Chapter 5. Scope determination

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0) Introduction

There are only two related- applicable clauses in this chapter. The reason why a whole chapter is devoted to them is because scope determination is now a responsibility of the organization. When the scope is incorrectly defined, it may lead to registration issues, findings and negative audit conclusions.

1) 4.3. Determining the Scope of QMS (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: (a) the external and internal issues, (b) the requirements of relevant interested parties, (c) the products and services. All the requirements of this International Standard are applicable within the determined scope. The scope of the QMS shall be a documented information. Any omission from the scope affecting the organization's ability or responsibility to ensure conformity of its products and services and the enhancement of customer satisfaction, will invalidate the claims of conformity to this standard.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- ISO now requires the organization to be responsible for defining the scope.
- It also warned that if an exclusion made which is not justified, the whole QMS is deemed not conforming to the international standard.

(Compliance Best Practice)

4.3. Determining the Scope of QMS
See Clause 4.3.1 for a combined discussion

2) 4.3.1 Determining the scope-supplemental (IATF16949)

(Clause Description-Paraphrase)

Supporting functions, whether on-site or remote (such as design centres, corporate headquarters, and distribution centres), shall be included in the scope of the Quality Management System (QMS). Any exclusion shall be justified. For design, only product design can be excluded, but manufacturing process design is still required in all cases.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.

- For automotive application, there is an additional requirement to record the addresses of all the manufacturing sites, remote locations, HQ etc, on the QMS documentation, as part of the scope.
- Exclusion need to be justified
- Finally the clause states that manufacturing process design cannot be excluded, which had always been the case.

(Compliance Best Practice)

4.3.1 Determining the scope-supplemental

1. *This clause and 4.3, are on how to define the scope. See **Exhibit 5-1 & 5-2.***
2. *The scope statement is a documented information. It can be listed in the Quality Manual or some other documents as an evidence of compliance.*
3. *Although not stated, review of scope is necessary. Notify your CB, by returning their request for updates. If you wish to retain a road map of your review for future reference, an example is given in **Exhibit 5-3.***
4. *Your certification body (CB) will help you to frame the scope during registration stage. They have to ensure the correct information are submitted for approval.*
5. *Subsequently. IATF auditors will also review the scope during each audit, to make sure it is still suitable. Therefore, on the whole, scope determination is not a major issue.*
6. *Request all your remote locations to include in their certificates, that they are supporting your site, and list out the services provided. See **Exhibit 5-4A & 5-4B**.*
7. *If your remote location is not an IATF-certified organization, they should include the information on their QM. Otherwise there will be complications. **See SN-5.4** for explanations.*

3) SIs & FAQs

No SIs & FAQs for this Chapter

4) Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
4.3	CBP	**SN5.1 Why are organizations asked to define the scope with this new version?**
4.3	CBP	**SN5.2 According to the example give, there are a lot of work. Do we have to do so much of spadework to define the scope?**
4.3	CBP	**SN5.3 Why remote locations must put the main site's particulars on their Certificates, or QM? What complications can arise?**
4.3	CBP	**SN5.4 What should the remote locations write in their QMs?**
4.3	CBP	**SN5.5 What happen if a IATF auditor find the scope is no longer suitable? What happens next?**
4.3	CBP	**SN5.6 How do I inform CB on changes of scope?**
4.3	CBP	**SN5.7 Must the scope written on my QM same as given on the certificate or audit notification issued by the CB?**
4.3	CBP	**SN5.8. Is review on scope statement necessary? And how do we do that?**

SN5.1 Why are organizations asked to define the scope with this new version?

The purpose of a correct scope is to ensure the QMS is adequately designed to support the operations. In the past, there were organization claiming activities in the scope which is not available e.g. assembly. There were also organizations hiding activities from the scope because they wanted to simplify the registration process. Frequent disputes amongst CB, organizations and the auditors occur, when things go wrong. By making the organization responsible for the scope definition, chances of getting the correct scope is better.

SN5.2 According to the example give, there are a lot of work. Do we have to do so much of spadework to define the scope?

Exhibit 5-1 is just a diagram showing how the scope is defined, and their elements. There is no work here. **Exhibit 5-2** systematically logs down the decisions that brings out the scope logically. It is there if you should want to use it, but it is not compulsory.

