THE QUALITY SYSTEM REGULATIONS

SUBPART M – (RECORDS) COMPLAINTS

October 2020

Complaints Poll

Are complaints good or bad?

21 CFR 820.198
Complaint files

Definition of a Complaint

820.3(b):"Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution"

21 CFR 820.198 Complaint files

- **What a Complaint is NOT:**
- General business complaints are not complaints as defined by 820.3(b). For example:
  - Pricing
  - Customer service agent was mean to me
  - Product enhancement (such as I want a gray panel not an off white panel)

21 CFR 820.198 Complaint files

Scope of product involved:

Nonconforming product discovered before distribution is handled via the 820.90 and/or 820.100 subsystems. Complaints (820.198) are for distributed product but a complaint can be raised by anyone at any time.

21 CFR 820.198(a) Complaint files

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

- *(1) All complaints are processed in a uniform and timely manner;*
- *(2) Oral complaints are documented upon receipt; and*
- *(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting*

21 CFR 820.198(b) Complaint files

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

21 CFR 820.198(c) Complaint files

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

*Notice the connection from the needs of complaint investigation to design and production specifications. Also, the investigation may lead to actions under the CAPA system.

21 CFR 820.198(d) Complaint files

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified

Note: To be able to determine reportability a complaint will need to connect to the risk associated with the failure being investigated

21 CFR 820.198(d) Complaint files

820.198(d): (continued)

In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:

1) *Whether the device failed to meet specifications;*
2) *Whether the device was being used for treatment or diagnosis; and*
3) *The relationship, if any, of the device to the reported incident or adverse event*

21 CFR 820.198(e) Complaint files

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section.

21 CFR 820.198(e) Complaint files

820.198(e) (continued)

The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant

21 CFR 820.198(f) Complaint files

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

21 CFR 820.198(g) Complaint files

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor

21 CFR 820.198 Complaint files

"…18 years of experience with these requirements shows that many manufacturers still do not understand and properly handle complaints. Therefore, FDA believes that the amount of detail in § 820.198 is appropriate and necessary…"

Preamble comment #190

21 CFR 820.198 Complaint files

FDA Trend for Complaints

- Inadequate complaint handling was the second most cited CAPA subsystem observation in 2017 at about 36% for domestic observations
- And it was the second most frequent Warning Letter citation in 2017.

21 CFR 820.198 Complaint files

Warning Letter Example:

Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as per 21 CFR 820.198(a). For example:

a. In May 2015, XX received a complaint from ZZ about observed negative bias in test results obtained from ZZ's devices when using blood collected in tubes. Your firm did not enter this information into its complaint system, evaluate the complaint to determine if it represents an MDR reportable event, or initiate an investigation of the complaint.

21 CFR 820.198 Complaint files

Warning Letter Example:

Failure to review, evaluate, and investigate, where necessary, complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR 820.198(c). Specifically,

a. Your firm replaced (b)(4) failed components on the dialysis devices, which did not meet your firm's design specification, and you did not investigate the cause of the failure as part of your investigation when the life expectancy of your device is 10 years.

b. Your firm's complaint investigations do not include an assessment as to whether there are other similar/same failures on the device to meet specification. For example, your firm had (b)(4) digital printed circuit board failures in the dialysis devices since April 2012; however, the individual complaint investigations documented that there was "no trend".

QUESTIONS?