Guidance Document Title: Guidelines on the Nonconformity Grading and Exchange Form **Document No.:** MDSAP AU G0019.4.005
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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

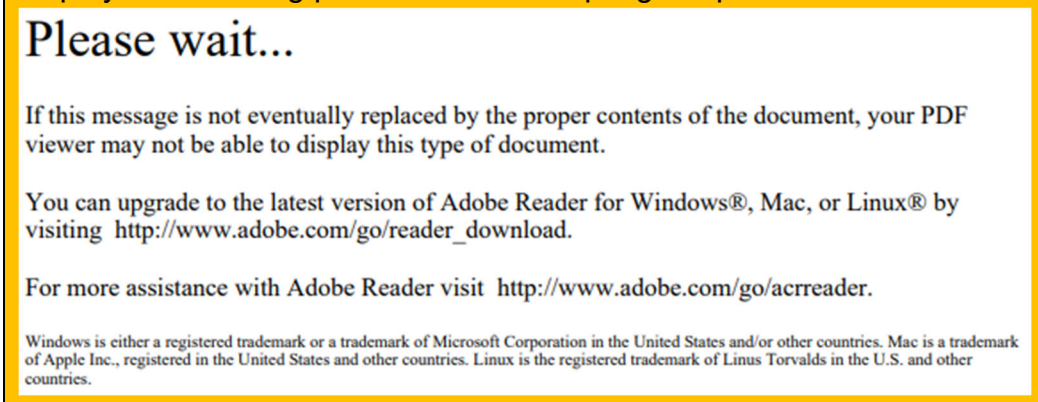
The dynamic PDF form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form – must be filled out and provided to the Regulatory Authorities as part of every audit report package (One record per audit report), unless no nonconformity was raised.

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

The requirements on how to document and grade nonconformities are specified in the document MSDAP AU P0037, based on the GHTF document N19

Compatibility

The form was developed using Adobe Experience Manager (AEM) Form Designer (formerly LiveCycle). This technology is incompatible with web browsers which often display the following picture when attempting to open the form.



Even if a browser is able to show the form correctly, the form won't function as expected.

The form must therefore be downloaded locally and must only be opened with Adobe Acrobat or Adobe Reader, version IX or higher. Adobe Reader can be obtained for free here. Other PDF processors can corrupt the form.

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 AEM or 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. See additional details in Appendix 2 on preventing the tempering of nonconformity information.

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.

Characters not to be used in the form
The curly brackets { and } prevent the merger of nonconformity information from one form to another. Therefore, they must not be used.

Reporting bugs
As for 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

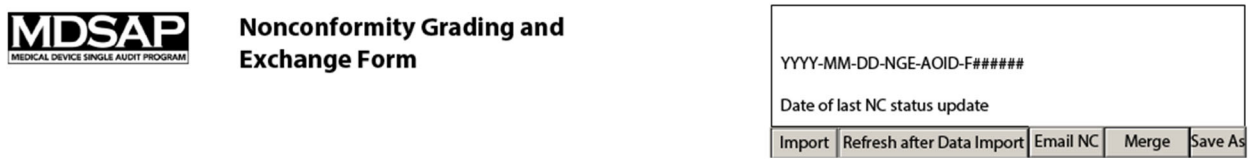
Content of the Form

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: synthesized view of the nonconformity information. This section includes additional navigation/function buttons
- 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

The header for the first 2 sections of the form differs from the header for section 3 regarding the navigation/function buttons they include.



The header for section 1 and 2 only includes function buttons.

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 “Merge” 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.

See detain on how to merge audit nonconformities from multiple auditors into a single report in the corresponding chapter below.

The “Refresh after data import” button is a new button in version 12 of the form. To optimize the form’s performance, some scripts were modified to run only on clear triggers (e.g. click, exit, change…). However, when data are imported into the form, those scripts are not executed automatically. Consequently the form does not display the data correctly until this button is used to trigger the scripts.

The header for section 3 includes the same “Save As”, “Email NC” and “Merge” function buttons, as well as navigation buttons.

