Nonconforming Material

The Context
Device manufacturers, as part of the production process, conduct acceptance activities. These steps compare the product with its requirements. If the product doesn't meet those requirements, it is nonconforming. QSR, in §820.90, requires a process, documented in a procedure, to control nonconforming product.

The process needs to include identification, documentation, evaluation, segregation, and disposition of the nonconforming product. It must also include steps to notify the people responsible for the product's quality as well as a documented decision on the need for an investigation.

The Warning Letter
FDA sent this January 23, 2015 Warning Letter to GVS Filter Technology UK Ltd. A manufacturer of Class II air filters and spirometers located in Lancashire, United Kingdom. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter included two citations related to nonconforming product. One involved documenting rework. The other, of interest here, asserts, "Your firm's nonconformance procedure … does not describe requirements for documenting the review and disposition of nonconforming product. The procedure also does not require documentation of justification and approval for use of nonconforming product."

The firm responded and FDA said, "Your firm provided an updated nonconformance procedure … to add requirements for authority, review, and disposition of nonconforming product, and an updated nonconformance report document … which specifically documents [disposition] actions."

The Requirement
The Quality System Regulation requires, in §820.90(b)(1), requires, "Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use."

ISO 13485:2003 has similar requirements in Clause 8.3:

> The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.
>
> The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained.

Note: A *concession* is permission to use or release a product that does not conform to specified requirements.

In ISO 13485:2016, the requirements are similar, but the text in Clause 8.3 and subclauses changes:

> The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.
>
> The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained.

Recommendations

The first recommendation prevents the QMS problem by ensuring the procedures have the necessary contents.

- The procedures set forth the review and disposition process. {820.90(b)(1)}
- The procedures require documentation of the disposition of nonconforming product. {820.90(b)(1)}
- The procedures require that, for a Use-As-Is disposition, the disposition record includes a justification for the use and the signature of the individual authorizing the use. {820.90(b)(1)}

The second recommendation uses the internal quality audit program to detect any issues. Check a sample of disposition records to ensure they are complete, correct, and legible.

- A person with disposition authority, as defined by the procedure, made the disposition
- Each record shows the review and disposition followed the process set forth in the procedure
- If the disposition is Use-As-Is, the record includes a justification and the signature of the authorizing person
- If the disposition is Rework, the record shows successful retesting and reevaluation after the rework
- If the disposition is Rework, trace forward to the DHF and check documentation of rework, revaluation, and any adverse effect