

Nonconforming Product

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Hello, my name is Vidya Gopal, and I'm a Consumer Safety Officer in the Division of Industry and Consumer Education. I've worked in Industry for many years, and I understand the pressures and difficulties associated with bringing and keeping a product on the market. I have done post market and compliance work at the FDA. So, I understand the agency's stance on safety and effectiveness. I hope to bring you a balanced perspective to my discussion on non-conformances and non-conforming product.

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Non-conformances are a key part of the Quality System for medical device manufacturing. When you don't pay proper attention to non-conformances, you may end up distributing non-conforming product. You will have to deal with the direct cost of the non-conforming product and possible recalls; but you also will have to deal with the indirect cost of liability, brand image and market share loss. These are expensive and cost the company both time and money. Conversely, when non-conformances are properly handled, and coupled with other corrective action systems, the result is a mechanism for continuous improvement. This can result in successful product longevity, increased market share, and consumers will ultimately benefit from a better, safer, and more effective product.

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Today, I will be focusing on the following Learning Objectives: First, we will understand the context of non-conformances within the overall Quality System and Corrective and Preventive Action or the CAPA subsystem. Then, Define nonconforming product. Next, we will go over the process flow and finally learn how nonconforming product disposition contributes to quality and safety. These Objectives will give you a firm start in understanding the role, function, and importance of non-conformances.

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What is the CAPA subsystem? It's a key component of the Quality System, and is itself comprised of three parts. This is articulated in this simplified and generalized table – Nonconforming Product, which functions primarily during Manufacturing; CAPA, which functions during both Manufacturing and After Distribution; and Complaint Files, which generally functions After Distribution. We are going to focus this talk on Nonconforming product, the regulatory requirements for which can be found in 21 Code of Federal Regulation, CFR, 820.90 as highlighted in the table.

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We are going to start with some definitions. Just so that you know, all definitions pertaining to the Quality system are found in 21 CFR 820.3. Specification is any requirement that you set for the proper functioning of the product during design controls. Products are components, manufacturing materials, in-process devices, finished devices, and returned devices. Nonconformity is the nonfulfillment of a specified requirement

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Nonconforming product is product that does not fulfill its specified requirements. Nonconformances can occur in both product and process. Nonconforming processes can lead to nonconforming product. I will give you examples of this a little later under identification of non-conformances.

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The regulation, 21 CFR 820.90 (a) requires manufacturer to establish and maintain procedures to control product that does not conform to specified requirements.

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And these procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product..." This means that you are responsible for your non-conforming product and the control of it. Now that we know you are responsible for your own non-conformances, let us try to figure where it comes from and what you do with it.

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Now, let's take a look at the Process flow for non-conformances - Identification,

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Documentation,

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Evaluation,

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Segregation,

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And Disposition. We will go over in detail each one of these in the following slides.

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Nonconformances need to be identified to be processed. So, this is our starting point in our process flow.

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We will talk about some of the common sources of nonconformances. First, received components that fail incoming inspection. For example: You obtain a part from your vendor. Your specification for the length is six plus or minus one inch. But when you measure it during incoming inspection it is eight inches. It does not meet your specification and therefore is nonconforming product.

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Second, products or components that fail to meet specification or inspection during manufacturing. An example of this is during a manufacturing process for thermal bonding, you set your process parameter to be three hundred degrees plus or minus ten degrees. During inspection, it was noted that the machine was set to two hundred eighty degrees. This is a nonconforming process. Now you will have to evaluate the product to verify if you have product that is within specification. This is also an instance of a nonconforming process that could lead to nonconforming product where the bond fails to hold.

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Lastly, Product returned to manufacturer with defects. For example, If a catheter is supposed to fit inside a six French guide and it does not fit during a procedure. The doctor or the facility decides to return the product to the manufacturer. This is then handled through complaint handling and is not in the scope of this presentation.

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When you become aware of a nonconformance or receive a nonconformance report, you have to evaluate it. One industry practice example is to assemble a group of experts to figure out what comes next. These convened groups are sometimes referred to as a material review board or MRB or material review committee or MRC. Please note that these groups are not formed ad-hoc but through approved procedures.

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Next in the process is Documentation.

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An example for documentation is to have a form, such as a nonconformance report, that walks through the entire process from identification to disposition along with signatures. The forms are sometime part of a larger standard operating procedure or SOP with a work instruction outlining how to use the form.

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Next let's talk about Evaluation.

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Evaluation of nonconformance product is addressed in 21 CFR 820.90(a). Manufacturers must evaluate the nonconformance to determine whether an investigation is necessary. If no investigation is pursued, the name of the responsible individual making that determination, as well as the reason, must be recorded. Also you must notify the person or group responsible for the non-conformance.