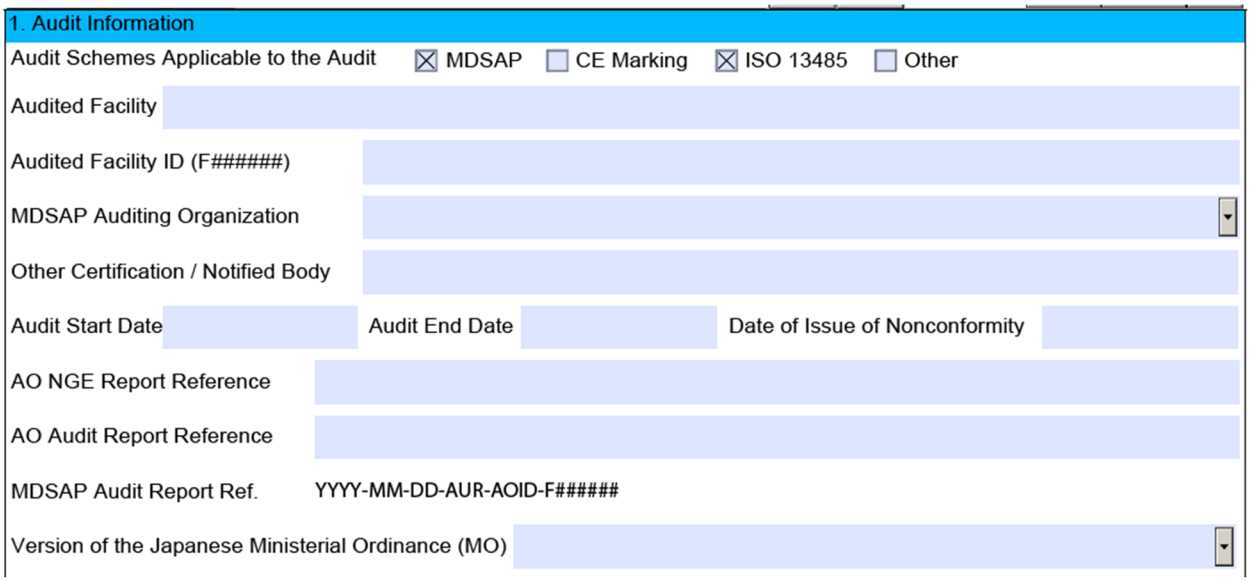
- The "Summary" button brings back to the top of Section 1 on the front page of the form;
- Any numbered *n* button brings to the top of the page relative to the *n*th nonconformity subsection.
  Note 1: the form can show up to 30 buttons but there is no limitation in the number of nonconformities that can be recorded in an NGE form. Use the scrolling bar to reach nonconformities after the 30th.

Additional navigation and function buttons were added for each nonconformity in section 2. Nonconformity Summary.

NC Ref.	Statement on Nonconformity	ISO 13485 Clause	Scheme & Grade	Status*
▲ - 1 + ▼ ABC1-2022	this states what the nonconformity was the nonconformity this explains what was observed that justifies the truthfulness of the nonconformity this provides context to the nonconformity to further explain its implication, its magnitude, its meaning to the ability of the organization to control the quality of their medical devices		☒ MDSAP ☒ CE Mark ☒ Other	Not responded

Button	Description
1	A numbered *n* buttons (e.g. [1]) brings to the top of the page relative to the *n*th nonconformity subsection.
▲ ▼	The up and down arrow buttons move the considered nonconformity up or down in the list, allowing to re-order the nonconformities in the form (in both the summary table and in section 3. *Nonconformity Details*).
-	The minus sign [-] button removes the nonconformity (in both the summary table and in section 3. *Nonconformity Details*).
+	The plus sign [+] button adds a new noncoformity right after the displayed nonconformity; In the example above, it would create a new second row to the table, and move all other nonconformities down in the list.

Section 1 – Audit Information



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

The checkboxes are to specify which audit / certification schemes were applicable to the audit. These checkboxes control the visibility and value of some fields. The table below lists some scheme-specific fields whose visibility and value are affected by these checkboxes.