SN5.3 Why remote locations must put the main site's particulars on their Certificate or QM? What complications can arise?

First and foremost, there is an IATF Rule that allows the main site auditor to accept a remote location's report in lieu of onsite audit, under certain conditions. It these conditions are not met, the main site auditor shall conduct onsite audit. If the distance between the 2 entitles are far (e.g. Vietnam Site and Japan HQ), it can be costly. The most common condition not met is the linkage of the two is not established. It is not stated in the audit report, nor on the certificate of the remote location. The result is onsite audit needed for the remote locations.

The best method is to include your site on their certificate. If the main site is on the certificate, there can be no argument. Next best thing is putting your organization as a supported site on the QM of the remote location. It alerts the QMR and the auditor (of remote location) of the existence of a supported site. The audit report can then mention about this support, and it will serve the purpose.

SN5.5 What happen if a IATF auditor finds the scope is no longer suitable? What happens next?

There are 2 scenario here: a) the certificate has not been issued yet, e.g. initial certification or recert, b) certificate has been issued e.g. surveillance audits, or special audits.
In case a), it is a matter of document change to be submitted along with the report. But if the change requires increase of mandays, auditor will seek authorization of regional office to change mandays, there and then. For case b), what is said of a) applies to b). However, the certificate will need to change and there will be some cost to this.

SN5.7 Must the scope written on my QM same as given on the certificate or audit notification issued by the CB?

Technically they should be identical. However, they are often not the same. One reason is due to a lack of checking of the documentation, especially after some modifications for done registration. This is a nonconformity because this is a documented information. It is interesting to note that the 2 statements can never be the same, not 100%. The certificate will only carry the scope statement. Exclusion is there, but in some corners of the certificate. So are the addresses. Your scope statement in your QM tends to be neatly placed in a good, flowing manner. But this is OK and acceptable.

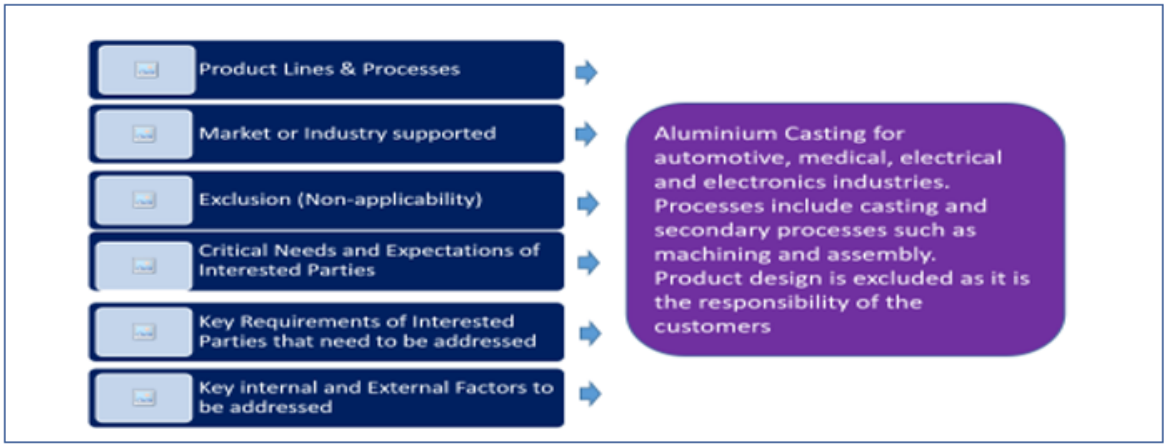
SN5.8 Is review on scope statement necessary? And how do we do that?