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Investigations are not always required, the regulation provides you with the flexibility to decide if an investigation is necessary or not. For example you may not need to investigate when a nonconformance is already known due to a similar issue. Please note that while a similar issue may not require an investigation under nonconforming product, it may require a referral to the CAPA system due to recurrence and a CAPA investigation. I'll discuss CAPA referrals later in this presentation.

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Next is Segregation.

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The important point to note is that you have to segregate non-conforming product to make sure that it is not released. We always get questions on what this segregation means. Does it mean locked cages, digital controls, separate area? It is whatever works for you to make sure that this is not inadvertently released. Again the regulation provides you this flexibility.

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Next is Disposition.

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Disposition is addressed in 21 CFR 820.90(b)(1). Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product.

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Let's briefly discuss the typically types of dispositions. First, let's talk about scrap where you decide not to use the product and destroy it. Even though you are destroying the product it is still important you understand what your scrap data is in order to bench mark if your processes are working in a particular norm. For example, this information would be important if one day you had a scrap rate of five and then the next day it was five hundred as that may be indicative that your process is moving all over the place and not in control.

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Second. Return to Supplier. For example, where you determine that the non-conformance is the supplier's mistake because they sent the wrong product. Depending upon the recurrence or severity of the mistake, it may be referred to outside of the nonconforming product process and could touch upon both CAPA and Purchasing Controls. Please note that the requirements within the regulation are not intended to be duplicative, but to be complementary.

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Third - Downgrade. This is when you have upgraded a version of your device and there is a problem with the upgraded version. So you decide to downgrade, which is still safe and effective, till you figure out the issues with your latest version.

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Fourth - Use as Is. An example of this is, you receive product from your vendor and notice that there is a cosmetic defect that does not affect the safety and effectiveness of the product. You still open a non-conformance and let your supplier know, but you end up using the product as you know that it does not hurt the product performance.

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And the Regulation says disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual authorizing the use. If you end up using nonconforming product then you must document a justification and the signature of the individual authorizing the use.

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The preamble to the Quality System states that the justification should be based on scientific evidence. Concessions should be closely monitored and not become accepted practice. And this is one of the connection points to CAPA. You will analyze your concessions and will refer it to the CAPA system based on your thresholds.

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In the example of the cosmetic defect, let's say that you start to see the same defect in every lot that the supplier provides. Then you may need to refer this non-conformance to the CAPA system, based on the criteria set in your procedures. And I will make one additional point regarding "Use as is" in that it may lead to another concern. For example, if there is a trend of "Use as is" for the same issue over and over, you may want to relook at your specifications and determine if they are appropriate.

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The last type of disposition is Rework. For example, your quality group notices that the inner pouches are not sealed when they are performing the final acceptance testing for sterilized product. You open a Nonconforming Report (NCR) and then decide the correction is to resterilize the product after sealing the pouch. When the product was re-tested, it was noted that the burst strength of the balloon did not meet the acceptance criteria.

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The regulation states that you must have procedures for rework and that the reworked product is retested and must meet the original approved specification. Basically, this is making sure that you do not have a special set of specifications for reworked product.

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So in the above example, the balloon burst strength did not meet the original specification.

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Rework and re-evaluation activities must be documented in the Device history record or DHR.

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When should Non-Conformance be handled under 21 CFR 820.90 and when should they be referred to Corrective and Preventive Action system, 21 CFR 820.100?

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Corrections may be handled locally under nonconforming product, 21 CFR 820.90. Here are some examples of the general criteria for handling a correction under nonconforming product: if it is an easy/specific correction; an isolated incident; a minor issue; not a design issue and not a manufacturing issue.

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In some cases, non-conformances may be referred to the CAPA system, 21 CFR 820.100. Here are some examples for when you should refer nonconformances to CAPA: there is no easy/specific correction; it is recurring, based on a valid analytical method of determination; it is a severe issue; a design issue or a manufacturing issue. Please note these are not all-inclusive lists, and where and how you handle nonconformances should be defined in your procedures.

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In deciding on which system to handle the non-conformances, balance is key. Too many nonconformances handled under 21 CFR 820.90, may fail to address systemic issues. Generally, nonconformance issues should be simple, specific, and contained. Conversely, too many nonconformances referrals to CAPA will overwhelm that system. Generally, CAPA handles more complex, ambiguous, and systemic issues.

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Additional information on the Quality System, its Preamble, and the FDA Inspection Guide can be found at the links on this slide.

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In concluding this presentation, I now ask you to take on the following Call to Action:

Use your Nonconformance system to “learn from mistakes”. They can impact everything from quality to design to manufacturing. Know that nonconformances are a gateway mechanism for CAPA, and leveraging a robust nonconformance system to avoid repeating mistakes can allow you to improve quality and safety of your product.

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We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you. Thanks for watching this program.

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