	Guidance Document Title: Guidelines on the Nonconformity Grading and Exchange Form	Document No.: MDSAP AU G0019.4.004
		Version Date: 2021-02-08

Purpose

This document explains the features of the dynamic PDF Form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form, and clarifies how to use it.

Preamble

The dynamic PDF form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form – must be filled out and provided to the Regulatory Authorities as part of every audit report package (One record per audit report), unless no nonconformity was raised.

The form should also be used to provide the Regulatory Authorities with an early warning (5-Day Notice), as described in document MDSAP AU P0027 – Post Audit Activities and Timeline Policy.


A 30 minute recorded training on how to use the Nonconformity Grading and Exchange (NGE) Form is available on the MDSAP Articulate-Online site (<http://mdsap.articulate-online.com>), under the name: Revised Nonconformity Grading and Exchange Form June 2017 (Optional recommended).

Compatibility

The form was developed using Adobe LiveCycle Designer ES2. The form must only be opened with Adobe Acrobat or Adobe Reader, version IX or higher. Adobe Reader can be obtained for free [here](#). While some compatibility tests were successfully performed, some functions/features in the form may not be fully compatible with all systems. Please report any difficulty using this form by email to MDSAP@fda.hhs.gov.

Form Protection

The form is password protected to prevent any modification in LiveCycle. However, no password is necessary to use the form in Adobe Acrobat or Adobe Reader. The technology does not ensure the protection of the recorded data. To keep the form as an unalterable record, an option is to print the document. The protection of the form does not enable to directly print into pdf. See additional details in Appendix 2 on preventing the tempering of nonconformity information.

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Characters not to be used in the form

The curly brackets { and } prevent the import of nonconformity information from one form to another. They must therefore not be used.

Merger of Nonconformity information from multiple NGE Forms into One

An important feature of the form is the ability for two auditors to work in parallel on two separate forms and then merge the nonconformities listed on these forms into a single NGE report to be issued to the Audited Facility and shared with the Regulatory Authorities.

→ See Additional details in Appendix 1 on how to merge nonconformity information into one reports.

Reporting Bugs

As any piece of software, the form may include bugs. Please report any bugs to the FDA's general MDSAP email address: mdsap@fda.hhs.gov

Content of the Form


The form is organized in three sections plus a header

- The header includes read-only traceability information (Audited Facility, Report References and last NC Status Update) and navigation/function buttons
- Section 1 – Audit Information: general identification information on audited facility, auditing organization, etc.
- Section 2 – Nonconformity Summary: synthetic view of the nonconformity information.
- Section 3 – Nonconformity Details: includes a subsection for each nonconformity regarding their nature, the unmet requirements, their grading, and their status.

Header - Navigation and Function Buttons

	Nonconformity Grading and Exchange Form	Organization Name 1900-01-01-NGE-BSIA-223334444 / Any_AO-specific_ID
		Date of last NC status update
Summary 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 Email NC Import NC Save		

The “Summary” button and the buttons numbered 1 to 30 help navigating the form:

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- Clicking the “Summary” button brings back to the top of Section 1 on the from page of the form;
- Clicking a numbered n button brings to the top of the page relative to the n th nonconformity subsection.

Note 1: a numbered button becomes active when the form includes at least as many nonconformity subsections.

Note 2: there is no limitation in the number of nonconformities that can be recorded in an NGE form. Use the scrolling bar to reach nonconformities after the 30th.

The “Save” button operates as a “Save As” function. It saves the PDF document (form + content)

The “Email NC” opens a draft email with an XML data file attached containing only the information contained in the form. This button is useful for the process of merging nonconformity information from one NGE form to another or to the audit report.

The “Import NC” button adds nonconformity information from an XML data file into the current form. This button is useful for the merger of audit nonconformities from multiple auditors into a single report.

Section 1 – Audit Information

1. Audit Information

Audited Facility

Audited Facility's MDSAP identifier (REPs-generated)

Auditing Organization

Audit start date Audit end date Date of issue of nonconformity


AO NGE report reference

AO Audit report reference

MDSAP Audit report reference null-AUR-null-null

Version of the ISO 13485 standard used during the audit ISO 13485:2016 (MDSAP Audit Model 2nd edition)

This section is to record audit information as illustrated in the picture above.

