

Shortened Dating – Process

Background:

Allowing an expiration date that is ½ of the allowable dating has been a practice in place since at least the early 1990s. It is a regulatory flexibility used as salvage for lyophilized and frozen products that cannot be reprocessed under title 9, *Code of Federal Regulations* (9 CFR), part 114.18, but are of some value in the marketplace.

Most steps follow the outline as listed in **ICSOP0010**, *Processing Serial Records*, with the following additions.

Biologics Compliance Assistant (BCA) Initial Review:

1. The BCA reviews the information on the incoming APHIS Form 2008 request marked by the firm as **Other – Shorten Dating** (hardcopy or NCAH Portal submission).
 - a. This regulatory flexibility is only allowed for lyophilized or frozen products that do not meet the release titer or count.
 - b. ½ **dating** is the maximum dating allowed.
 - c. NOT used when a serial is short dated due to reasons other than insufficient potency titer/count, such as export requirements.
2. The BCA may audit the submission back in accordance with the current version of **ICWI0075**, *Audits and Reference Slips for IC Documents*, if the submission does not meet the above criteria.
3. If the submission is not audited back, it can be submitted to the Specialist for review.

Specialist Review:

1. Review the data submitted.
 - a. All individual potency test results (titration or counts) must be above the end of dating criteria. If the average is above, but there is one or more individual results below the end of dating criteria listed in the Outline of Production, the request must be DENIED.
 - b. The product must be lyophilized or frozen. This pertains mostly to modified live virus, live virus, live culture, and avirulent live culture. Check the Outline of Production to determine final product format.

NOTE: Shorten-Dating IS NOT ALLOWED for liquid killed product (virus or bacterin). Reprocessing in accordance with 9 CFR 114.18 is the avenue of regulatory flexibility for these products.

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- c. The maximum allowable dating is $\frac{1}{2}$ of the dating listed in the Outline of Production, Section VI. Item C. For example, if 18 month dating is allowed, a serial submitted for Shorten-Dating can only have a maximum of 9 months.
2. The Specialist may require that additional information be submitted concerning the results of the investigation conducted by the firm to determine a root cause of this deviation.
 - a. Results of the investigation conducted by the firm to determine root cause of lower potency.
 - i. Normally this is reviewed during on-site inspections.
 - ii. One factor to request the investigation outcome prior to approval would be an increase in the Shorten-Dating requests from a firm. This request is not common.

DATA: From October 2010 through October 2016 (6 years) there have been 110 requests for Shorten-Dating. This equals 3,539,971,742 doses in 6 years out of 576,573,373,886 doses processed (0.61% of total doses).
 - b. May require “release requirements” for the serial, such as mid-date titration.
3. NOTE – While it may not apply to most vaccines that contain a rabies fraction, Shorten-Dating IS NOT GRANTED for products containing a rabies fraction.
4. Provide your conclusion in LSRTIS:
Other - Shorten Dating Approved
Other - Shorten Dating DENIED
5. Submit to BCA for finalization.