

Indian Register Quality Systems (A Division of IRCLASS Systems and Solutions Private Limited)	III IRQS - OPM : 20 : <u>10</u>
Operational Procedures Manual Issue No. 2	Page 1 of 8 Eff. Dt. : 27 July 2023
SUSPENDING, WITHDRAWING OR REDUCING THE SCOPE OF CERTIFICATION	Developed By : NR Approved By : DH - IRQS

A. Purpose :

This process provides a description of suspension, withdrawal or scope reduction to ensure proper control over IRQS-issued certificates and certified clients with the intent of meeting the requirements of ISO/IEC 17021-1,ISO/IEC 17065, IAF MD 11 and Accreditation Bodies' requirements for certification.

- **B.** Scope : Applies to all certifications provided by IRQS to relevant audit criteria, throughout all stages of the certification process.
- C. Cross Reference : ISO/IEC 17021-1, ISO/IEC 17065, IAF MD 11, IAF MD 22, IAF MD 9
- D. Process Owner : Head Operations
- E. Responsibilities : Nominated representative / Divisional Head-IRQS

F. Process Measurement :

- Number of certificates suspended
- Number of certificates revoked/restored
- Number of certificates withdrawn

G. Process Description :

1.0 Definitions

1.1 **Suspension** is a temporary status which can only end by full reinstatement or withdrawal of certification. During this period, the client's certification is temporarily invalid. Suspension is not to exceed 180 days.

In the case of suspension, the client shall refrain from further promotion of its certification. IRQS will make the suspension status of the client publicly available and take any other measures it deems appropriate.

In the case of multi-site organizations, suspension applies to the certification of the entire organization, although the issue may relate to one or more of the sites only.

- 1.2 **Reduction of scope** consist of excluding from the scope of certification the parts not meeting the requirements when the client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the audit criteria used for certification.
- 1.3 **Cancellation:** Action to nullify a certificate at the request of the certified client.
- 1.4 **Withdrawal:** Action taken by IRQS to terminate the validity of the client's certificate.

2.0 Suspension

A certificate's validity is maintained based on satisfactory compliance of on-going requirements for surveillance audits, recertification audits, and other conditions specified in the client's contract with IRQS. A Suspension process may begin when any of the following occur:

- 2.1 The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
- 2.2 The certified client does not take 1st surveillance audit at the required frequency of once annually. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date of Stage 2 / Recertification audit.
- 2.3 The certified client does not take up subsequent surveillance audit at the require frequency of once annually i.e. within 21-25 months from certification decision date of Stage 2 / Recertification audit.

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[NOTE: If organization has opted & agreed upon for more than 2 Surveillance Audits then the Surveillance Audits shall be planned & conducted as per Contract Review.]

2.4 The certified client has voluntarily requested a suspension.

- 2.5 Nonconformance is not closed within the specified timeframe as identified in III IRQS-OPM:15 at Sr. No.5.
- 2.6 Violations of IRQS contract (includes unpaid invoices).
- 2.7 As a result of investigation conducted on a complaint against a certified client.

Based on the above identified conditions, the recommendation for suspension shall be made by Operation personnel and authorized by Head-Operations / Head-Accreditation / NR and Divisional Head–IRQS.

In case of situation 2.1, Lead Auditor or Technical review Personnel may recommend for suspension. For cases identified under 2.2 to 2.4, the zonal co-ordinator (planner) will intimate the central scheduler at HO for recommending the issuance of suspension letter.

For cases identified under 2.5 to 2.6 Divisional Head – IRQS / NR shall recommend for suspension.

For the client under suspension beyond 4 months, additional on-site mandays approximate 50% of surveillance audit shall be allocated to verify the effectiveness of the compliance to the certified management system.

The approved decision shall include the conditions for lifting the suspension or reinstating the complete scope of certification. When suspension or reduction of scope action is determined, the Regional Outport and the client shall be notified within five (5) working days of the approval of the decision of suspension or reduction of scope, the affected client will be notified in writing of the suspension of its certification. The letter typically indicates:

- Reason for suspension or reduction of scope.
- > Maximum duration of suspension or reduction of scope.
- Conditions for the suspension or reduction of scope to be lifted (i.e. timeline submission of corrective actions, special surveillance visit, etc.).
- Failure to resolve the issues that have resulted in suspension or reduction of scope in the specified timeframe shall result in withdrawal or permanent reduction of the scope of certification.
- Other parties to be notified, if applicable.

Operations personnel shall update certification status in the internal database and the directory of certified clients posted on the website.

Extension of certification validity may be granted for subsequent surveillances upon receipt of request from client for situations such as (but not limited to)

- 1) Client ceases due to major operational changes (such as expansion shifting of premises etc).
- 2) Unavailability of IRQS resources or key resources of client due to unforeseen circumstances etc.

