

SCAN Corrective Actions (CAPAs) Completion Training

By SCAN Program Management Team April 2025

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Training Course Overview

- Access to Your SCAN CAPA Task
- Actions to Take Before Working on SCAN CAPAs
- Unacceptable CAPA Responses
- CAPAs Reopened and Reassigned
- SCAN Audit Cadence and Report Validity
- CAPA Timelines and Notifications
- Additional Recommended Resources

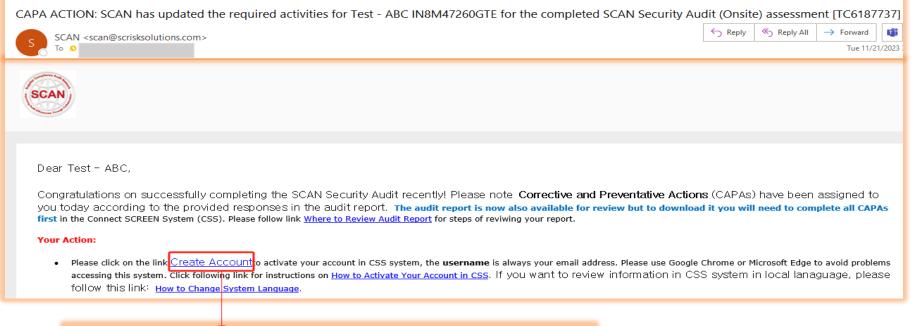
^{*}Please note: This training is applicable to all SCAN external (onsite/immersive) audits where CAPAs have been assigned.

Access to Your SCAN CAPA Task





Activate Your Account in Connect Screen Supplier



Welcome | @gmail.com

Passwords must meet the following requirements:

• Password should be minimum 8 characters in length

• Password should contain at least three of the four following criteria

• At least one upper case letter [A-Z]

• At least one lower case letter [a-z]

• At least one numeric [0-9]

• At least one special character [(10#\$%^5");]

• Previous 10 passwords cannot be used

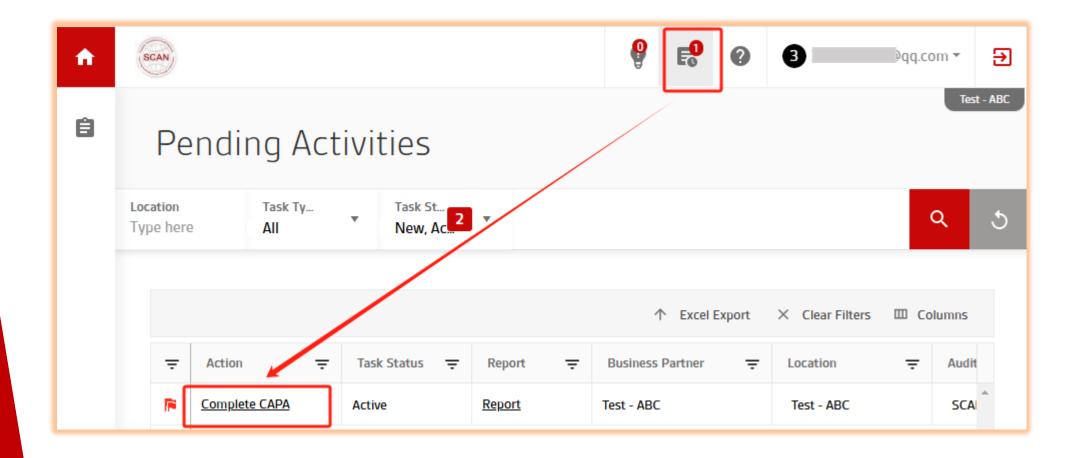
Enter New Password

Confirm New Password

After the audit gets completed by the audit firm, you will receive a CAPA Action notification from SCAN within 17 days, and you will have the access to your online audit report and the assigned corrective actions in the system by that time.



