Guidance Document Title: Guidelines on the use by MDSAP of document GHTF/SG3/N19:2012 – *Nonconformity Grading System for Regulatory Purposes and Information Exchange*
Document No.: MDSAP AU P0037.002
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Contents

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1. Purpose

Information on nonconformities and their significance is essential for an auditing organization to make decisions on the certification status of medical device manufacturers, and for regulatory authorities to make regulatory decisions according to their processes.

This document is intended for regulatory authorities and auditing organizations participating in or utilizing the results of the Medical Device Single Audit Program (MDSAP). It provides guidance on the application of the document GHTF/SG3/N19:2012: Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange for appropriately writing and grading nonconformities resulting from MDSAP audits.

2. Scope

The document applies to all audits performed under MDSAP during which nonconformities are identified. It concerns the application of GHTF/SG3/N19:2012 and the requirements of ISO/IEC 17021-1:2015 clauses 4.2.3 and 9.4.5 for the grading on nonconformities identified during an MDSAP audit.

The intent of this grading system for regulatory purposes is to support the exchange of information about nonconformities from audit findings that go beyond the binary concept of “major” and “minor” defined in ISO/IEC 17021-1:2015 – 3.12 and 3.13, to a 5 level grading system of nonconformities.

3. Definitions/Acronyms

AO: Auditing Organization

RA: Regulatory Authority

NC: Nonconformity

4. Authorities/Responsibilities

Auditing Organizations: responsible for oversight of audits that are conducted in accordance with MDSAP, including ensuring adherence to this procedure and all other relevant MDSAP policies and procedures.

Regulatory Authorities: responsible for evaluation of the graded nonconformities and MDSAP audit reports per their legislation.

5. Policy

5.0 General

Regulatory audits conducted under the MDSAP should be performed in accordance with MDSAP AU documents and other applicable regulatory references. The output of those audits may include nonconformities.

Appropriately documenting a nonconformity is essential for effective use of the information by each audience:

- Medical device organization: to acknowledge, accept and investigate, and to define effective corrections and corrective actions.
- Auditing organization: to make informed decisions on the certification status of the medical device organization.
- Regulatory authorities: to monitor medical device organizations and to take regulatory actions according to their specific regulatory framework.

When an auditor identifies occurrences of nonconformity, it is essential to record and document their findings so that they are seen to be:

- **O**bjective and factual: able to be proven to be true. A nonconformity must be based on facts, i.e., from information provided in a documented form or orally, by direct observation of practice, infrastructure, etc., and free of bias and personal opinion.
- **C**lear: precise, unambiguous, concise and accurate so that any independent reader should reach the same understanding of the situation.
- **C**oherent: the various pieces of information within the individual nonconformity record, as well as the additional information in the audit report package, must not contradict each other.
- **U**nderstood and agreed: communicated to the auditee, with opportunity to react (e.g., by

offering additional contradictory evidence), and eventually agreed. If a finding of NC is maintained by the auditor, and remains contested by the auditee, this needs to be recorded in the statement of nonconformity.

- **R**elevant: explicitly tied to an applicable requirement, whether from ISO 13485, any applicable regulatory requirement, another external requirement, or an internal requirement, that are applicable to the organization considering their activities, range of devices, specificities and scope of certification.

- **S**ignificant: the degree of significance towards the marketed devices' safety and performance should be clear, considering the complete nonconformity information. Auditors should apply a risk-based approach to challenge the organization's quality management system controls where a failure of compliance would have a significant impact on the safety and performance of the device.

A nonconformity is defined as the nonfulfillment of a requirement. Therefore, if there is no requirement, there can't be a nonconformity. Prior to writing a nonconformity, the auditor must therefore be clear which requirement was unfulfilled.

Prior to issuing a nonconformity, an auditor should explain it to the auditee and confirm that it is understood and agreed or acknowledged.

Nonconformities identified during an MDSAP audit must be recorded on the Nonconformity Grading and Exchange (NGE) form (MDSAP AU F0019.2). See Guidance on the use of this form in the document MDSAP AU G0019.4.

The nonconformity information to record in the NGE form includes the following elements:

- Statement of nonconformity
- Supporting evidence
- Context and significance
- Unfulfilled requirement
- Grading

The following sections provides guidelines on how to write the nonconformity information and introduce a standardized nonconformity grading system for regulatory purposes.

5.1 Writing Nonconformities

5.1.1 Statement of nonconformity

The statement of nonconformity explains how a requirement is not being fulfilled, using or rephrasing at least some of the words of the requirement. It should not be written as or a

copy of a requirement. It preferably uses the past tense. It often starts with language like "the organization/process/procedure... did not..."

It is important that it is to the point, clear, unambiguous, concise, and accurate, so that it may assist the auditee to determine the cause. Avoid including positive language or mitigating circumstances; their place is in the Context and significance section of the form.

The statement of nonconformity must not be opinionated. Avoid terms like "not enough" or "not appropriate" which are often subjective.