In any such case, approval shall be sought from Head-Operations or Divisional Head-IRQS, prior to the due date of audit.

The period of extension shall commensurate with the prevalent situation and shall not exceed 2 months in all probabilities.

For cases exceeding 4 months, suspension shall be issued.

The provision of extension shall not be applicable to clients in the period of 1st Cycle of certification. Expiry of certification shall pre-dominate all extension criteria.

Deliberate or consistent non-compliance shall be considered a serious failure to support the policy commitment to achieving legal compliance and shall preclude certification or cause an existing OH&SMS standard certificate to be suspended, or withdrawn.

3.0 Subsequent actions for Suspension:

3.1 If the client submits a timely response, follow-up and or verification shall be performed as per the disposition of the conditions for lifting the suspension or reinstatement of the complete scope of certification. Results of the required follow-up and/or verification activity are to be documented. If satisfactory, the results are to be forwarded to Decision Making personnel for re-instatement of the certificate.

If the results are unsatisfactory, or if the client fails to respond adequately to IRQS's request, a recommendation shall be forwarded to Decision Making personnel for:

1. Withdrawing in accordance with the requirements listed below, or

2. Permanent reduction of scope in accordance with the requirements of Amendment to Certification Process.

Upon suspension and lifting of suspension, or reduction and re-instatement of scope of certification, Operations personnel shall update certification status in the internal database and the directory of certified clients posted on the website.

3.2 Under suspension/withdrawal :

IRQS certified clients are required to refrain from using the Certificate and/or Logo from all points e.g. the packaging of a product, labels, publicity material, written announcements and other promotional material like letterheads, etc.

3.3 Verification under suspension/withdrawal for misuse of certificate information, logo or mark :

- 3.3.1 IRQS shall verify the certified client through visiting website of the clients under suspension or gathered information from the client's customer or interested parties or during the audit for misuse of the information.
- 3.3.2 Under suspension/withdrawal, if client is found to misuse Certificate information / logo / mark in contravention to condition specified in this procedure then the concerned organization would be requested to give the corrective action, in situations of repeated contraventions by the organization, IRQS may withdraw the certificate or may lead to legal action.

4 Revocation / Restoration :

Depending upon the nature of suspension identified under section 2, after the verification of the corrective actionstaken, decision on revocation / restoration shall be taken.

The monitoring target for issuance of revocation / restoration letter within 2 working days after the completion of Decision making process.

5 Withdrawal

A certificate's validity is subject to ongoing requirements for surveillance and recertification audits, and other conditions specified in the client's contract with IRQS.

On a monthly basis, Head-Operations shall select clients on random basis from the List of withdrawn certificates and confirm their actual status from the data reflecting in the irclass website.

The delisting process may begin upon verification when any of the following occur:

- a. Client wishes to cancel and sends formal notification (in writing)
- b. Failure to resolve the issues that have resulted in the suspension within the time-line of 180 days.
- c. If the client does not take up the Recertification audit before expiry of certification the certificates is deemed withdrawn / expired.
- d. Deliberate or consistent non-compliance shall be considered a serious failure to support the policy commitment to achieving legal compliance and shall preclude certification or cause an existing OH&SMS standard certificate to be suspended, or withdrawn.

6 Subsequent actions for Withdraw:

Based on any of the above-identified conditions, any Management or Decision-Making personnel may recommend a client's de-listing. Withdrawal process shall be initiated after approval from NR and Divisional Head – IRQS.

The process is initiated with a formal letter to the client indicating the reason and the effective date of the Withdraw. Additionally, the following information is included:

- a. The client is advised to return all certificates, destroy all artwork and marketing material, and cease use of the logo in advertising, etc.
- b. A follow-up is made to the client if the certificate is not returned.
- c. If it is a requirement of the applicable audit criteria, the client is required to send written notification to its customers who require certification, advising them that they are no longer certified.
- d. The client may appeal the decision of delisting by IRQS following IRQS Appeals Procedure.
- e. Upon withdrawal of the certification, Operations personnel shall update the internal database & the directory of certified clients posted on the web site.