Access to Your CAPA Task



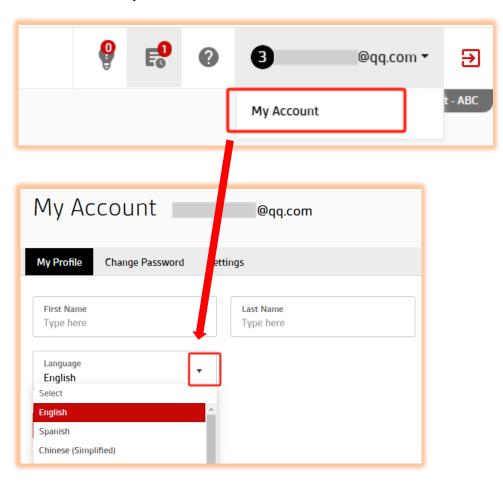
Actions to be Taken Before Working on SCAN CAPAs





Select Language Preference

Thirteen languages are available for SCAN Audit, CAPA templates, and guidance in the system. Follow the steps in the screenshots below to change the system language as needed.



Available Languages

English (by default)

Spanish

Chinese (Simplified and Traditional)

French

German

Japanese

Russian

Italian

Polish

Portuguese

Turkish

Vietnamese

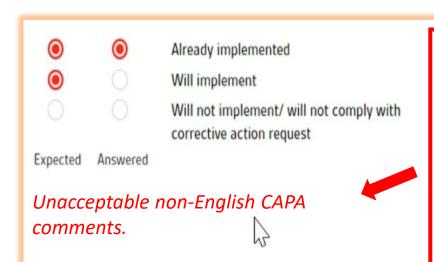




Select Language Preference

Why is it necessary to change the system language to the local one you're speaking?

- 1. It allows you to review the assigned corrective actions, guidance, and the report information in the preferred language.
- 2. You can provide your CAPA comments in the selected language in the system, such as your local language; the system will automatically generate translations in English based on your submitted comments in the CAPA report.

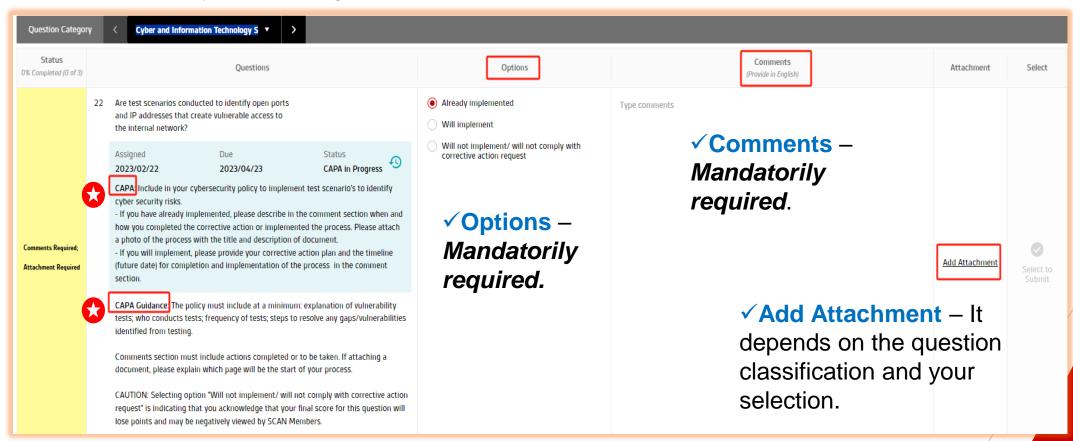


Comments: 更改了我司对于计算机密码维护的要求: 每月更改一次; 至少10个字符长; 大写字母、小写字母、数字和符号的组合; 不要使用人员姓名、出生日期、城市名、本公司名称、产品名称等相关字符; 和以前的密码大不相同。8月19日我司IT专员已监督公司所有计算机密码进行更改,核实更改后的密码符合规范后登记在册,并会在每月15-20日按照计算机密码更改要求进行维护,安全经理每月会对该项工作进行审查。

*SCAN does not accept non-English CAPA comments in your CAPA report. Thus, *DO NOT FORGET* to change the system language to the one you will use **before** submitting your CAPAs.



- ✓ CAPA To indicate what necessary information is required on how you have implemented the process, or how you will implement the concerned process.
- ✓ CAPA Guidance To provide you with the SCAN minimum standard criteria that you must follow and implement, if you want to get full compliance for this question.





