Nonconforming Materials Reports – Compliance and Implementation

An important part of a successful Quality Management System (QMS) is having a compliant Nonconforming Materials Report Program. Control of nonconforming product is required within the Medical Device Industry, but is also relevant to many industries. This White Paper focuses on regulations according to 21 CFR 820.90, ISO 9001 § 8.3, ISO 13485 § 8.3 and the Medical Devices Directive 93/42/EEC.

Please Note: Nonconforming Material Reports are sometimes referred to as NCMRs. Nonconformance Reports are sometimes referred to as NCRs. For the purposes of this White Paper, the acronym NCRs will be used.

Why is it important?

Lack of or inadequate procedures for Nonconforming Product is one of the top ten 483s issued, as listed in FDA FY2015 Inspectional Observation Summaries. This is further described as "Procedures have not been [adequately] established to control product that does not conform to specified requirements."

Adequate establishment of Nonconforming Product procedures is critical in demonstrating and ensuring control of product.

Steps

Identification of Nonconforming Material is not necessarily bad. It shows that appropriate Quality Systems are working and nonconforming materials are properly identified. Once nonconforming materials are identified; however, appropriate steps need to be taken.

1. Identification
2. Documentation
3. Evaluation
4. Segregation
5. Disposition

This above steps, properly executed, provide valuable feedback and/or linkages into other QMS processes.

Identification

Nonconforming product must be identified and controlled to prevent its unintended use or delivery. Nonconforming product can be identified at any stage of the manufacturing process, including (but not limited to) incoming inspection, in-process inspection and final release.

One way to achieve this is through the use of NCR tags. Inclusion of the NCR # on the NCR tag allows for traceability from the NCR to the physical product. Once product is identified as Nonconforming, the NCR tag can be placed on the product and the product moved to a quarantine (segregated) location.

The NCR # can be established via an NCR Log or computer generated according to the Nonconforming Materials Product program.

Documentation

Evaluation and any investigation shall be documented. 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.

Document NCR details on an NCR report. The NCR # listed on the NCR tag should correspond to a Nonconforming Material Report for documentation of the details of the event. The description of the nonconformity should be clearly stated so it is easy to distinguish between the requirement and the discrepancy.

For example, Part Number 123, Lot Number XYZ was received on August 1, 2016. Incoming Inspection revealed that product does not meet specification criteria of “may not contain burrs” in that products sampled were confirmed to “contain burrs”.

Also include relevant details such as Date, Inspector, Part Number, Lot Number, Lot Size, Quantities, and other details as applicable. It is important that anyone reading the NCR can understand and follow the details of the event.

Evaluation

Evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations (external party) responsible for the nonconformance. The evaluation and any investigation shall be documented and maintained.

There are several investigation tools that can be used to aid in this process. Many organizations develop an Investigation Procedure to ensure this process is outlined and appropriately defined.

Segregation

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

There is no requirement for a locked cage; however, nonconforming product must be identified and segregated from conforming product. This can be achieved through the use of a quarantine location such

as a cage, rope and cones, floor tape, colored bins, etc. An area identified as appropriate for this purpose, with the use of proper signage may be adequate.

The use of colors for this purpose may also be helpful. Red is typically associated with STOP or CAUTION and can be a good visual identifier for nonconformance. This can be achieved through the use of red stickers, red tabs, red signage, red bins, etc.

Disposition

Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. 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. The most common dispositions are:

- Return to Vendor (RTV)
- Use As Is (UAI)
- Rework
- Scrap

Return to Vendor (RTV)

There are times when nonconforming material is received from the supplier. This is generally identified during Receiving and/or Incoming Inspection steps; however, this can also be identified later in the production process.

RTV dispositions are an indicator of supplier performance. RTV disposition trends provide valuable insight into the adequacy of the Supplier Qualification and/or Control program. Where appropriate, RTV dispositions and/or trends may lead to the issuance of Supplier Corrective Action Requests (SCARs).

