

Subcontractor evaluation

(International Standard ISO/IEC 17043)

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CTCB



- * The CTCB is a French association, with a nonlucrative goal, which has been organizing EQA in various disciplines of medical biology since 1973.
- * CTCB is the first EQA organization accredited in the field of medical biology in France (2009)

Accreditation n° 1-2178, see www.cofrac.fr

Subcontractor, What's that ?



International Standard ISO/IEC 17043 :

3. Terms and definitions

3.14 Subcontractor

Organization or individual engaged by the proficiency testing provider to perform activities specified in this International Standard and that **affect the quality** of a proficiency testing scheme

Note : the term « subcontractor » includes what many proficiency testing providers call collaborators

What is forbidden to outsource

ISO/IEC 17043

- * **5.5.2** The proficiency testing provider shall not subcontract the planning of the proficiency test scheme (see 4.4.1.2), the evaluation of performance (see 4.7.2.1) or the authorization of the final report (see 4.8.1).

To distinguish a subcontractor of a supplier: Easy or not ?



Office Supplies	=	no impact	=	Supplier
Statistical analysis	=	Impact	=	Subcontractor
Carrier	=	Impact	=	Supplier = ?
Samples Manufacturer	=	Impact	=	it depends = ?

Where to find useful information?



GUIDELINES :

- **International guidelines**

eg : International Laboratory Accreditation Cooperation

ILAC-G13 « Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes »

- **National guidelines**

Help from national accreditation body (guideline)



Founded in 1994 under the law of 1 July 1901, **Cofrac** was designated as the unique national accreditation body by the Decree of 19 December 2008, thus recognizing accreditation as an undertaking with public authority .

In order to harmonize their practices, the accreditors draw up guides on the interpretation of accreditation requirements.

Cofrac : LAB CIL REF 02 (*Requirements for accreditation of EQA organizers according to NF EN ISO/CEI 17043*)

LAB CIL REF 02

about carriers



- * At the 5.6 ,the note for the distribution of samples explains that mail, express carriers or company distributing the proficiency test items should be considered as suppliers.

Discussion with auditors about samples Manufacturer



- * **CTCB** : 3 ways to product samples:
 - * Samples produced by CTCB with sera furnished by the Blood Bank ☞ Blood bank = Critical supplier
 - * Samples bought to a manufacturer (finish products from the catalog) which is accredited / certified for this activity ☞ manufacturer = Critical supplier
 - * Samples prepared by an Hospital (selection of patients and preparation) which is not accredited for this activity ☞ manufacturer = Subcontractor

Critical suppliers at CTCB

- * Carrier
- * Blood bank
- * accredited manufacturers of samples
- * Informatique (Computer server, Telecom for retrieve data...)
- * metrology

Subcontractors and critical suppliers : Same Evaluation ?

Further monitoring for subcontractors :

- More documents must be provided by the manufacturer (different procedures : Preparation, Homogeneity, Stability, empowering staff...)
- Audit (once a year):
 - Mandatory, advisable every 12 months : ISO/IEC 17043 (5.14.1)
 - Mandatory every 12 months if systematic subcontracting : LAB CIL REF 02

Subcontractors' audit

An exemple of the CTCB

Subcontractor = Hospital as samples provider

- * Spot Audit :
 - * we use a predefined grid
 - * This grid consists of 3 parts :
 - General requirements (legal aspect : contract, confidentiality...)
 - Technical requirements (procedures : Production, stability / homogeneity ; control of records ; personnel : technical competence...)
 - Resolution of previous departures (customer complaint, external audit, audit COFRAC on ISO 15189 ...)



Subcontractors and critical suppliers evaluation (the common procedure)

ISO/IEC 17043

5.6.4 The PT provider shall **evaluate suppliers of critical supplies and services** which affect the quality of proficiency testing schemes...shall **maintain records** of these evaluations, and list those suppliers that are approved.