Definition for the CAPA Option

- 1. Already Implemented Select it when you have completed the corrective action, and the evidence of completion/ implementation is available for uploading. Only CAPA with this option selected and accepted by SCAN will ensure you a full score for that question, and the post-CAPA score will improve.
- 2. Will Implement Select it when you only have a corrective action *plan and a future date* of completion/implementation. Usually, when you need longer time beyond 60 days to rectify the issue, you can select this option if available.
- 3. Acknowledged Will consider implementation in future. This options applies to best practices, which may become a requirement in the future. Selecting this option allows you to defer commitment to implementation.
- **4. Will not implement/will not comply with corrective action request –** Select it when you *REFUSE* to complete the corrective action. Failure to meet this requirement will negatively affect the overall audit score and shorten the interval until the next audit request.



Question Classification

The CAPA options change with the question classifications, which means each question may have different options. The SCAN questions are classified as *Critical*, *Must*, and *Material*.

Critical

- Already implemented
- Will not implement will not comply with the corrective action request

Recommended Options:

Already Implemented

- Provide descriptions of the implemented corrective action, and a past date when it was completed.
- Attach relevant supporting documentation.

Must

- Already implemented
- Will implement
- Will not implement will not comply with the corrective action request



Recommended Options:

Already Implemented

- Provide descriptions of the implemented corrective action, and a past date when it was completed.
- ✓ Attach relevant supporting documentation.

Will Implement

✓ Provide descriptions of the corrective action plan and a future implementation date.

Material

- Already implemented
- Acknowledged will consider implementation in future



Recommended Options:

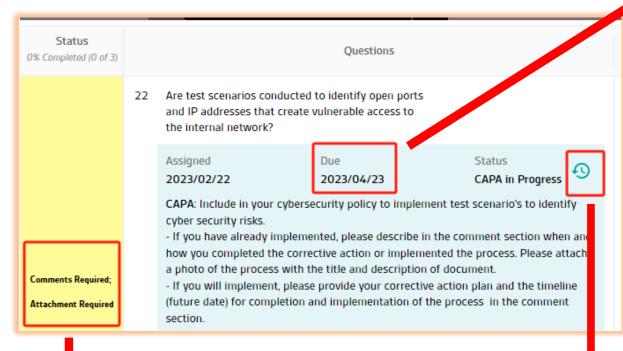
Already Implemented

- Provide descriptions of the implemented corrective action, and a past date when it was completed.
- ✓ Attach relevant supporting documentation.

Acknowledged

✓ Acknowledge the request without taking any action currently.

Additional Information



The Color Bar indicates the mandatory information required before submitting a CAPA.

Due indicates the deadline by which the CAPA submission must be completed.

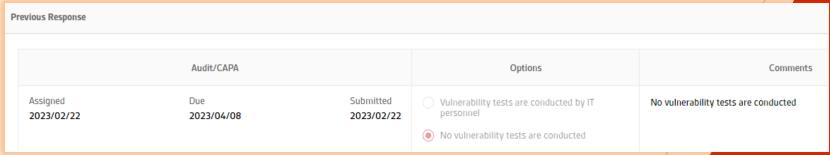
Due indicates the deadline you must complete the CAPA submission.



Previous Response:

Click on the timer icon, a pop-up window will be opened and displaying the auditor's original comments in the audit report. If you previously submitted a CAPA but got reopened and reassigned by SCAN, you can view all your earlier CAPA comments along with SCAN's "Reopen Comments."

These previous responses are intended to help you understand the specific areas that require improvement for the question in concern.