Use As Is (UAI)

Upon review of the nonconformance, there may be times when it is determined that the parts may be used as is. The use of the UAI disposition should be infrequent. Overuse may be caused by specification criteria that is subjective or vague. In this case the inspector may identify material as nonconforming when it may actually be conforming. Where possible, specification criteria should be very clear (quantitative is desirable) regarding when to Accept and when to Reject.

Rework

Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after work, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

One way to perform rework according to these criteria is to supplement the DHR and original manufacturing steps with Rework Instructions per the NCR. This rework instruction shall undergo the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the rework instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

After completion of the rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained.

In situations where organizations desire to sort product. This can be accomplished under the Rework category, following the same requirements as defined for rework. The details associated with the sorting process shall be outlined within the Rework/Sort Instructions.

Please note: Many Auditors are keen in looking for specific details within the NCR procedure. It is important to ensure that these details are included. Two key details are:

- Rework instruction shall undergo the same authorization and approval procedure as the original work instruction.
- Prior to authorization and approval of the rework instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

Many times companies are doing this; however, the procedures don't clearly state this requirement. Additionally, rework instructions must include any specific inspection instructions that have been added appropriate to the rework process. Repeating the normal inspection criteria alone may not be adequate for reworked product, as new defect types may be introduced through the rework process.

Scrap

There are times in which the best option is to scrap the nonconforming product. This may be because the nonconforming material cannot be returned to the vendor, is not salvageable via rework, and cannot be accepted as is. Of course, it may also be because it is easiest option or perhaps the option with the least financial burden on the organization. Because there may be a cost associated with the scrap of nonconforming product, it may be beneficial to include an Accounting representative in the NCR approval process.

Disposition Execution

Once a disposition has been assigned and approved, it is critical to ensure that it is carried out appropriately and the NCR receives a Final Close Out. For example, if an NCR disposition reflects that product was approved to be scrapped, the product should be scrapped within a reasonable time frame and closed out as evidence that the disposition was executed appropriately. Auditors never want to

review NCRs reflecting the product as scrapped, only to walk back to Quarantine and find the product still present.

Material Review Board (MRB)

Companies may choose to create a Material Review Board (MRB). In this scenario, the MRB is responsible for deciding how to disposition nonconforming material. MRB meetings may be scheduled on an established frequency, or ad hoc to review nonconformities. The board may consist of a cross functional team with representatives from:

- Quality Assurance
- Engineering
- Manufacturing
- Accounting
- Regulatory

The purpose of a cross functional team is to assemble key decision makers for discussion. Disposition options may be discussed to review potential adverse effects of rework and potential risks associated with UAI dispositions. If the decision is made to rework, the cross functional team may have the ability to create a rework instruction and to review and approve that rework instruction.

Feedback into other processes

Ideally, the NCR process should be streamlined and executed without unnecessary delay. This will aid in materials management as well as helping to keep process interactions flowing efficiently.

NCRs provide valuable insight into an organization's operations. Trending of NCRs is useful for Management Review Meetings, as well as for identifying areas for improvement. NCR trends can lead to the initiation of Corrective and Preventive Actions (CAPAs) where other problems may be identified and Corrections / Corrective Actions implemented, as appropriate. Effective Corrective Action implementation will help to prevent additional NCRs.

ISO 13485:2016 § 8.3 expands upon the above requirements to include nonconforming product detected after delivery.

When nonconforming product is detected after delivery or use has started (product has been released into the field), the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained.

The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained.

This is another example of feedback into other processes and is part of ensuring compliance of the overall Quality Management System.

Summary

Establishment and maintenance of a complaint Nonconforming Materials Report program is an important part of a successful Quality Management System. Implementing these key concepts within the procedure, documenting and executing accordingly will aid in the overall success in controlling nonconforming product. Feedback of the Nonconforming Materials Report program into other associated Quality Management System programs will also result in improved regulatory compliance.

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