Scheme	Scheme-specific fields
MDSAP	- Audited Facility's MDSAP Identifier (REPs-generated) - MDSAP Auditing Organization - MDSAP Audit Report Ref. - MDSAP NGE Form reference (in the header) - Version of the Japanese Ministerial Ordinance (MO) For each nonconformity: - Check box to specify if the NC is relevant under MDSAP - Fields relative to the Australian, Brazilian, Canadian, Japanese and US regulations

	As well as the MDSAP logo and a warning when the form is not used for an MDSAP audit.
CE Marking	- Other Certification / Notified Body – a field to use For each nonconformity: - Check box to specify if the NC is relevant to CE Marking - Fields relative to the European requirements
ISO 13485	- Other Certification / Notified Body For each nonconformity: - Check box to specify if the NC is relevant to ISO 13485
Other	- Other Certification / Notified Body - For each nonconformity: check box to specify if the NC is relevant to the schemes other than MDSAP or CE Marking.

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: If the Japanese requirements are applicable to an audit, the auditor must select the version of the Japanese Ministerial Ordinance (MO) to be able to select a clause of the MO against which the nonconformity is raised.

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**
Relevant to MDSAP	**0**	**0**	**0**	**0**	**0**	**0**

NC Ref.	Statement on Nonconformity	ISO 13485 Clause	Scheme & Grade	Status*
ABC1-2022	this states what the nonconformity was the nonconformity this explains what was observed that justifies the truthfulness of the nonconformity this provides context to the nonconformity to further explain its implication, its magnitude, its meaning to the ability of the organization to control the quality of their medical devices		☒ MDSAP ☒ CE Mark ☒ Other	Not responded

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. In cases where multiple audit / certification schemes apply, including MDSAP, the table shows 2 rows: one row only counts those nonconformities that are marked as applicable to MDSAP.

A warning appears in orange, to remind the Auditing Organization of the potential need to communicate with the MDSAP Regulatory Authorities through a 5-day notice in case the list of nonconformities relevant to MDSAP include:

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

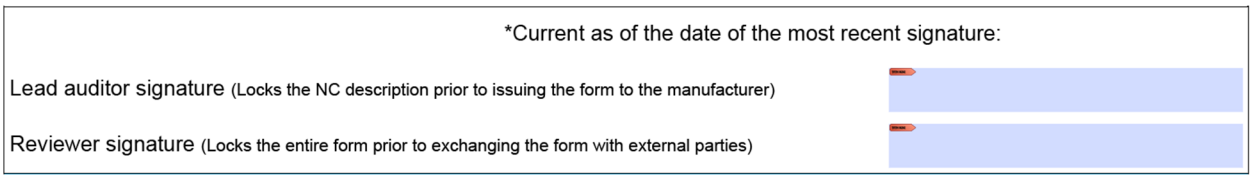
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Number of NC	**0**	**0**	**0**	**3**	**1**	**4**

The auditing organization must determine if the audit is subject to a 5-day notice (considering the relevance of the nonconformities under the MDSAP).

The second table displays selected information relative to each individual nonconformity:

- reference,

- statement of nonconformity, supporting evidence and context,
- relevant clause of ISO 13485,
- audit / certification scheme to which the nonconformity is relevant and grade of the nonconformity (according to both the MDSAP and ISO/IEC 17021-1 grading criteria),
- status of the nonconformity.



Section 2 also includes 2 signature fields:

- The first signature locks the fields relative to the description of the nonconformity (i.e. from the nonconformity reference field to the grading fields) and is to be applied by the lead auditor (or someone acting on their behalf) before issuing the document to the audited facility;
- The second signature locks the entire form and is to be applied prior to submitting the document in REPs.

Both signatures update the date field above and that date is also reflected in the header.

Alternatively, if the nonconformities and the response of the audited facility are initially recorded on the AO's nonconformity forms, and the NGE is completed and provided to the audited facility only after the auditors reviewed their response to the nonconformity, it is acceptable to sign only the Reviewer signature field.