Subcontractors and critical suppliers :

An exemple of a procedure for selection and evaluation

 CTCB 33 Route de Bayonne 31300 TOULOUSE		Ref : FOR.AACH.013.02 Version : 02	
		Selection and Evaluation form	
			

Name	Microbiology samples
Adress	
Adress	
Zip code / Town	
Country	FR
Phone	
Fax	
E-mail	
Web site	http://www.elitechgroup.com/en/
Evaluation date	03/10/2013
Evaluation Period	15/06/2012 - 03/10/2013
critical supplier / subcontractor	<input checked="" type="checkbox"/> Oui <input type="checkbox"/> Non

QUALITY MANAGEMENT (Coef. 2)			
Accreditation, certification or other evidence	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +3
Transmission of documents	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Claims processing	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Overall Rating (0: Unsatisfactory - 1: Unsatisfactory - 3: Satisfactory - 5: Very Satisfactory) <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input checked="" type="checkbox"/> 5			

Subcontractors and critical suppliers :

An exemple of a procedure for selection and evaluation

DEADLINES (Coef. 2)			
Delivery time	<input type="checkbox"/> NA	<input checked="" type="checkbox"/> 0	<input type="checkbox"/> +1
Average response time on phone	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Response time following a message	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Overall Rating (0: Unsatisfactory - 1: Unsatisfactory - 3: Satisfactory - 5: Very Satisfactory)			
<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5			

PERFORMANCE (Coef. 2)			
Product delivery error	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Error of sample quantity on delivery	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Altered products on delivery	<input type="checkbox"/> NA	<input checked="" type="checkbox"/> 0	<input type="checkbox"/> +0,5
Packaging integrity on delivery	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Temperature during transport	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Shelf life too short	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Information on the delivery note (batch number, expiry dates ...)	<input type="checkbox"/> NA	<input checked="" type="checkbox"/> 0	<input type="checkbox"/> +0,5
Documentation (user manual...)	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Overall Rating (0: Unsatisfactory - 1: Unsatisfactory - 3: Satisfactory - 5: Very Satisfactory)			
<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 <input type="checkbox"/> 5			

Subcontractors and critical suppliers :

An exemple of a procedure for selection and evaluation

PRICE (Coef. 2)			
Discounts	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Credits or Refunds	<input checked="" type="checkbox"/> NA	<input type="checkbox"/> 0	<input type="checkbox"/> +1
Compliant billing	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Price change over time	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Payment terms and deadline	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Price	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Overall Rating (0: Unsatisfactory - 1: Unsatisfactory - 3: Satisfactory - 5: Very Satisfactory)			
<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input checked="" type="checkbox"/> 5			

Others (Coef. 1)			
Visiting frequency of the commercial agent	<input type="checkbox"/> NA	<input checked="" type="checkbox"/> 0	<input type="checkbox"/> +1
Qualities of services (reception included)	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Problem with the supplier documentation	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Length of relationship	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Constance of quality	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +1
Availability of vendors and / or technicians	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
quickly connected with a responsible	<input type="checkbox"/> NA	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> +0,5
Overall Rating (0: Unsatisfactory - 1: Unsatisfactory - 3: Satisfactory - 5: Very Satisfactory)			
<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 4 <input type="checkbox"/> 5			

Subcontractor and critical suppliers : An exemple of a procedure for selection and evaluation

CONCLUSION		
Rate on 10	Of SELECTION	Of EVALUATION
<input type="checkbox"/> 1 à 3	unselected	Supplier does not meet our goals, must progress or be changed, contacting ...
<input type="checkbox"/> 3 à 5	Unselected, contacting ...	Supplier must progress, contacting ...
<input type="checkbox"/> 5 à 8	Can be selected	Efficient provider able to meet our goals
<input checked="" type="checkbox"/> 8 à 10	Can be selected	performant Supplier , fully in line with our goals

Note

Approval of the suppliers

- * Presentation of evaluations at the management review for approval
- * Approved Suppliers List (ISO 17043 :5.6.4)

Thanks for your attention