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The reference of the NGE report and the audit report according to the MDSAP record naming convention is auto-generated by the form. The reference of the NGE report is displayed in the header.

Important: the auditor must select the version of the ISO 13485 standard before entering the nonconformity information to be able to select the clause of the standard against which the nonconformity is raised.

Important: upon import of the nonconformity information into the audit report form, the following fields are verified for consistency between the NGE report and the audit report:

- Audited Facility
- Audited Facility’s MDSAP identifier (REPs-generated)
- Auditing Organization
- Audit start date
- Audit end date
- AO audit report reference
- Version of the ISO 13485 standard used during the audit

Section 2 – Nonconformity Summary

2. Nonconformity Summary


	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Number of NC	0	0	0	0	0	0

NC Ref.	Statement on Nonconformity	ISO 13485 Clause	MDSAP Grade	Status*

*Current as of:

This section auto-populates two tables summarizing the nonconformity information:

- The top table counts the number of nonconformities of each grade and calculates the total number of nonconformities.
- The second table displays selected information relative to each individual nonconformity (reference, statement of nonconformity, supporting evidence,

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relevant clause of ISO 13485, grade of the nonconformity (according to both the MDSAP and ISO/IEC 17021-1 grading criteria), and status).

The status of the nonconformities documented in the NGE report must be current at the time the form is submitted to the Regulatory Authorities.

Reminder: The NGE report may be submitted multiple times, including:

- As part of a 5-day notice;
- As part of submission of the full audit report package;
- As requested by a Regulatory Authority (for example, if needed by ANVISA to issue a GMP certificate);
- As part of the submission package relative to the next audit.

Important: The date of the last NC status update is the only field in this section that is not auto-populated in the strict NGE configuration. The Auditing Organization’s processes must ensure that this field is correct each time the form is submitted to the Regulatory Authorities.

A warning appears in orange, to remind the Auditing Organization of the potential need to communicate with the Regulatory Authorities through a 5-day notice in case there is:

- One or more NC graded as “5”; or
- More than two NC graded as “4”.

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Number of NC	0	0	0	3	1	4
The auditing organization must determine if the audit is subject to a 5-day notice (considering the relevance of the nonconformities under the MDSAP).						

Note: Reaching such a level does not automatically trigger a 5-day notice, for example if a one of the nonconformity is irrelevant to MDSAP. However, the Auditing Organization should be mindful that in a case where the supporting evidence of a nonconformity points to a certification scheme other than MDSAP, it could potentially still relate to the program. For example, if the auditor identifies a nonconformity against the European Medical Device Directive’s Essential Requirements of the medical device directive, there are chances that the nonconformity also relates to the Australian Regulation’s Essential Principles.



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Section 3 – Nonconformity Details

For each nonconformity, the auditor fills in the following subsections:

Subsection 3.1 – Individual Nonconformity Information

Individual Nonconformity Information

Nonconformity number or reference

Statement of nonconformity

Supporting evidence

The Regulatory Authorities do not require specific format for the number or reference of the nonconformity. It must at least be unique to the NGE report.


Note: without a nonconformity number or reference of the nonconformity, the form will not display the status of the nonconformity in section 2.

Subsection 3.2 – Unsatisfied Requirements

Unsatisfied requirements	Hide/Show Audit Task and Linkages
Audit task: process <input type="text"/>	<input type="button" value="Task number"/> <input type="text"/>
ISO 13485 Clause <input type="text"/>	<input type="button" value="Clauses linked to task"/>
Regul. clause: AUS <input type="text"/>	<input type="button" value="Clauses linked to task"/>
Regul. clause: BRA <input type="text"/>	<input type="button" value="Clauses linked to task"/>

This subsection serves to identify the clauses of the ISO 13485 standard and of the applicable regulations and other audit criteria.

The greyed fields are read-only, and for information only. They are auto-populated after the auditor specifies the task of the Audit Approach (process and task number). They show the requirements associated with each task (per document MDSAP AU P0002). However, the auditor may select any requirement that could better relate to the nonconformity.