Also, the NGE form must only be provided to external parties after the second signature is applied. (for example, regulatory authorities, or another auditing organization in the context of a transfer of certification). In the context of a transfer of certification, the receiving AO should always request the most current version of the NGE from the original AO (per IMDRF document N3 – 8.7.1).

Note: the person who signed the document can clear the signature field by right-clicking the signature and select "Clear Signature". None else can. If a signature needs to be removed but that person is no longer available, an unsigned version of the record can

be generated with Adobe Acrobat (not with Adobe Reader). See corresponding instruction below.

A hidden field in the form logs the activity of the signature fields (i.e. signature added or cleared), as well as any detection of mismatch between recorded signature information and the actual signature field status. Such a mismatch occurs when nonconformity information is imported into a new form. The content of that field becomes visible when the Reviewer signature is applied.

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.

Section 3 – Nonconformity Details

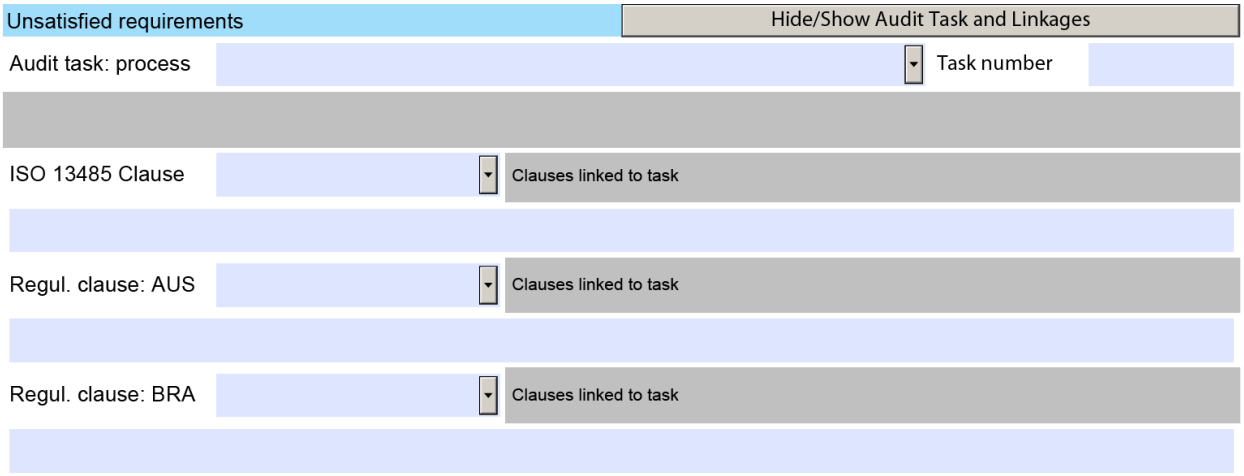
For each nonconformity, the auditor fills in the following subsections:

Subsection 3.1 – Individual Nonconformity Information

Individual Nonconformity Information	
Nonconformity number or reference	
Statement of nonconformity	
Supporting evidence	
Context and significance	
The nonconformity is relevant under the following schemes	☒ MDSAP ☒ CE Marking ☒ Other

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



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

It is optional to specify the audit task associated with the nonconformity as it is a tool to facilitate the identification of linked requirements in the MDSAP Audit Approach (MDSAP AU P0002). 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.
However, the auditor should select the requirement that best corresponds to the nonconformity, even if not listed in the greyed fields.

The button labeled “Hide/Show Audit Task and Linkages” provides a way to show or hide these fields, that are hidden by default. By default, the audit task’s fields and the greyed fieldsd are hidden to streamline the form.