Instead of...	Prefer...
"*The procedure was not detailed enough*".	"*The procedure did not address all applicable requirements*" [and specify which requirements were not addressed in the *Supporting evidence* section of the form].

The wording of the statement of nonconformity must be explicit and accurate. In particular:

Stating that *a requirement or a process is not*…	Means that…
Defined or documented	The requirement cannot be identified in documentation, or the definition of the requirement is inadequate or incomplete.
Implemented	The requirement or process is not implemented as documented
Effective	The outcome of a process does not meet some of the applicable requirements or does not achieve consistent results.

An auditor authoring a nonconformity needs to make clear whether the nonconformity only affects the definition/documentation, the implementation or effectiveness of a requirement or process, or a combination of those. The statement must combine these terms as applicable (e.g., "the calibration process of [a measuring equipment] was not fully defined nor effective"). In other words, if a nonconformity only states that "a requirement was not documented", it suggests that the requirement is effectively implemented in practice.

The coherence should be obvious between the statement of nonconformity, the selection of the unfulfilled requirement, and with the supporting evidence that demonstrates the nonconformity to be true.

5.1.2 Supporting evidence

The supporting evidence includes two types of information:

- The detailed factual example(s) observed during the audit that justifies or illustrates the NC and proves it to be true.
- The identification of the source of the information justifying the nonconformity. This should enable the auditee, or any independent reviewer, to find and verify that information. It could be, for example:
    - the reference of a document or record (including title and date or version, regardless of the medium),
    - a statement made by interviewed people (to identify by title/position),
    - contemporary notes or recording of direct observation by the auditor.

Multiple instances or examples of non-fulfillment of the same requirement, or non-fulfillment of requirements of the same sub-clause of ISO 13485, should generally be grouped within a single nonconformity record.

However, if the deficiencies refer to the same sub-clause of ISO 13485 but are unrelated, then separate nonconformity records are warranted.

Example of nonconformities against the same subclause but that would not be grouped in the same nonconformity record

The following two nonconformities refer to different aspects of ISO 13485:2016 subclause 4.2.5 – Control of records – and apply to different types of records that are to be implemented by totally distinct groups within the organization, and have most definitively different causes.

1. *Personally Identifiable Information (PII) on complainants was not effectively protected.*
2. *10-year-old electronic records generated by an equipment using a proprietary format are no longer readable by the organization's current IT systems.*

For that same reason, these two nonconformities, if identified during successive audits, would not be considered as Repeat Nonconformities (see 5.2.2)

5.1.3 Context and significance

This section should help answer the questions: *"So what? Why and how much does the nonconformity matter?".* This is particularly important for any nonconformity where the safety and performance of medical devices could be impacted.

Understanding the context and significance of the nonconformity may highlight audit trails an auditor should follow to make sure this initial symptom of nonconformity in not just the "tip of the iceberg".

Use the *Context and significance* section to:

- Justify the grading of the nonconformity.
- Include additional facts related to the nonconformity, that help understand its significance, especially if the nonconformity could impact the safety or performance of the device.
- Indicate any disagreement between auditees and the audit team on the nonconformity.

To address this, consider the following, if applicable or relevant:

- *Occurrence*:
  - Does the NC appear to be an isolated case, a repeating issue, or a systemic problem?
  - What sampling method (statistical vs. judgment based, sample size) was used?
- *Repeat nonconformity*:
  - Was a similar nonconformity identified in a previous audit? [if so, specify the reference of the previous nonconformity]
  - If so, did the organization fail to implement the planned corrective actions or was the corrective action not effective?
- *Affected medical devices*:
  - Does the nonconformity affect any medical device? [if so, specify the affected device type or device family].
  - Are there other controls in place as part of the organization's QMS that might mitigate the potential impact of the NC?
  - Are there any controls in place that would likely detect the nonconformity and prevent the release of nonconforming medical device?
  - Did the organization receive complaints or disseminated advisory notices that could be connected to the nonconformity?
  - Is there evidence – or is it likely – that nonconforming medical devices were released in the field?
- *Spread across the organization*:
  - Is the NC applicable to the facility, the larger organization, or a subset of the

facility's activities or devices?
- Are there other facilities or external organizations involved or affected by the nonconformity?

While an auditor may not have the opportunity to answer every questions above and follow every audit trail highlighted by the nonconformity, this section should concisely summarize what the audit team was able to determine, as well as any critical audit trail that could not be followed considering the constraints of the audit.

This information may also assist the manufacturer when further investigating the nonconformity to determine its full extent and causes.

5.1.3 Unfulfilled requirements

The nonconformity information must identify the sources of the requirement including:

- An ISO 13485 subclause [required]
- As applicable, any additional requirement, whether external or internal (e.g., article or clause from a country-specific regulation, international standard to which the organization claims to comply, procedure or specification, etc.)

Deviation from GHTF document N19: all nonconformities related to a country-specific requirement must also be associated with ISO 13485's best-fit clause. The term "applicable regulatory requirement" appears 33 times within sections 4 to 8 of the standards.