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The button labeled “Hide/Show Audit Task and Linkages” enables to hide these fields in order to streamline the form.

Selecting the applicable clause of ISO 13485 from the dropdown menu is required to determine the grade of the nonconformity.

Reminder: the dropdown menu is not populated until the version of the standard is selected (see Section 1).

When a regulation includes a requirement to which the nonconformity also relates, the auditor should select that requirement. Otherwise, the auditor should select “NA”.

When a clause of ISO 13485 or a regulation is selected, the text of the clause is displayed in the field underneath. It is editable so that the auditor can remove the parts of the clause that are irrelevant to the nonconformity. To reverse the change, re-selecting the clause from the dropdown menu provides the full text of the clause again.

Subsection 3.3 – Auditee’s Response to the Nonconformity – Optional

The form can be used in two ways, at the discretion of the Auditing Organization.

1. The form 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 such 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.
2. Otherwise, the form can also be used to also record the Audited Facility’s response to the nonconformity.

In this configuration (default configuration), the fields highlighted in green in each nonconformity subsection are filled in by the Audited Facility’s organization.



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Auditee's response to the nonconformity
I. Remediation plan
Due date for providing the remediation plan
<i>Outcome of the investigation of the nonconformity, including its cause analysis</i>
<i>Proposed correction, to fix the observed nonconformity</i>
<i>Proposed corrective action, to address the cause of the nonconformity and prevent recurrence</i>
II. Evidence of implementation
Due date for providing the evidence of implementation of the proposed actions
<i>Evidence of implementation of the proposed correction</i>
<i>Evidence of implementation of the proposed corrective action</i>


A button in Section 1 toggles the form from one configuration to the other. The button's label indicates the configuration in which the form will be if clicked.

Form optional functionality: inclusion of the audited facility's response to nonconformities Enabled Disabled

Each Auditing Organization must decide whether they use the form strictly as a tool to exchange information with the Regulatory Authorities, or also to record the Audited Facility's response to the nonconformity.

Note: Regardless of how the Auditing Organization records the response of the medical device organization, the procedure MDSAP AU P0027 *Post Audit Activities and Timeline* specifies that the Audit Report Package to be submitted to the Regulatory Authorities includes the remediation plan developed by the medical device organization.

- ➔ See additional details in Appendix 2 relative to the use of the form for both follow-up tracking and submission, and the protection of data.

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Subsection 3.3 – Nonconformity Grading

Nonconformity grading					
QMS Impact	Repeat NC ?	Required Procedure Lacking ?	Nonconforming Products Released ?	MDSAP Grade	ISO 17021 Grade
<input type="radio"/> Indirect <input type="radio"/> Direct	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes		
<input type="checkbox"/> The organization detected and properly addressed the nonconformity prior to the audit					

This subsection relates to the grading of the nonconformity.

The auditor must determine the MDSAP grade using the criteria from GHTF/SG3 document N19.

Four independent parameters must be specified:

- Whether the clause of ISO 13485 against which the nonconformity is raised is considered having “direct QMS impact” – this parameter is automatically determined by the form, based on the clause of the standard identified in the previous sub-section of the form;
- Whether it is a “repeat nonconformity”;
- Whether the nonconformity relates to the absence of a required procedure;
- Whether nonconforming medical devices were released to the field.


The MDSAP grade is automatically calculated by the form based on the status of these four parameters.

Additionally, the Auditing Organization may be required to grade the nonconformity as major or minor per ISO/IEC 17021-1 to satisfy the needs of certification schemes other than MDSAP. In such case, this grade can be recorded in the form as well.

Note: Both grading systems use different criteria and the determined grades per the GHTF and ISO/IEC 17021-1 can appear inconsistent. The grade per ISO/IEC 17021-1 is not used by Regulatory Authorities participating in MDSAP.

Per MDSAP policies, auditors are required in some instances to record nonconformities that they have identified during the audit but for which the audited facility can demonstrate that they had already identified and recorded that nonconformity in their QMS and that they appropriately acted to resolve and prevent the recurrence of that nonconformity (See MDSAP AU P0019).