7 Conditions for Expanding and Reducing the scope of Certification:

- a. The scope of certification can be extended or reduced on receipt of written request from the client under any or more of the following:
 - i. When products/services are added or deleted from the existing scope.
 - ii. When the client increases or decreases the production capacity or range covered in the scope, with additional or less manpower or resources within the existing QMS /EMS /OHSMS /FSMS /FSSC /EnMS /ISMS /SCSMS/PIMS /SRMS /IATF 16949 / MDQMS certified.
 - iii. Change in number of sites.
- b. IRQS can reduce the scope if during an audit; the client organization is not able to demonstrate its capability to render the scope of activities as specified in the Certificate of Approval.
- c. IRQS has the option to verify during surveillance audits or on receipt of any information, the continuation of scope certified and any variations that can lead to change in the scope. However, this situation will be informed to NR who will resolve with the client and changes are made as per the above procedure.
- d. In case, if absence of objective evidence for all activities of Scope of certification", on a case to case basis conditional grant of certification or reduction of scope will be undertaken in consensus with Operations-Head/Head-IRQS (Top management).

8.0 For Integrated Management System:

For the conducted Integrated Management System Audits, IRQS issues separate "Certificate of Approval" for each scheme.

Sr. No.	Criteria	Impact analysis	
1	The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.	Failure shall be evaluated, if it's applicable for other schemes also then all the schemes certified under IMS shall be suspended / withdrawn as applicable else only that particular Management System Scheme shall be suspended / withdrawn.	
2	The certified client does not take 1 st surveillance audit at the required frequency of once annually	Earliest audit date among the schemes certified shall be taken into account for execution of Audit. All the	
3	The certified client does not take up subsequent surveillance audit at the require frequency of once annually.	schemes under integration shall be suspended / withdrawn as applicable.	
4	Nonconformance is not closed within the specified timeframe	Evaluation / Impact analysis of the NC raised on other schemes shall be done, if it has impact on other schemes, then respective schemes under the integration shall be suspended / withdrawn as applicable. If not, then only that particular scheme under which NC is raised shall be suspended / withdrawn.	
5	Violations of IRQS contract (includes unpaid invoices).	All schemes under integration shall be suspended / withdrawn as applicable.	
6	As a result of investigation conducted on a complaint against a certified client.	Will be dealt with scheme wise. If has an impact on other schemes, then all the schemes integrated shall be suspended / withdrawn as applicable.	

The above referred Suspension, Reduction and Withdrawal procedure is followed based on the Impact analysis given below:

9.0 Maintaining Certification

Independently from the involvement of the competent regulatory authority, if necessary IRQS may conduct a special audit in case of a serious incident related to occupational health and safety, for example, a serious accident, or a serious breach of regulation, in order to investigate if the management system has not been compromised and did function effectively. IRQS shall document the outcome of its investigation.

Information on incidents such as a serious accident, or a serious breach of regulation necessitating the involvement of the competent regulatory authority, provided by the certified client or directly gathered by the audit team during the special audit, shall provide grounds for IRQS to decide on the actions to be taken, including a suspension or withdrawal of the certification, in cases where it can be demonstrated that the system seriously failed to meet the OH&S certification

requirements.

10. Under Management of extraordinary events (A circumstance beyond the control of the organization, commonly referred to as "Force Majeure" or "act of God". Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters) for circumstances affecting certified clients for issuance, maintenance, re-certification, suspension and withdrawal following will be applicable:

IRQS shall evaluate the risks presented to its organization and to the certification(s) concerned & carry out as per III IRQS:OPM:33 and III IRQS:OPM:34

10.1 Initial certification and scope extensions

Initial certification and extension of existing scopes shall be granted subject to the certification decision based on demonstration of the certification scheme requirements through remotely conducted audit using ICT in satisfactory manner.

10.2 For Surveillance activities

Surveillance assessment objectives shall be assessed and achieved by remote assessment should take place within the current certification year. In case, on-site audit is not possible.

In case of the first surveillance audit after initial certification a postponement of the audit should not exceed six (6) months (18 months from date of initial certification). In case of subsequent surveillance audits a postponement of the audit should not exceed six (6) months.

These extended periods between surveillance visits, (as specified above) may result in a need for additional surveillance visits for the remainder of the certification cycle.

If the above assessment is not undertaken within 6 months as noted above the certificate put under suspension & the suspension procedure noted above will be applicable.

For withdrawal, the procedure as noted above shall be followed.

10.3 Re-certification

Based on Desk review / remote assessment on gathering sufficient audit evidences to provide confidence that the certified management system is effective, IRQS will consider to extend the certification for a period not exceeding six (6) months beyond the original expiry date. If the re-certification assessment is undertaken within six (6) months the certificate shall be suspended & the suspension procedure noted above will be applicable.

For withdrawal, the procedure as noted above shall be followed.