It is essential that the most specific requirements from ISO 13485, and from applicable regulations directly related to the finding, are correctly identified. The selection of a requirement must also accurately reflect whether the nonconformity had a direct impact on controls for the safety and performance of a medical device, or for a marketed medical devices to comply with regulatory requirements. (See 5.2.1 below).

Annex 1 provides guidance on the selection of an ISO 13485 clause for nonconformities against regulatory requirements.

5.2 Grading of Nonconformities

5.2.0 Relationship with the GHTF document N19 and with ISO/IEC 17021-1

This document presents the application of the grading method developed in the GHTF document N19 as the combination of 4 independent criteria, rather than in the original 2-step process. This has been reflected in the NGE form from its first version. This different presentation does not affect the resulting grade of the nonconformity.

The contribution made by each grading criterion to the final grade of a nonconformity is summarized in the following table.

Criteria	Contribution to the final grade
1) Impact of a QMS requirement on MD safety and performance (QMS Impact)	• Indirect: 1 • Direct: 3
2) Repeat nonconformity?	• No: 0 • Yes: 1
3) Combination of the absence of a documented process or procedure and failure to implement?	• No: 0 • Yes: 1
4) Release of nonconforming devices?	• No: 0 • Yes: 1

However, the final grade is limited to a maximum of 5.

The “major” and “minor” classification of nonconformities commonly used in medical device audit and certification schemes does not provide enough detail for global information exchange. However, these terms “major” and “minor” are defined in ISO 17021-1:2015 clauses 3.12 and 3.13 and are often utilized in medical device certification programs, including those for regulatory purposes other than MDSAP, to assign a priority to the implementation of corrective actions.

While the terms “major” and “minor” are not the subject of this document, general correlation between “major” and “minor” nonconformities as defined in ISO 17021-1:2015 and the grading system defined in this document is discussed in the following sub-sections.

5.2.1 Criterion 1 – Indirect or Direct QMS Impact

To stratify the grading system, the clauses of the standard are divided into two categories:

- **Indirect QMS Impact**: ISO 13485:2016 clauses 4.1 through 6.3 (except 4.2.3 – Medical device file) are seen as “enablers” (making it possible or feasible) for the QMS processes to operate.

  These clauses are therefore considered to have indirect influence on medical device safety and performance and are generally analogous to “minor” nonconformities as defined in ISO 17021-1:2015 clause 3.13.

Deviation from the GHTF document N19: A NC related to the medical device file (clause 4.2.3) is considered to have a Direct QMS impact.

- **Direct QMS impact**: ISO 13485:2016 clauses 6.4 through 8.5 (except 8.2.4 – Internal audits) are seen as having direct influence on design, and manufacturing controls.

  These clauses are therefore considered to have direct influence on medical device safety and performance and are more likely to be analogous to "major" nonconformities as defined in ISO 17021-1:2015 clause 3.12 when there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements.

  Deviation from the GHTF document N19: A NC related to 8.2.4 – Internal audits, is considered to have indirect QMS impact

There are two basic principles that the auditors should follow when writing the statement of nonconformity and assigning a clause number for purposes of utilizing this grading system.

1. When an audit observation or audit evidence indicates that an applicable requirement has not been fulfilled and that does, or has the potential to, affect safety or performance of a medical device, then the nonconformity must be written against the specific requirement in ISO 13485:2016 found in clauses 4.2.3 or 6.4 through 8.5 (except 8.2.4), because it has "*direct QMS impact*".

   [In general, nonconformities that have the potential to affect safety or performance are comparable to a "major" nonconformity per ISO 17021-1:2015 clause 3.12. These types of nonconformities would require the Auditing Organization to review, accept and verify the correction and corrective actions prior to granting a certification decision in accordance with ISO 17021-1:2015 clause 9.5.2(b).]

2. When an audit observation or audit evidence indicates that a internal requirement (not specifically required by ISO 13485 or any applicable medical device regulatory requirement) was not fulfilled without affecting the medical device safety and performance, then the nonconformity should be assigned to clauses 4.1 through 6.3 (except 4.2.3) because it has "*indirect QMS impact*".

Nonconformities can often be written up against more than one clause. Therefore, it is the auditor's obligation to determine the impact of the nonconformity on design, and manufacturing controls and assign the appropriate clause. The QMS impact of the nonconformity will determine whether the resulting clause will be Direct or Indirect. Some examples to help illustrate the grading process for direct versus indirect impact are provided below.

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Examples of nonconformities where safety issues raise the grading to Direct Impact:

A manufacturer distributes a product in Australia, Canada and the US. The manufacturer has a documented procedure for notification of adverse events that meets the criteria of Canada and the US, but has no references or requirements for adverse event reporting in Australia. The medical device caused an adverse event within Canada and the manufacturer followed their procedures related to adverse event reporting. The manufacturer reported the event to Health Canada and the US FDA, but did not consider reporting it to Australia. This nonconformity should therefore be assigned to clause 8.2.3 – Reporting to regulatory authorities and not to 4.2.1(e) – Quality Management System documentation.

