeframes of inspections generally range from 3 to 6
151 continuous business days. These standards are based on the type of surveillance inspection
152 (abbreviated or comprehensive) and the extent of coverage needed for a pre-approval inspection.
153 The estimated duration for each inspection should be shared with the firm at the time of pre-
154 announcement. Inspection duration is impacted by factors such as the complexities of the firm's
155 operations, availability of knowledgeable staff, and the nature of observed deficiencies.
156

157 Additionally, it may be necessary to extend the duration of an inspection for a number of
158 reasons, including for FDA to follow-up on post-market safety information such as recalls,
159 Medical Device Reports, and complaints received by the Agency. Updated processes provide
160 that, unless an investigator or the firm identifies a reason that additional time is needed and
161 communicates this verbally to the other party, inspections of both domestic and foreign device
162 establishments should take place within a standard timeframe and occur over consecutive
163 business days. FDA recognizes that circumstances may arise, for either FDA or the firm, where
164 exceptions to these timeframes may be appropriate. Exceptions to the timeframe should be
165 communicated verbally during the course of the inspection.
166

Communication During Inspections

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168
169 FDA's updated processes also address regular verbal communications during the inspection
170 between the FDA investigator and the owner, operator, or agent in charge of the establishment
171 about the status of the inspection. When time and circumstances permit, investigators should
172 make every reasonable effort to discuss all observations with the management of the
173 establishment as they are observed, or on a daily basis, to minimize errors and
174 misunderstandings. These communications may be recorded by either FDA or the firm, if there
175 is advance notice and mutual consent by the other party.
176