Review is not stated as a requirement, but in all intents and purposes, it is a requirement by the CB. That makes it a requirement. If you have derived the scope statement the way given in **Exhibit 5-2**, the review is easy. If not, **Exhibit 5-1** can guide you through, and you can summarize your evidence in **Exhibit 5-3.**

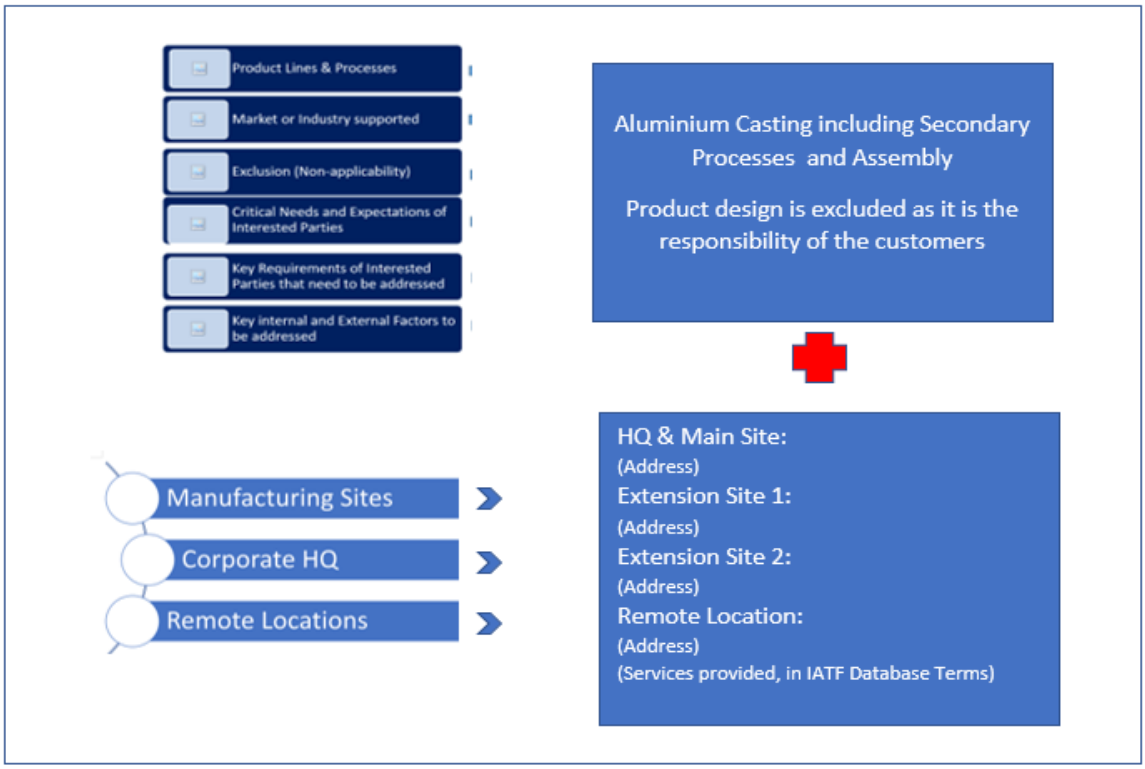
5) Exhibits

Exhibit 5-1. Determining the Scope

1. (ISO9001:2015 Scope Statement)



2. (IATF16949:2016 Scope Statement)



Remarks given here explain on the Exhibit. Do not include them as part of the document

- CB will assist you on how to word the scope, but you have to provide the information.
- Note that you are not required to state "for automotive industry". In fact, IATF will not entertain you even if you request.