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

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

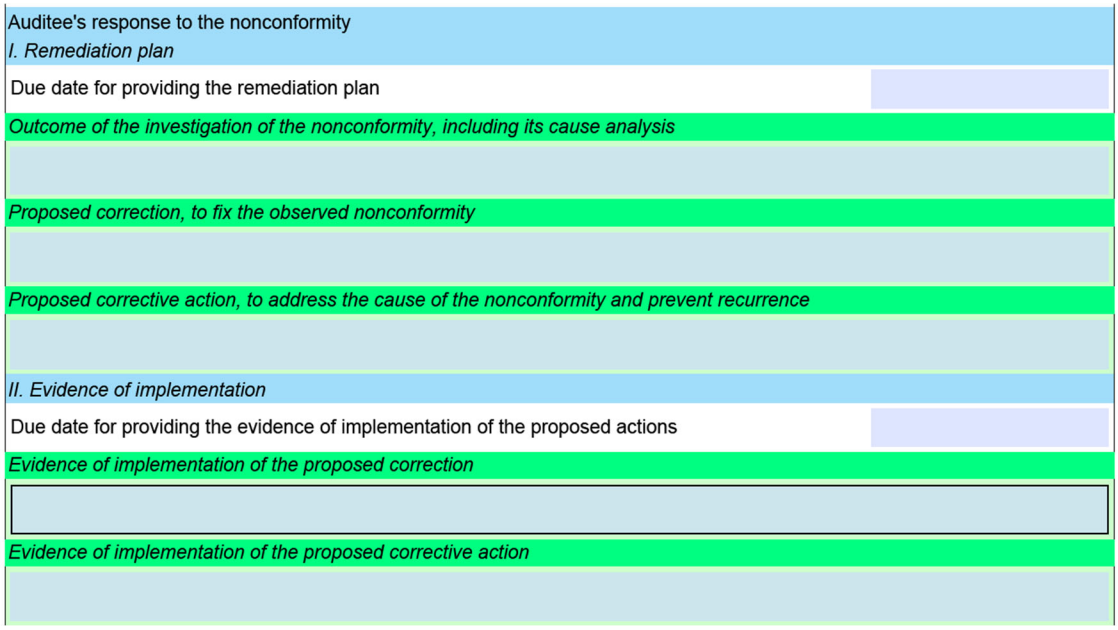
Reminder: the dropdown menu for the Japanese regulatory requirements is not populated until the version of the Ministerial Ordinance (MO) is selected (see Section 1).

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.

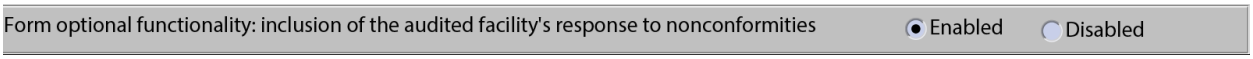
Unlike regulatory fields related to MDSAP or CE Marking requirements, which are only visible if a nonconformity is relevant under these schemes, the fields relative to “Other applicable standard or internal document / clause” remain always visible as it allows the user of the form to record any relevant requirements regardless of the applicable scheme (e.g., nonconformity against a standard to which the audited facility claims compliance, or an internal procedure).

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 or other external parties 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 to be filled in by the Audited Facility’s organization.



A radio button in Section 1 toggles the form from one configuration to the other.



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.

Subsection 3.3 – Nonconformity Grading

Nonconformity grading					
QMS Impact	Repeat NC ?	Failure to document and implement ?	Nonconforming Products Released ?	MDSAP Grade	ISO 17021 Grade
○ Indirect ○ Direct	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes		
☐ 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 detailed in MDSAP AU P0037 (based on GHTF/SG3 document N19).

Four independent parameters must be specified:

- Whether the clause of ISO 13485 against which the nonconformity is raise 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 is a failure to both document and implement an applicable requirement that is required to be documented;
- Whether nonconforming medical devices have been released to the market.