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SUSPENDING, WITHDRAWING OR REDUCING THE SCOPE OF CERTIFICATION

	Scenario description	IRQS will follow for following as noted:		
NO.	Below restrictions should all be read as "Due to Covid19"	Initial/extension of scope	Initial/extension of scope	Initial/extension of scope
1	Client does not carry out any activities (e.g. no demand for product/service travel agencies or complete closure of universities).	Not accepted.	The certificate shall be suspended. Re- instatement of certificate is possible based on regular maintenance activities (original cycle maintained).	The certificate expires. Re-instatement of certification is possible after resumption of activities within 12 months from the original extension date with a re-certification audit. The re-instated certificate shall indicate the gap in the certification and the original cycle shall be maintained. After this date, a full initial audit shall be performed.
2	Client is (temporarily) carrying out only part of activities in scope of certificate. According to the IRQS regular assessment programme, these activities that are not carried out, should have to be assessed (taking the scheme requirements into account)	Certification only possible for scope indicating activities carried out and confirmed in audit.	The scope of the certificate shall be (temporarily) reduced. Re- instatement of the original scope is possible, based on regular maintenance activities (original cycle is maintained).	The certificate is reduced in scope (provided that certification activities for the rest of the scope have been completed). Re-instatement of the original scope of certification is possible after resumption of activities within 12 months from the original extension date with a re-certification audit. The re-instated certificate shall indicate the gap in the certification and the original cycle shall be maintained.
3	Client does carry out activities, but cannot receive visitors (not allowed or required social distancing is physically not possible). The scheme and/or the IRQS risk analysis demonstrate that remote assessment is insufficient to achieve audit objectives.	Certification only possible after assessment objectives have been achieved.	IRQS shall consider video conferencing, mobile cameras or other ICT tools. If assessment objectives can't be achieved using alternative tools (or scheme/client prohibits the use), the certificate shall be suspended. Re-instatement of the original scope is possible, based on regular maintenance activities.	IRQS shall consider video conferencing, mobile cameras or other ICT tools. If assessment objectives can't be achieved using alternative tools (or scheme/client prohibits the use), after an extension period of six (6) months, the certificate expires. Re-instatement of original scope of certification is possible after resumption of activities within 12 months from the original extension date with re- certification audit. The re-instated certificate shall indicate the gap in the certification and the original cycle shall be maintained.
4	Client is carrying out activities with higher risks to health and safety (e.g. health care)	IRQS shall consider additional protective measures (PPE).	IRQS shall consider additional protective measure (PPE).	IRQS shall consider additional protective measures (PPE).

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	Scenario description	IRQS will follow for following as noted:		
No.	Below restrictions should all be read as "Due to Covid19"	Initial/extension of scope	Initial/extension of scope	Initial/extension of scope
5	Client does carry out activities, and can receive IRQS, but due to travel restrictions IRQS cannot visit client (e.g. in case of travel or quarantine restrictions). Scheme and/or IRQS risk assessment indicate that audit objectives cannot be achieved with remote audit techniques only.	IRQS may consider co- operation of Local auditors	IRQS shall consider co-operation with local IRQS. If not possible, certificate should be suspended	IRQS shall consider co-operation with local IRQS. If not possible, certificate shall expire.
6	Client does carry out activities, but has restrictions due to Covid-19 infections having been found out in personnel	Certification only possible after achievement of audit objectives. IRQS shall consider additional protective measures (PPE).	Only regular postponement exceptions accepted, i.e. no further extension possible. IRQS shall consider additional protective measures (PPE).	Only regular postponement exceptions accepted, i.e. no further extension possible. IRQS shall consider additional protective measures (PPE).
7	Client cannot receive IRQS due to increased work load related to the Covid-19 pandemic (e.g. hospitals, health centres, research or production facilities of Covid- 19 abatement/control materials).	Certification only possible after achievement of audit objectives.	When conditions as described in this scenario can be objectively confirmed by IRQS, an additional suspension of audit activities (up to one (1) year in total) is accepted.	When conditions as described in this scenario can be confirmed by IRQS objectively, additional extension of the certificate (up to one (1) year in total) is accepted.



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11. This chapter is referred into the respective III IRQS System Protocol Manual.

H. Records :

- Master Data base
- Suspension / Revocation / Withdrawal letter as applicable in respective file

I. Revision History:

Rev. No.	Effective Date	Details
01	10-08-2016	Amendment made at 2.2,2.3 & 2.5
02	26-10-2017	Added new point 3.2,3.3
03	25-04-2018	Added reference of ISO/IEC 17065 at A & C
04	27-09-2018	Added requirement of IAF MD 22 at Cross reference, 2.0, 5.0 & 9.0
05	21-01-2020	Added point (d) under Section 7
06	09-04-2020	Added reference of IAF MD 9 at Section C
		Added reference of Medical Devices ISO 13485 at 7 (a-ii)
07	24-11-2020	Added Section 10 for Under Management of extraordinary events
08	02-11-2021	Added Section 11
09	02-11-2022	Updated Section 6 (d)
10	27-07-2023	Updated at Section 4