Records were not available to provide evidence of conformity with the Australian Essential Principles of Safety and Performance. Audit trails identified that Essential Principles were neither documented as an applicable regulatory requirement as a design input nor as a prerequisite to the distribution in Australia, and that evidence of compliance to that Essential Principles was not available although the organization distributed the medical device in Australia. This nonconformity should be assigned against 7.2.1 if the manufacturer excluded design and development controls from the QMS, or against one of Clauses 7.3.3, 7.3.4 or 7.3.10 if design and development controls were required to be applied. It is not appropriate to make a finding against 4.2.1(e).

Example of nonconformity where safety is not an issue that is against a self-imposed requirement in a procedure leads to a starting grade with an Indirect Impact:

A manufacturer had a documented procedure for the annual verification of their measuring and monitoring equipment, regardless of whether the device was used in that timeframe. The annual verification of measuring equipment was not performed; however, the measuring equipment had not been used in over a year. In this example, ISO 13485:2016 clause 7.6 does not specifically require an annual verification and hence the period may appear arbitrary, and unnecessary, if the measuring equipment is not actively being used. This nonconformity should be assigned to clause 4.1.3 – General Requirements – for the manufacturer not following their own procedure and not against clause 7.6 – Control of monitoring and measuring equipment.

Example of nonconformity where safety is an issue, that is against a self-imposed requirement based on a standard, leads to a starting grade of a Direct Impact:

A manufacturer is utilizing standard ISO 11137-1 for validating their radiation sterilization process and the standard requires quarterly dose audits. This was not performed as required by the standard. In this example, the standard requires quarterly dose audits to assure product sterility, i.e., its safety. Therefore, this nonconformity should be assigned to clause 7.5.7 – Particular requirements for validation of processes for sterilization and sterile barrier systems.

5.2.2 Criterion 2: Repeat nonconformity

A new nonconformity is considered as a "Repeat Nonconformity" if a similar nonconformity against the same ISO 13485 sub-clause (X.X.X) has been identified during any audits within the previous 3 years. Such a nonconformity poses an increased risk because it is an indicator that a cause was not correctly identified for the first occurrence or that a corrective action has not been adequately taken or implemented.

Note: some ISO 13485 clauses (X.X) are not split in sub-clauses (e.g., 6.2. on Human resources). In that case, the grading criterion applies if a previous nonconformity was identified against the same clause.

"Any audits within the previous 3 years" was selected because:

1. in order to assess the risk of repeat occurrence accurately, it is important to assess comparable nonconformities.
2. historical data beyond any audits within the previous 3 years may not represent the current state; and
3. review of more audit reports may be counterproductive for an efficient grading system. However, it is important to ensure that the audits reviewed for the Occurrence assessment, have at a minimum evaluated the same sub-clause.

Occurrence in this document is directed at the frequency of a nonconformity cited from one audit to the next performed by the same auditing organization, or after a transfer, by the previous auditing organization. It is not the occurrences of instances or examples within a given sample size that the auditor may take to determine if a nonconformity exists during an audit.

Example of nonconformity to grade as a *Repeat Nonconformity*:

An initial nonconformity was found in 7.5.6 relating to a nonconformity in a coating process validation. A subsequent audit found a nonconformity in 7.5.6 in an injection molding process validation. Both nonconformities fall within 7.5.6 - Validation of Processes for

Product and Service Provision. Therefore, the subsequent occurrence should be categorized as a Repeat Occurrence.

If two nonconformities are issued against the same subclause of ISO 13485 but are unrelated in term of requirement within that subclause, likely have different causes, and apply to different groups within the organizations, the new nonconformity would be seen as a repeat nonconformity. See example in 5.1.2.

If the device organization is implementing accepted corrective actions to address a nonconformity from a past audit within the expected timeframes, auditors should avoid issuing a repeated nonconformity citation.

If an auditor can demonstrate that previously proposed actions are not effective, considering new occurrences of the nonconformities, then a nonconformity may be issued for an ineffective corrective action system.

Note: see also MDSAP AU P0019 on how to handle nonconformities previously recognized by the device organization and under process of remediation.

5.2.3 Criterion 3: Combination of the absence of a documented process or procedure and the failure to implement a requirement?

This is an adjustment from the original escalation rule from the GHTF document N19, which escalated the grade when a required procedure had not been documented, regardless of the outcome of the process. The absence of a documented process or procedure can fundamentally affect consistency and effective implementation of any process. However, the absence of a documented process or procedure can sometimes be compensated by the competence, skills and knowledge of the employees. So, while the fact that a required procedure remains a nonconformity, this escalation criterion should be limited to situations where a nonconformity arose due to a combined failure to document and implement a requirement.

Documenting a process or procedure aims at ensuring the consistent and effective implementation of the corresponding activities. However, failing to document a procedure or process does not systematically lead to noncompliant implementations of that activity, and conversely, documenting a procedure or process does not always ensures it will be implemented accordingly.