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

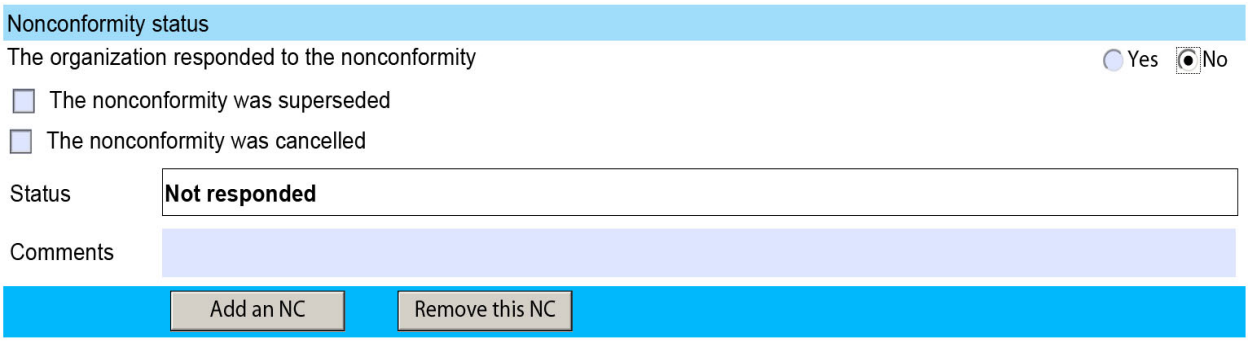
Additionally, the Auditing Organization may be required to grade the nonconformity as major or minor per ISO/IEC 17021-1 to satisfy the needs of certification schemes other than MDSAP. In such case, this grade can be recorded in the form as well.
Note: Both grading systems use different criteria and the determined grades per the GHTF and ISO/IEC 17021-1 can occasionally seem inconsistent. The grade per ISO/IEC 17021-1 is not used by Regulatory Authorities participating in MDSAP.

Per MDSAP policies, auditors are expected 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 acted appropriately 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. It is to be monitored 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



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 on 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".

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.

How to use the optional Auditee’s Response to the Nonconformity

The revision 12 of the form simplifies the process for obtaining and reviewing the audited facility’s response to nonconformities. The auditor’s signature is only necessary to lock the nonconformity description but all other fields are open.

The audited facility can therefore fill in the fields with a green background and is responsible for providing the following information, as appropriate:

- The outcome of the investigation of the nonconformity, including the identified cause of that nonconformity;
- The proposed correction, as applicable, intended to resolve the observed nonconformity (including for example the quarantine, sorting, reworking, downgrading, repurposing of any nonconforming product, the recall of nonconforming products in the field, etc.);
- The proposed corrective action, as applicable, that is intended to address the identified cause of the nonconformity to prevent any future recurrence;
- The evidence of implementation of both the correction and the corrective action provided to the Auditing Organization.

If the audited facility's response needs to be amended, successive inputs by the Auditee are recorded in the same fields.

The Auditing Organization should communicate with the Audited Facility on how to best document updates to a field, to distinguish new information from previously shared information, and to avoid removing any previously shared information. It is recommended to follow the following principles, as illustrated in the example below: Input should be entered in reverse-chronological order in order to see the most recent input on top. Each input should be preceded by the date, using the international date format: YYYY-MM-DD

Outcome of the investigation of the nonconformity, including its cause analysis
**** 2017-06-30 **** *The nonconformity is confirmed as valid. A review of 25 process records, on a sampling basis, during a one month period before and after the example identified in the evidence supporting the nonconformity, enable to identify only two other occurrences presenting a similar nonconformity. The risk associated with this nonconformity is therefore perceived as moderate. The cause of the nonconformity identified in our original response is confirmed by the records of these additional occurrences to be a misunderstanding of one step of the process. However, the new records show that this misunderstanding was not unique to one operators, but several experienced the same difficulty understanding the work instruction.* **** 2017-06-27 **** *The identified nonconformity was found to have no impact on the safety and performance of the affected devices.* *The problem is a human error. The operator misunderstood the description of one step in the process.*
Proposed correction, to fix the observed nonconformity
**** 2016-06-30 **** *The additional lots identified as having the same issue will be sorted the same way as described in the original response.* **** 2016-06-27 **** *The devices from the lot potentially affected by the nonconformity were sorted. Those devices that did not meet their specifications were segregated, pending their final disposal, which might be the rework of the affected devices, if technically feasible, or their destruction otherwise. Devices from the affected lots that were confirmed to be conforming to their specifications were put back in inventory.*

Once the Audited Facility provided a response, the auditing organization can document their review and update the status of the nonconformity (no need to remove any signature as in earlier versions of the form).

How To Merge 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.

