SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

GENERAL INFORMATION ON THE AUTHORIZED THIRD PARTY PROCESS

WHAT IS AN AUTHORIZED THIRD PARTY?

They are persons authorized by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) to support the authority in sanitary control and surveillance through the performance of various analytical tests, sampling and/or verification acts or to carry out bioequivalence and/or bioavailability studies.

WHAT ARE THE ADVANTAGES OF BEING AN AUTHORIZED THIRD PARTY?

Nationally recognized studies on health risks.
They provide services to the entire export and import market for products within the country subject to Sanitary Control.

The only results that can legally support acts of authority are those issued by the authority itself and by Authorized Third Parties.

WHAT ARE THE TYPES OF AUTHORIZED THIRD PARTY AUTHORIZATION?

- **Interchangeability Units:**

- Call published in the DOF on March 26, 1998 addressed to individuals or legal entities interested in operating as authorized third parties to perform drug interchangeability tests and issue the corresponding results, which can be accessed through the following link:

  http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

- **Testing Laboratories.**
- Call published in the DOF on October 10, 2002 addressed to individuals and legal entities in general interested in acting as authorized third parties, assistants in sanitary control, which can be accessed through the following link:
  http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

- **Verification Units**

- Call published in the DOF on October 10, 2002 addressed to individuals and legal entities in general interested in acting as authorized third parties, assistants in sanitary control, which can be accessed through the following link:
  http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

- Call published in the DOF on June 30, 2011 addressed to individuals and legal entities interested in acting as Authorized Third Parties, assistants in the sanitary control of medicines, which can be accessed through the following link:
  http://dof.gob.mx/nota_detalle.php?codigo=5198705&fecha=06/30/2011

- Call published in the DOF on June 30, 2011 addressed to individuals and legal entities interested in acting as Authorized Third Parties, assistants in the sanitary control of establishments, which can be accessed through the following link:
  http://www.dof.gob.mx/nota_detalle.php?codigo=5198706&fecha=06/30/2011

- Call published in the DOF on July 6, 2011 addressed to individuals and legal entities interested in acting as Authorized Third Parties, assistants in the sanitary control of medical devices, which can be accessed through the following link:
  http://www.dof.gob.mx/nota_detalle.php?codigo=5199684&fecha=06/07/2011

WHAT IS THE FLOW OF THE THIRD PARTY AUTHORIZATION PROCESS?

- Verification Units

- Testing Laboratories and Interchangeability Units

WHAT ARE THE GENERAL REQUIREMENTS NEEDED TO BECOME AN AUTHORIZED THIRD PARTY? (For any item)?

ÿ **Submit the application and corresponding documents to act as an authorized third party in:**

At the Comprehensive Service Center (CIS) of the Federal Commission for the Protection against Sanitary Risks located at Oklahoma No. 14, Colonia Nápoles, Del. Benito Juárez, Mexico DFCP 03810, by requesting an appointment through the Telephone Service Center at 01 800 033 5050 or through the Internet page

http://www.cofepris.gob.mx/TyS/Paginas/Solicitud-de-Cita-para-el-Ingreso-de-Trámites.aspx

If the applicant is located outside the Federal District, he/she can send his/her application and documentation by courier and we will send the response to his/her request by the same means, just attach a prepaid guide with delivery service. harvest.

1.- Application and payment format:
Authorization, certificate and visit form duly completed and preferably filled out by machine.

http://www.cofepris.gob.mx/TyS/Paginas/Formatos.aspx

Proof of payment of e5cinco rights. http://201.147.97.100:82/jsp/AGFPD/jspDPA/principalDPAJsp.jsp

Note: In the case of public higher education institutions and state public health laboratories, they are exempt from paying fees (section II of article 195-C of the Federal Fees Law).

2.- Have a Quality Management System

Quality Manual based on:

For Testing Laboratories: NMX-EC-17025-IMNC-2006.
For Verification Units: NMX-EC-17020-IMNC-2000.
And for interchangeability units: NOM-177-SSA1-1998.

Deliverables: Copy of the Quality Manual that considers all aspects according to the corresponding regulatory reference.

For the application of the rules, the application criteria can be consulted:

- NMX-EC-17025-IMNC-2006, in the following link: http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx - NMX-EC-17020-IMNC-2000, in the following link: http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

3.- Legal identity of the natural or legal person:

Deliverables: Articles of incorporation in which the area that will be subject to authorization is specified within the corporate purpose and no conflict of interest is observed between the shareholders (certified or apostilled copy)

4.- Demonstrate that there is no Conflict of Interest

Formats of No Conflict of Interest and Confidentiality:

Deliverables: Required and signed formats of no conflict of interest and confidentiality (originals)

The format to address matters related to avoiding conflicts of interest can be found at the following link: http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

The format relating to the confidentiality declaration of all personnel working in the organization can be found at the following link: http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

5.- Have technical, human and financial capacity.

5.1 Organization Manual:
Deliverables: Copy of the Organization Manual or equivalent that includes the organizational structure, organization chart with names, and job profiles according to the corresponding regulatory reference.

5.2 Staff
Deliverables: Copies of the CVs of all personnel working in the organization with the documents supporting their technical competence, Job descriptions, Detection of training needs, Training program, Supervision program, a document that ensures that the organization's personnel are free from pressures that could influence their technical judgment, Procedures related to training (including the detection of training needs) in accordance with the corresponding regulatory reference.