Reminders

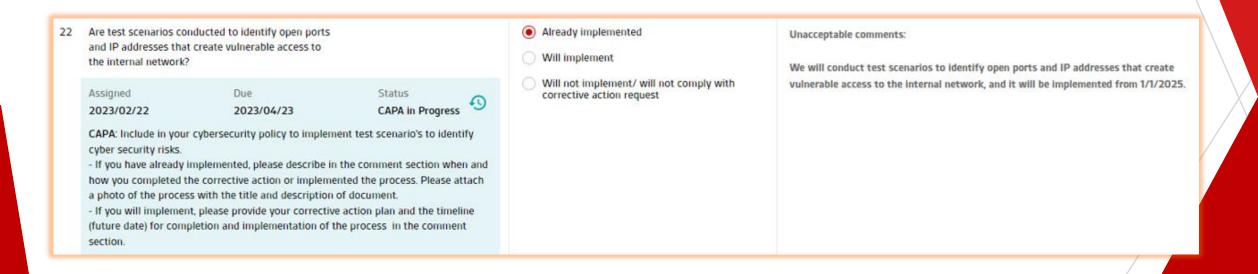
- Regardless of the question classification, an attachment will be mandatorily required when
 "Already Implemented" is selected by you. It's highly recommended if you have completed the
 corrective actions and the evidence is available, select this option to obtain full score.
- DO NOT select the option "Will not implement will not comply with corrective action request".
 Refusing to comply with the requests may be negatively viewed by the SCAN members. This indicates that you acknowledge your final score for this question will be reduced. More importantly, it may negatively affect your report's validity, making it ineligible for the two-year audit cadence.
- When submitting an attachment of a written procedure, upload only the page(s) containing the required processes. Avoid uploading just the cover page or the entire procedure document.
- DO NOT include any retailer (importer) company name in your CAPA comments or attachments.
 SCAN is an audit sharing platform so it's crucial to keep the confidentiality of your customer information, whether it's a SCAN member or not.





O Discrepancies Among Options, Comments, Attachments

In below scenario, factory selected the option "Already Implemented" but only provided a corrective action plan and a future date in the comments box. SCAN reopened and reassigned the CAPA to the factory due to the discrepancies between the selection and comments.





- Missing the date of implementation for CAPA (corrective and preventative action).
- Missing future date of completion for CAP (corrective action plan).

In below scenario, factory selected the option "*Already Implemented*" but a past date of implementation is not provided in the comments box. SCAN reopened and reassigned the CAPA to the factory requesting them to add a past date in the comments box to confirm the corrective action has already been taken and completed.

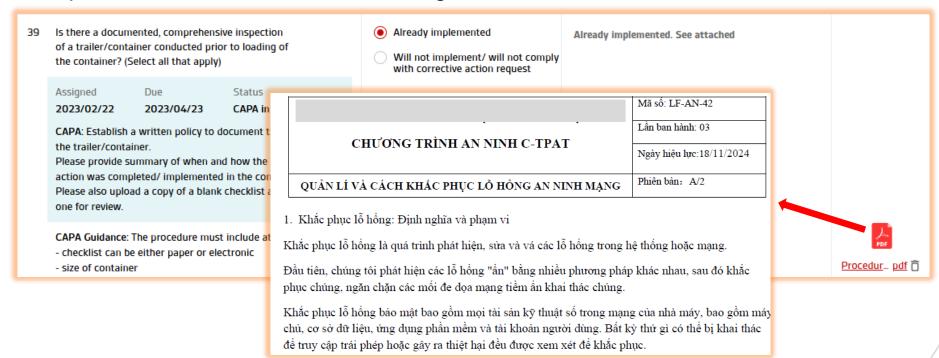




Uploaded attachment is NOT in English, and NO clear descriptions of the procedure or corrective actions provided in comments box.

Example: A factory added an attachment and it's a copy of a written procedure. In the comments box, factory simply commented "Already Implemented. See attached", but the attached procedure was in Vietnamese.

SCAN reopened and reassigned the CAPA to the factory, requesting them to provide a description of the relevant processes and actions taken in English within the comments box for further review.



CAPAs Reopened and Reassigned



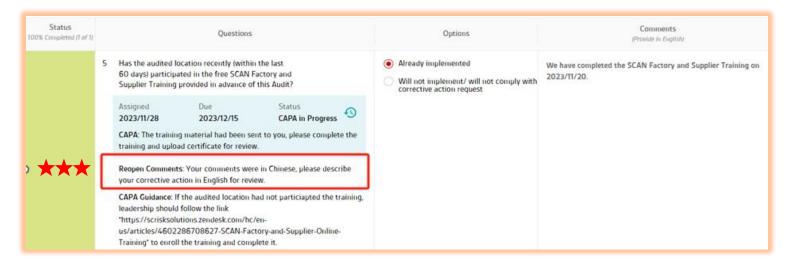


CAPAs Reopened and Reassigned

According to the process, SCAN will review your CAPAs and notify you within 10 days whether further action, or a new round of CAPA is required or not. If any CAPAs are reopened, you will receive a new CAPA Action Notification from SCAN.