However, where an organization fails to 1) document a procedure or process that ISO 13485:2016 or an applicable regulatory requirement require to be documented and 2) fails to implement the corresponding activities in ways that comply with these same requirements, then the grading of the nonconformity shall be escalated.

This escalation rule also applies in cases where a process is generally documented, but fails to adequately address the requirements of a jurisdiction and, there is evidence that the implementation of the process failed to meet the requirements of that jurisdiction.

This escalation rule may be invoked in cases where the documented procedure entirely fails to address the topic, or only addresses an applicable regulatory requirement by referencing the regulation. However, it would not be invoked when a procedure addresses the topic but fails to comprehensively identify how the requirement is to be fulfilled.

5.2.2 Criterion 4: Release of a Nonconforming Medical Device?

A nonconformity which resulted in the release of a nonconforming medical device to the market is direct evidence of a QMS failure. This escalation criteria is grading the QMS nonconformity at a higher risk because nonconforming product is on the market and outside the control of the manufacturer's QMS.

This type of direct evidence of QMS failure by release of nonconforming products to the market is analogous to a "major" nonconformity per ISO 17021-1:2015 clause 3.12 and would require that the Auditing Organization review, accept and verify the correction and corrective actions prior to granting a certification decision in accordance with ISO 17021-1:2015 clause 9.5.2(b).

If a nonconforming medical device is released under concession with adequate technical and scientific justification, then the nonconformity has been resolved. It is no longer considered a nonconforming product and the escalation rule will not be applied.

Examples of nonconformity to illustrate a *Release of a Nonconforming Medical Device*:

An organization received a complaint suggesting that some adverse events occur at a higher rate than anticipated. The organization stopped shipping any considered medical device, investigated the causes of the problem, and decided to modify the design of the device to prevent the recurrence of these adverse events. However, they did not recover the devices that had already been distributed and did not initiate an advisory notice to inform the healthcare professionals and the patients treated with the device of the verifications or monitoring to detect early, and possibly prevent the adverse event.

An organization releases their medical devices based on an automated testing of the medical device intended for the diagnosis of a serious health condition. During the periodical calibration of the measuring equipment involved in the automatic testing, it appears that it was out of specification. The equipment was re-calibrated at that time. However, the manufacturer did not investigate whether the medical devices that were previously released by that equipment were affected by it being out of specification. The auditor finds information suggesting that using the affected diagnostic device could result in an increased rate of false negative results.

5.3 Applying the Nonconformity Grading System

While it is possible to have the sum of the steps in grading equal a "6" if the nonconformity is a direct QMS impact and all the escalation rules apply, the final grade for a nonconformity under this grading scheme will be a number between 1 and 5. A grade of "5" will be the highest grade.

The grade assigned to each nonconformity should not be changed as a result of any correction(s) or corrective action(s) taken by the manufacturer during or after the audit, however it may be amended as a result of the auditing organization's documented appeals process (ISO 17021-1:2015, clause 9.7).

After the auditing organization has completed the audit process, the final MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form should be provided to the manufacturer. The intent is that the grading and the NGE form be a method to accurately capture the assessment of the audit and to provide uniformity and consistency within the process of grading nonconformities.

5.4 MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form

The MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form is used for information exchange between auditing organizations and regulatory authorities, as well as between regulatory authorities.

Form MDSAP AU F0019.2 can strictly be used as a tool to exchange information with the Regulatory Authorities about the nonconformities issued and their status at the time of the submission. In that case the response of the Audited Facility's organization to the nonconformity is not recorded in the form. The Auditing Organization using this option needs to record the back and forth with the Audited Facility's organization using their own tools.

Otherwise, the form can also be used to also record the Audited Facility's response to the nonconformity.

Nonconformity Reports and NGE forms should be actively updated until the effectiveness of the corrections and corrective actions proposed by the audited facility or organization has been verified. The status of each nonconformity should be current at the time it is shared with the regulatory authorities and the rationale for that status should be recorded in the NGE form. It is not necessary for nonconformity reports to be closed at the time an AO shares the reports with the Regulatory Authorities.

Upon request from an MDSAP Regulatory Authority, the Auditing Organization is expected to provide updated nonconformity reports within 10 calendar days.

Form MDSAP AU F0019.2 purposely does not provide a cumulative grade for the overall audit. How the form is utilized is the decision of each regulatory authority for their appropriate assessment based for their own needs or requirements.

MDSAP AU G0019.4 - Guidelines NC Grading Exchange Form explains the features of Form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form and clarifies how the form is used.

5.5 Nonconformity Evaluation Rubric

An evaluation rubric is a methodology and tool to assess the adequacy of documented manufacturers' nonconformities detected by MDSAP Auditing Organizations. It was developed to help in the review of nonconformities documented by auditors, with the goal of assisting them to improve their adherence to the principles of the present document, and ultimately increase the ability of the audience of the nonconformity – i.e., the audited manufacturer, auditing organization's final reviewer and the regulatory authorities – to use it effectively.