Exhibit 5-2. Determining Scope, Step-by-Step

<table>
<tr><th>S/N</th><th>Guide</th><th>Actual</th></tr>
<tr><td>1</td><td>a) Current Scope
b) If no current scope, scope is determined by (2) below</td><td>Example Injection Molding and Secondary Processes</td></tr>
<tr><td>2</td><td>Scope Determination
Product, activities/processes, industries supported, Non-applicability /exclusion</td><td>
<table>
<tr><th>Categories</th><th>Specifics</th></tr>
<tr><td>Product</td><td>Plastic parts</td></tr>
<tr><td>Activities/ Processes</td><td>Injection moulding, secondary processes</td></tr>
<tr><td>Industry Supported</td><td>Electrical and Electronics, automotive</td></tr>
<tr><td>Exclusion</td><td>Product Design</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Any other significant types of interested parties in the scope?
a) Regulators.
b) Suppliers
c) Employees
d) Community
e) Emergency Agency
If yes, provide a phrase to fit into the scope</td><td>
<table>
<tr><th>Interested Parties</th><th>Yes/No</th><th>Remarks</th></tr>
<tr><td>Customers</td><td>Yes</td><td></td></tr>
<tr><td>Regulators</td><td>No</td><td>We have ISO14001 and ISO45000 for EHS</td></tr>
<tr><td>Suppliers</td><td>Yes</td><td></td></tr>
<tr><td>Employees</td><td>Yes</td><td></td></tr>
<tr><td>Community</td><td>Yes</td><td></td></tr>
<tr><td>Emergency Agency</td><td>No</td><td>We do not have processes that can lead to emergency situations</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Are all significant Internal Issues identified in Internal processes being considered? Any key issues to add to the scope statement?</td><td>Yes. No significant issue to be added to scope statement</td></tr>
<tr><td>5</td><td>Are all External Issues identified being considered? Any key issues to add to the scope statement?</td><td>Yes. No significant issue to be added to scope statement</td></tr>
<tr><td>6</td><td>Final Scope Statement, in 2 parts:
• Scope
• Non-applicability and justification</td><td>(Scope) Manufacture of Plastic Parts for Electrical and Electronics, and automotive.
(Additional statements-if applicable)
Example 1: The product shall be in compliance to XXX Act 2016.
Example 2: The production and related activities shall not create environmental problems to the immediate community
(Non-Applicability and Justification) Product Design is excluded as Organization shall manufacture to Technical Specs and Drawing provided by Customers.</td></tr>
</table>

Remarks given here explain on the exhibit. Do not include them as part of the document

- You may keep a record like this, but it is entirely optional. What is mandatory is the final scope statement is recorded somewhere in the QMS documentation.
- Note the yellow highlight section. ISO9001 actually wants open critical issues of organization context and interested parties issues to be considered for inclusion.
- In practice, CB will not encourage you to do so. You should just tackle them elsewhere in your QMS. Example 1 may be taken as a customer requirement and managed from there. Example 2, on the other hand, can be managed via your ISO14001:2015 EMS.

Exhibit 5-3. Scope Review Records

Scope Review For Year (2019)

Current Scope:

Plastic Injection Moulding for electrical, electronics, medical and automotive industries

A. Considerations

No	Areas of Consideration	Scope Change Needed		If yes, describe change needed
		No	Yes	
1	Product Lines & Processes		✓	Add Assembly
2	Market and Industry Supported	✓		
3	Exclusion (Non-Applicability)	✓		
4	Critical Needs and Expectations of Interested Parties	✓		
5	Key Requirements Risk & Opportunities. need to be addressed	✓		

B. Final Scope Statement of EMS

☐ No Change needed, Remain
☑ Changes as below:
(ISO:9001:2015:)
Plastic Injection Moulding & Assembly for electrical, electronics, medical and automotive industries
(ISO:16949:2016:)
Plastic Injection Moulding & Assembly

Prepared by Approved by

Remarks given here explain on the Exhibit. Do not include them as part of the document

- This is another optional document. If you need to have a trail how you reviewed the scope, this is one way.
- This record is good to show evidence. It is just a 'tick' job with a pen, and sign. No elaborate typing or calculations

Exhibit 5-4A Supported Sites on Certificates

Exhibit 5-5B. Indicate supporting sites on the certificate

Remarks given here explain on the Exhibit. Do not include them as part of the document

- This is the best way to establish the link between you and the remote locations
- Other alternatives include placing remote location details in you QM, and also request them to include your site in theirs
- A third way to via a contract between you and the remotes.

Exhibit 5-4B. Inclusion of supported sites in Remote Location's QM

Quality Manual QMXYZ . Rev XX

… … …

… … …

8. Support Services to Other Plant

No	Name of Organization and Address	Support services Provided
1	XYZ Thailand (Your plant)	Product Design & Testing
2	XYZ Hungary	Product Design & Testing
3	XYZ Poland	Product Design & Testing, Purchasing
4	XYZ Brazil	Product Design & Testing

Remarks given here explain on the exhibit. Do not include them as part of the document

- The best way to link you up to the remote locations is to include your names, addresses, and supported services, on their IATF 16949 certificates.
- The next best thing is to request all your remote locations to include your name in their Quality Manuals like the above example.
- This statement can also be placed on any other QMS documentation instead of the QM, although QM is the easiest and most practical.
- You can also sign a contract with the remote location, and use the contract as evidence.

>>End of Chapter 5 <<