We need your serious attentions to following guidance in such situation:

- ✓ To complete the new round of CAPAs efficiently, in addition to reviewing the CAPA guidance carefully, please review the "Reopen Comments" provided by SCAN on the CAPA page. These comments will outline what specific information are still needed for an acceptable CAPA.
- ✓ DO NOT submit the same responses which you previously submitted. If you are unable to complete and have any assigned CAPAs approved by SCAN within three rounds, those will be rejected, and your final audit report may be ineligible for the two-year audit cadence.



SCAN Audit Cadence and Report Validity





Audit Cadence and Report Validity

SCAN Security Audit Cadence and Report Validity

The SCAN onsite/immersive audit is valid for one year. To qualify for a 2-year audit cadence, the following criteria must be met:

- A compliance score of 95% or higher, with all Corrective Actions addressed and approved by SCAN; or
- A compliance score between 85% and 94%, provided the country security risk is Low,
 Guarded, or Elevated, and all Corrective Actions are addressed and approved by
 SCAN
- In addition to either of the above requirements, 12 months from the day the audit was conducted, the facility must complete a SCAN self-audit assigned by SCAN PMT.

Please note: Addressing the corrective actions means that your submitted CAPA responses have been accepted and approved by SCAN. These responses may include a corrective action plan or descriptions for completed corrective actions. Please refer to the key information and guidance provided in previous sessions to make proper decisions what you need to provide for concerned CAPA question.



Audit Cadence and Report Validity

Regardless of your original audit compliance score and the country security risk rating, when any of the assigned corrective actions are not addressed and accepted by SCAN, your audit report will not be eligible for two years' cadence in SCAN system.

The following circumstances are considered CAPA NOT addressed, and your audit report will be valid for one year. The audit report will also be tagged with sub status "CAPAs: No responses – Closed", or "CAPAs: Partially addressed - Closed" in the system.

CAPAs: No responses – Closed

 No assigned corrective actions are ever completed and submitted in the system.

CAPAs: Partially addressed – Closed

- One or above corrective actions are rejected by SCAN due to factory not submitting proper and sufficient responses after *three* (3) CAPA rounds.
- Option "Will not implement will not comply with corrective action request" is selected for one or above corrective actions due to factory refusing to improve the non-compliant issues.

CAPA Timelines and Notifications





CAPA Timelines and Notifications

- ✓ You can expect an the initial "CAPA Action" Notification from SCAN within 17 days after audit day.
- ✓ Upon receiving the initial "CAPA Action" notification, you are expected to log into the system for acknowledgement, then **complete the assigned CAPAs within 60 days**. There will be additional six automatic CAPA reminders sent to you on 5, 10, 15, 30, 45, and 60-day mark until CAPAs are all completed. SCAN members are blind copied in the last two CAPA reminders.
- ✓ After receiving your submitted CAPAs, SCAN PMT would review the responses within 10 days and determine whether to accept, reopen, or reject the CAPA responses based on SCAN CAPA requirements.
- ✓ In the situation that the submitted CAPAs are reopened due to insufficient responses, you will have at least 14 days to complete the new CAPA round.
- ✓ You are expected to complete all SCAN CAPAs within three CAPA rounds. Once all CAPAs are closed, SCAN PMT will update the audit status to "Reviewed" in the system. A "CAPA Completed" notification will be sent to you notifying the final status of each closed CAPA, such as accepted, rejected, or cancelled.

Additional Recommended Resources







The following are recommended links to some useful articles and guidance you may find helpful:

- SCAN CAPA Submission in Connect Screen Technical Steps
- SCAN Supplier and Factory Training Registration Guide
- Review and Download SCAN Audit Report
- Cannot Find My CAPA Task in Connect Screen
- SCAN Association Website Vendor/ Location Page



Thank you

If there are any questions, please contact SCAN@scrisksolutions.com.