The rubric considers the following 7 parameters:

1. Nonconformity and NGE identifying information - for unique referencing
2. Statement of Nonconformity - for an explanation of how a requirement was not fulfilled
3. Objective Evidence - for whether it is objective (able to be proven to be true) and relevant to support the finding
4. Context and Significance - for how the nonconformity relates to the quality of medical devices.
5. Selection of a Requirement - for the selection of an appropriate ISO 13485 requirement and, as applicable, additional applicable regulatory requirements, and

other external (e.g., standard) or internal requirements (e.g. manufacturer's own procedures).
6. Grading - for the justification of the correct application of escalation rules.
7. Coherence with the Audit Report - for consistency of information between the nonconformity information and the other information in the audit report.

Assessment against each criterion will conclude whether all, some, or few (or none) of the salient characteristics of a criterion are evident in the record and grade the recording of a nonconformity as "Complete" (alt. Fully Satisfactory or Effective …), "Less than Complete" (alt. Suboptimal but still usable, Less than Effective …), or "Not Acceptable" (alt. Poor, Absent, Unusable…)

A possible maximum score of 12 may be achieved for a complete record of a nonconformity and improvement should be encouraged when a lower score is obtained.

Each element of the record of a nonconformity is important, hence a record of a nonconformity is seen as "Not Acceptable" if any element is graded as "Not Acceptable".

The Nonconformity Assessment Rubric form (MDSAP AU F0037.1) facilitates the practical implementation of this methodology.

The Nonconformity Assessment Rubric form is available to auditing organizations and can voluntarily be used to train or provide feedback to auditors about how closely they adhere to the principles of the present document. It is also available to regulatory authorities for example to

- perform periodical check on the auditing organization's general performance
- provide ad-hoc feedback when the review of an audit report was made difficult due to some deficiencies of the documented nonconformities.

6. Forms

MDSAP AU F0019.2 – Nonconformity Grading and Exchange (NGE) form

MDSAP AU F0037.1 – Nonconformity Assessment Rubric form.

7. Reference Documents

GHTF/SG3/NI9:2012: Quality management system - Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

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MDSAP AU P0019 - Medical Device Regulatory Audit Reports Policy

MDSAP AU G0019.4 - Guidelines NC Grading Exchange Form

MDSAP AU P0027 - Post Audit Activities and Timeline Policy

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2021-09-01	Initial Release	Kimberly Lewandowski-Walker, US FDA
002	2024-02-21	Major revision of the document: - Expansion of sections 5.0 – *General* - and 5.1 – *Writing Nonconformities.* - Addition of section 5.5 and Annex 1 - Editorial changes across the entire document - Annex 2 - Annex 3 Update formatting for improved accessibility	Marc-Henri Winter

Version Approval: 002

Approved: Signature on File, CHAIR, MDSAP RAC

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Annex 1 – Guidance on the clauses to apply for regulatory requirements

The application of the term "regulatory requirements" is limited to requirements for the quality management system and other related requirements relevant to control the safety or performance of the medical device, such as medical device listing and facility registration, reporting of adverse events and advisory notices.

Regulatory requirements can specify processes or records to be documented through the organization's quality management system. For example, as part, or all, of the medical device file (see 4.2.3), activities such as the conduct of clinical evaluations (see 7.3.7) or review of post market experience (8.2.1).

The practice of recording a NC against 4.2.1(e) is rarely appropriate as the clause is mainly about ensuring that documents generated to meet specific regulatory requirements are subject to the requirements for the control of documents and records. Recording the absence of a regulatory document against 4.2.1(e) results in a low-grade NC that does not adequately reflect the impact of the finding.

The documents that need to be generated to meet specific regulatory requirements, those required by ISO 13485, those determined by an organization as necessary for the effective control of their activities, and the associated records, form the QMS documentation **and are subject to controls for documents and records, in 4.2.4 and 4.2.5**.[1]

Clause 4.2.4 relates to the **control of documentation** and is not to be used as a general requirement for the inclusion of regulatory requirements in procedures. Such requirements are specified in multiple locations elsewhere within the standard. (See Table below)

Clause 4.2.5 relates to the **control and maintenance (continuing availability) of records** and is not to be used as a general requirement to establish records. Such requirements are specified in multiple locations elsewhere within the standard. (See Table below)

Selecting a clause that requires a procedure or record to be established and implemented will result in an appropriate grade for the impact of the finding.

The following table identifies clauses that should be considered when a document or procedure has not been established or implemented. Clause 4.1.1 for documents, and Clause 4.1.3 for

[1] Adapted from *ISO 13485:2016 – Medical devices – A practical guide* published by ISO in 2017.

records, may be used for the absence of documentation for a regulatory requirement only if documents or records for the specific purpose are not required elsewhere in the Standard.