To add the nonconformities from a first NGE form (F1) into a second NGE form (F2) following the nonconformities already in F2, the auditors must follow the 2-step process described below.

Step 1: Generate the XML data file from F1

- In F1, click on the “Email NC” button
- Right-click on the XML data file attached to the draft email and save it on the computer

Step 2: Import the nonconformity information into F2

- In F2, click on the “Import NC” button
- Select the XML data file saved in Step 1
- Click OK.

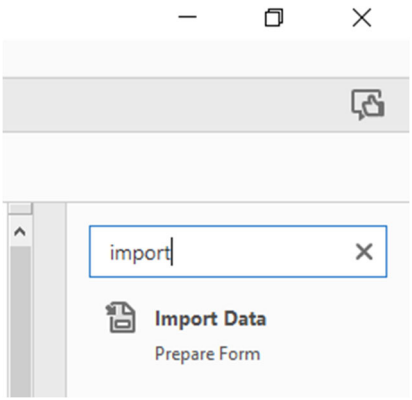
If the merger fails, check if curly brackets { and } have been used in the form. If so, remove or replace them by parentheses or square brackets, and try again.

How to generate an unsigned copy of an NGE record if the person who signed it is unavailable to clear their signature

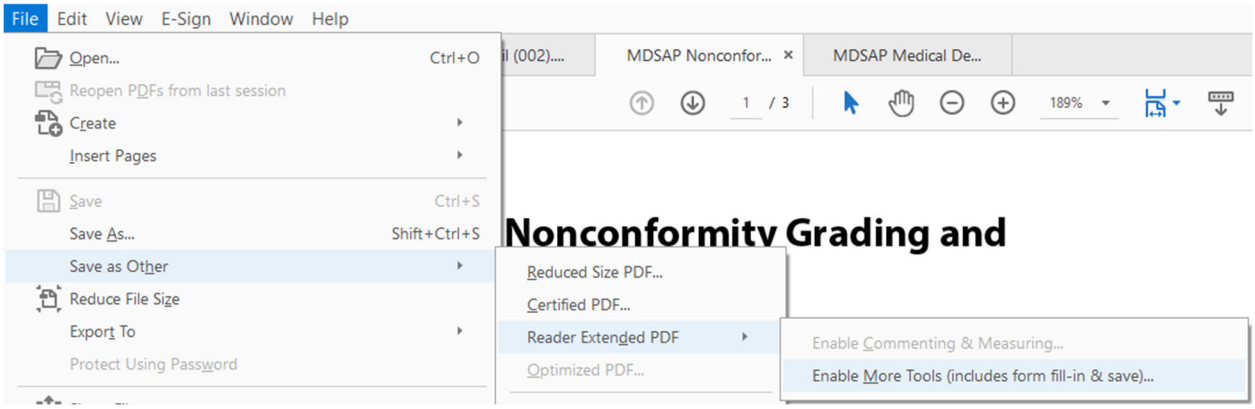
This process can only be completed using Adobe Acrobat, as Adobe Reader does not offer the necessary features to complete it.

- Create an XML data file, using the “Email NC” button as described above.
- Open a blank NGE form, preferably using the same version of the form.
- In the File menu, select “Save a Copy” to remove the “Reader Extension” from the form. This is necessary to enable Adobe Acrobat to import data into the form.

- Import the data from the XML data file into the saved blank form by searching the Import Data tool in Adobe Acrobat's right-hand side menu pane, and follow the prompts.



- Once the data is imported, save the file with the Reader Extension to enable users of Adobe Reader to use all its functionalities by selecting File > Save as Other > Reader Extended PDF > Enable More Tools (…).



Reference Documents

MDSAP AU P0027 – Post Audit Activities and Timeline Policy
MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form

Guidance Document Title: Guidelines on the Nonconformity Grading and Exchange Form **Document No.:** MDSAP AU G0019.4.005
Version Date: 2024-02-21

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
005	2024-04-26	Updated to reflect revision 12 of the NGE. See the margin to identify modified paragraphs. Update formatting for improved accessibility	Marc-Henri Winter