In this situation, the auditor needs to fully document the grade of the NC, tick the box below the grading matrix and document the reference of the Audited Facility’s recorded evidence of their appropriate actions, to show that this NC is recorded to be monitored

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as part of future audits or surveillance activities. The status applied to this NC says “Monitoring”. The grade of such a nonconformity is displayed between parentheses and although the NC appears in the list in section 2 of the form, it is not counted in the first summary table of section 2.

Subsection 3.4 Nonconformity Status

Nonconformity status

The organization responded to the nonconformity Yes No

The nonconformity was superseded

The nonconformity was cancelled

Status

Comments

Add an NC
Remove this NC

When the form is strictly used for Nonconformity Grading and Exchange purposes, the next section in the form corresponds to the status of the nonconformity.

The status is automatically determined by the form, based a series of statements considering:

- The response of the audited facility’s organization to the nonconformity;
- Whether the nonconformity was superseded and therefore replaced by another nonconformity, for example in the case of a repeat nonconformity;
- Whether the nonconformity was cancelled, for example if the Auditing Organization finds that this is not a supportable nonconformity, or if the audited facility justifies, through the Auditing Organization’s dispute or appeal process, that the nonconformity was not valid (e.g. if there is no applicable requirement supporting the nonconformity, or if the audited facility had evidence of compliance that the auditor did not see, ask for or had disregarded).

The table below summarizes the status of a nonconformity based on whether each statement is true (yes), false (No), not applicable (NA) or “pending effectiveness check”.



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Q#	Question	Status if Yes	Status if No	Status if NA	Status if Pending Effectiveness Check
1	The organization responded to the nonconformity	see Q2	Not Responded		
2	The outcome of the investigation of the NC and the analysis of its cause are adequate	see Q3 and Q4	Inadequate investigation		
3	The organization's response specifies adequate correction to fix the observed NC	see Q3.1	Inadequate proposed actions	see Q4	
3.1	The organization provided evidence of full implementation of the correction	see Q3.2	see Q3.3		
3.2	The correction appears to be effective	Verified	Ineffective		Pending effectiveness check
3.3	The timeline to implement the correction was respected	Pending implementation	Late implementation		
4	The organization's response specifies adequate corrective action to prevent the reoccurrence of the observed NC	see Q4.1	Inadequate proposed actions	see Q3	
4.1	The organization provided evidence of full implementation of the corrective action	see Q4.2	see Q4.3		
4.2	The corrective action appears to be effective	Verified	Ineffective		Pending effectiveness check
4.3	The timeline to implement the corrective action was respected	Pending implementation	Late implementation		

Statements Q3 and Q4 are “NA” if the correction of the identified nonconformity or a corrective action are not necessary, respectively. Q3 and Q4 should not be considered “NA” unless the nonconformity is cancelled.

The comments field is a free text field for the auditors to further explain the status of the NC. Additional recommendation will be provided through guidance documents. Finally, the form includes buttons to add another NC or to remove the individual NC being reviewed.

Note: once an NC is recorded in the NGE form and issued to the Audited Facility’s organization, it should not be removed afterwards, even after the effectiveness of the correction and corrective action is fully verified, the NC is cancelled or superseded.

Reference Documents

MDSAP AU P0027 – Post Audit Activities and Timeline Policy

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Document History

Version No	Version Date	Description of Changes	Author/Project Manager
001	2013-08-09	Initial Release	Marc-Henri Winter, FDA
002	2015-10-09	Added paragraph on nonconformity previously recognized by the manufacturer Updated the paragraph on merging nonconformity information from multiple files, to reflect the changes of the form	Marc-Henri Winter, FDA
003	2018-04-02	Complete revision due to the change of the NGE form from an Excel file to a dynamic PDF form.	Marc-Henri Winter, FDA
004	2021-02-08	Reformatted document to MDSAP QMS template Added "Reference Documents" heading Deleted DUNS in section 1 Replaced Audit Model with Audit Approach in section 3	Kimberly Lewandowski-Walker FDA/Hiromi Kumada, PMDA