Table 1: Direct QMS Impact

A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Medical device file	4.2.3	to show that documents generated to demonstrate compliance with applicable regulatory requirements are included in the file. For example, statements regarding the incorporation of a medicinal substance or a material of animal origin that has been rendered non-viable within a device under the Australian conformity assessment procedures.
Identification of requirements	7.2.1	to show that relevant regulatory requirements related to a product for the relevant jurisdictions have been determined. [Defer to 7.3.3 b) unless Design Controls are a permitted exclusion] to show that marketing authorization requirements have been determined
Review of requirements	7.2.2	to show that a manufacturer has considered relevant regulatory requirements and can demonstrate that they will be able to meet those requirements to show that marketing authorization requirements can be met
Obtaining marketing authorization	7.2.2	To restrict the distribution into a country to medical device that have the necessary marketing authorization

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A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Communication	7.2.3	for communications with Auditing Organisations acting on behalf of regulatory authorities in relation to significant changes to quality management system process for communications with authorized representatives in foreign countries in relation to complaints, adverse events, and advisory notices or other marketing authorization requirements that are to be fulfilled by the representative in their jurisdiction.
Design and development validation	7.3.7	for the performance of Clinical (non-IVD?) or Performance Evaluations (IVD?) in accordance with regulatory requirements or guidelines.
D&D changes	7.3.9	for determining the significance of a change in relation to compliance with Essential Principles or Safety and Effectiveness Requirements
Purchasing	7.4.1	for the handling of non fulfilment by a supplier of purchasing requirements affecting the regulatory compliance of a device
Identification	7.5.8	for the compliance to national or regional Unique Device Identification requirements
Traceability	7.5.9.1	for the implementation of device tracking of specifically designated implantable devices (e.g., per US regulation 21 CFR 821)
Review of post-market experience	8.2.1	for the review of experience from postproduction activities within the feedback process
Complaint handling	8.2.2	for the handling of complaints in accordance with relevant regulatory requirements for all relevant jurisdictions.

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A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Reporting to Regulatory Authorities	8.2.3	for the notification of complaints that meet specified reporting criteria for adverse events or advisory notices for all relevant jurisdictions for records of reporting to all relevant jurisdictions in accordance with relevant criteria.
Non-conforming product	8.3.2	for verification that a device that has been accepted under concession will comply with Essential Principles or Safety and Effectiveness Requirements. for records of concession that show verification of relevant requirements for all relevant jurisdictions.
Advisory notices	8.3.3	for inclusion of jurisdiction specific arrangements / process for handling / notifying recalls or other advisory notifications. for records of action for all relevant jurisdictions
Rework	8.3.4	for a re-verification of compliance with Essential Principles or Safety and Effectiveness Requirements
Corrective actions	8.5.2	for a re-verification of compliance with Essential Principles or Safety and Effectiveness Requirements
Preventive actions	8.5.3	for a re-verification of compliance with Essential Principles or Safety and Effectiveness Requirements

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Table 2: Indirect QMS Impact

A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Roles	4.1.1	to show the roles undertaken by the organization for a relevant regulatory jurisdiction.
Requirement, procedure, activity, or arrangement required to be documented	4.1.1	to establish a document to demonstrate compliance with a regulatory requirement. (Only if documents or procedures for a specific purpose are not specifically required elsewhere in the Standard)
Regulatory Authority requirements for a QMS	4.1.1	to show requirements specified by a Regulatory Authority for a quality management system have not been documented or maintained. (Only if documents or procedures for a specific purpose are not specifically required elsewhere in the Standard) For example, requirements under the Australian Conformity Assessment Procedures for a quality management system.
Establishment of records	4.1.3	to establish a record to demonstrate compliance with a regulatory requirement. (Only if records for a specific purpose are not specifically required elsewhere in the Standard)
Management and changes to processes	4.1.4	to show that significant changes to processes that may affect the QMS have been notified to an Auditing Organisation or relevant Regulatory Authority

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A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Written agreements	4.1.5	to show that an adequate agreement is available between a manufacturer and an authorized representatives in a foreign country for outsourced activities that are, by regulation, to be fulfilled by the representative in their jurisdiction. For example, applications for marketing authorization, complying with conditions of a marketing authorization, adverse event reporting and advisory notice management (including recalls) by a representative within a foreign jurisdiction.
Retention of documents	4.2.4	to show that documents will be or have been retained by the manufacturer for a relevant period specified by a regulatory requirement.
Confidentiality	4.2.5	to show the arrangements for the protection of confidential health information in accordance with applicable regulatory requirements. (See also Clause 0.2 for the application of statutes, regulations, ordinances or directives)
Retention of records	4.2.5	to show that records will be or have been retained by the manufacturer for a relevant period specified by a regulatory requirement.
Management commitment	5.1	to show in policy or action that top management is committed to the development and implementation of the QMS and the maintenance of its effectiveness.
Customer focus	5.2	to show in policy and process that top management have ensured that applicable regulatory requirements are determined and met.

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A nonconformity about establishing a procedure or record for an applicable regulatory requirement related to …	**… should be raised against subclause…**	**For example, documented procedures or records not available …**
Management Review input	5.6.2	to show whether information related to reporting to regulatory authorities has been presented as an input to management review. to show whether applicable new or revised regulatory information is available and has been presented as an input to management review.
Management Review output	5.6.3	to show decisions and actions related to changes needed to meet new or revised regulatory requirements.
Resources	6 .1	to show that the manufacturer can meet obligations for timely reporting, record keeping to regulatory authorities and to establish and maintain access to regulatory authority interfaces, databases, and communication channels.
Internal audit	8.2.4	to show that the relevant regulatory requirements of relevant jurisdictions have been included within the criteria and scope of internal audits. to show that the QMS is in conformance with relevant regulatory requirements for all relevant jurisdictions.

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Annex 2 – Differences between GHTF document N19 and MDSAP AU P0037

Subject	GHTF/SG3/N19:2012	MDSAP AU P0037
ISO 13485 version	References ISO 13485:2003	References ISO 13485:2016
Application of grading criteria	A 2-step grading matrix with escalation rules	4 independent criteria. However, no impact on final grade
Unfulfilled country-specific requirements	Nonconformities that are within the manufacturer's QMS but are outside the specific requirements within the clauses of ISO 13485… should reference the specific section of the applicable Regulation or Legislation against which the nonconformity is cited.	…all nonconformities related to a country-specific requirement must also be associated with ISO 13485's best-fit clause
Direct or indirect QMS impact	**Indirect** - ISO 13485 clauses 4.1 to 6.3 **Direct** – ISO 13485 clauses 6.4 to 9.5	**Indirect** - ISO 13485 clauses 4.1 to 6.3 except for 4.2.3 Medical device file **Direct** – ISO 13485 clauses 6.4 to 9.5 except for 8.2.4 Internal Audits
Repeat nonconformity	The auditor should check the previous two audit reports which evaluated the same sub-clause to see if a nonconformity that is identified in the current audit was previously raised.	A new nonconformity is considered as a "Repeat Nonconformity" if a similar nonconformity against the same ISO 13485 sub-clause (X.X.X) has been identified during any audits within the previous 3 years.

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Subject	GHTF/SG3/N19:2012	MDSAP AU P0037
Absence of a documented process or procedure	Absence of a documented process or procedure of any requirement…	…the absence of a documented process or procedure can sometimes be compensated by the competence, skills and knowledge of the employees. So, while the fact that a required procedure remains a nonconformity, this escalation criterion should be limited to situations where a nonconformity arose due to a combined failure to document and implement a requirement.
Writing of nonconformities		*Additional requirements to improve how nonconformities are documented, including information on the context and significance of the nonconformity.*

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Annex 3 – Nonconformity Writing Job Aid

Statement of Nonconformity

Does the nonconformity involve an unfulfilled ISO 13485 or country-specific requirement?

- Rephrase or reword the requirement negatively to describe what was not fulfilled.
- Was there a combined failure to document a process and implement a requirement?
- Use terms such as “not defined,” “not documented,” “not implemented,” and/or “not effective.”
- Avoid subjective terms such as “not enough” or “not appropriate.”
- Avoid unnecessary details, fluffy or flowery language

Supporting Evidence

Did you include an example of evidence to support your nonconformity?

- Provide examples or, in the case of a missing procedure or record, include the individual’s title who claimed it did not exist.
- Does it support the failure/nonconformance you are citing?
- Objective evidence should include the relationship of nonconformances to a given population. For example, “Five out of 50 records from the last 2 years examined were…”
- For complaints, include the number of complaints reviewed. For example, “10 out of 30 complaints for broken tubing were reviewed. All of the 10 showed…” or “5 of the 10 complaints reviewed for broken tubing showed…”

Do you need to reference the procedure?

- Reference the SOP when available. The SOP should be referenced when the facility is not following it’s own procedure.
- Include the title/document number/revision/date of the SOP referenced, as applicable.
- Does the SOP require what you are describing?
- Does the revision of the SOP cover the timeframe of the nonconformance?

Is the nonconformance repeated in other nonconformities?

- Combine objective evidence where appropriate.

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Context and Significance

Is it an ongoing or systemic problem, or an isolated incident?

- Clarify if the nonconformity affects devices released for distribution or have already been distributed.
- Include frequency with a date range (When did the nonconformance occur?).
- If the nonconformity is related to complaints, include how many products were distributed during the timeframe.
- Check the verb tense (e.g., The facility continues to distribute devices).

Is it a repeat finding from a previous audit?

- Did the organization fail to implement the planned corrective actions or was the corrective action not effective?

What device is affected?

- Does the nonconformity address one device, a family of devices or all devices manufactured at the facility?
- Include the device name/family, where possible.
- Where applicable, include the number of devices affected (e.g., 50 units that did not meet acceptance criteria)
- What is intended use of the device? Consider using a brief description, for example, “a sterile device used during orthopedic surgeries”.
- Are you able to link the NC to any specific complaints/adverse events?

Is the nonconformity process-related?

- Describe the devices/units that were impacted. (e.g., Sterilization cycle failure affected xx lots of device A and xx lots of device B).

Remember OCCURS…

- Objective and factual, Clear and concise, Coherent, Understood, Relevant, Significant
- Would a layperson reviewing the nonconformity understand the problem?
- Is it written in plain language?