5.3. Items to be Authorized
Deliverables: Letter on letterhead indicating the area in which you wish to be an Authorized Third Party, signed by the legal representative of the organization (original)

6.- Responsibility
Deliverables: Letter on letterhead indicating responsibility for all activities carried out within the organization and by the technical staff and the results issued, signed by the legal representative of the organization (original)

WHAT ARE THE SPECIFIC REQUIREMENTS NEEDED TO BECOME AN AUTHORIZED THIRD PARTY?
(According to the requested item)?

Testing laboratories

1.- Analytical framework that you wish to authorize described as follows, which must be integrated into the document indicated in point 5.3 of General Requirements:

Bibliographic Reference	Determination
NOM-092-SSA1-1994. Assets and services. Account method of aerobic bacteria on plate	Method for the Accounting of aerobic bacteria in plaque

2.- Review of applications and contracts
Deliverables: Copy of the Procedure related to review of applications and contracts.

3.- Acquisitions
Deliverables: Copy of the Procedure for the selection and acquisition of services and supplies.

4.- Control of non-conforming work
Deliverables: Copy of the Procedure for non-conforming work.

5.- Corrective and preventive actions
Deliverables: Copy of the Corrective and Preventive Actions Procedure.

6.- Facilities
Deliverables: Copy of the plan of the organization's facilities that indicates in detail the location of the areas, evaluation routes and emergency exits.

7.- Measuring equipment and instruments
Deliverables: Copy of the inventory of measuring equipment and instruments, calibration program, maintenance program, calibration certificates, files of each and every one of the measuring equipment and instruments.

8.- Materials and reagents
Deliverables: Copy of the inventory of materials and reagents.

9.- Sample control
Deliverables: Copy of the Sample Control Procedure.

10.- Methods
Deliverables: Copy of the Test Methods, procedures or instructions related to the tests to be Authorized.

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11.- Registration forms
Deliverables: Copy of the Procedure related to the registration forms.

12.- Results report
Deliverables: Copy of the results report format, in accordance with the corresponding regulations, as well as the document indicating how the results report should be prepared.

13.- Supervision
Deliverables: Copy of the Supervision Procedure, supervision program.

14.- Archive
Deliverables: Copy of the Archiving Procedure.

15.- Safety
Deliverables: Copy of the Constitutive Act of the Joint Safety and Hygiene Commission, work regulations.

VERIFICATION UNITS

1.- Verifiers

Within the document indicated in point 5.3 of General Requirements, the areas in which you wish to be authorized and the personnel proposed as verifiers for each of these must be specified.

The original CV of the staff proposed as verifier must be submitted, with all supporting documentation.

2.- Liability insurance Simple
copy of the document that proves that the verification unit has current comprehensive liability insurance.

3.- The documents referred to in the application criteria of NMX-EC-17020-IMNC-2000

UNITS OF INTERCHANGEABILITY

1.- Copy of the Pilot Study (for any area). This must
consider each of the requirements of the standard.

2.- Copy of the Discharge of the Health Officer

3.- For the case of Clinical Units.

A copy of the Authorization of the clinical protocol, as well as a copy of the discharge notice from the Ethics and Research Committee, must be submitted.

4.-
Equipment *Deliverable:* Copy of the calibration, verification and/or equipment maintenance program.

5.- ***Deliverable***

Facilities : Copy of the plan of the organization's facilities that indicates in detail the location of the areas, evaluation routes and emergency exits.

6.- Safety
Deliverables: Copy of the Constitutive Act of the Joint Safety and Hygiene Commission, work regulations.

CAN DOCUMENTATION BE SUBMITTED ELECTRONICALLY?
If possible, except for those documents that specifically indicate that they must be originals.

HOW IS THE EVALUATION VISIT NOTIFIED?

Notification of evaluation visits is by means of a letter, which is sent by email or fax to the organization. The letter states the following:

- Evaluation days
- Evaluation group
- Scope of the visit depending on the area to be authorized.

For organizations located outside of Mexico City or the metropolitan area, an additional letter with the corresponding cost will be sent to the Commission. Payment for the visit must be made using the e5cinco form. http://201.147.97.100:82/jsp/AGFPD/jspDPA/principalDPAJsp.jsp

WHAT HAPPENS IF THERE ARE OBSERVATIONS DURING THE EVALUATION VISIT?

If findings are detected during the evaluation visit, a corrective action plan with commitment dates for compliance must be sent, which must be sent, within a period of no more than 15 days after the evaluation visit, to the Comprehensive Service Center (CIS) of the Federal Commission for the Protection against Sanitary Risks located at Monterrey No. 33, Col. Roma, Cuauhtémoc Delegation, Mexico City, CP 06700
ground floor.

If the applicant is located outside the Federal District, he/she can send his/her application and documentation by courier and we will send the response to his/her request by the same means, just attach a prepaid guide with collection service.

Subsequently, and in accordance with their corrective action plan, they must send evidence of their implementation in a single presentation and in accordance with the time frames established in the Health Supplies Regulation and the Sanitary Control Regulation for Products and Services.

Once all evidence of the implementation of corrective actions has been received, the corresponding verification visit will be carried out, if applicable, since verification visits will not be carried out for documentary findings.

WHEN DO THEY DELIVER THE AUTHORIZATION?

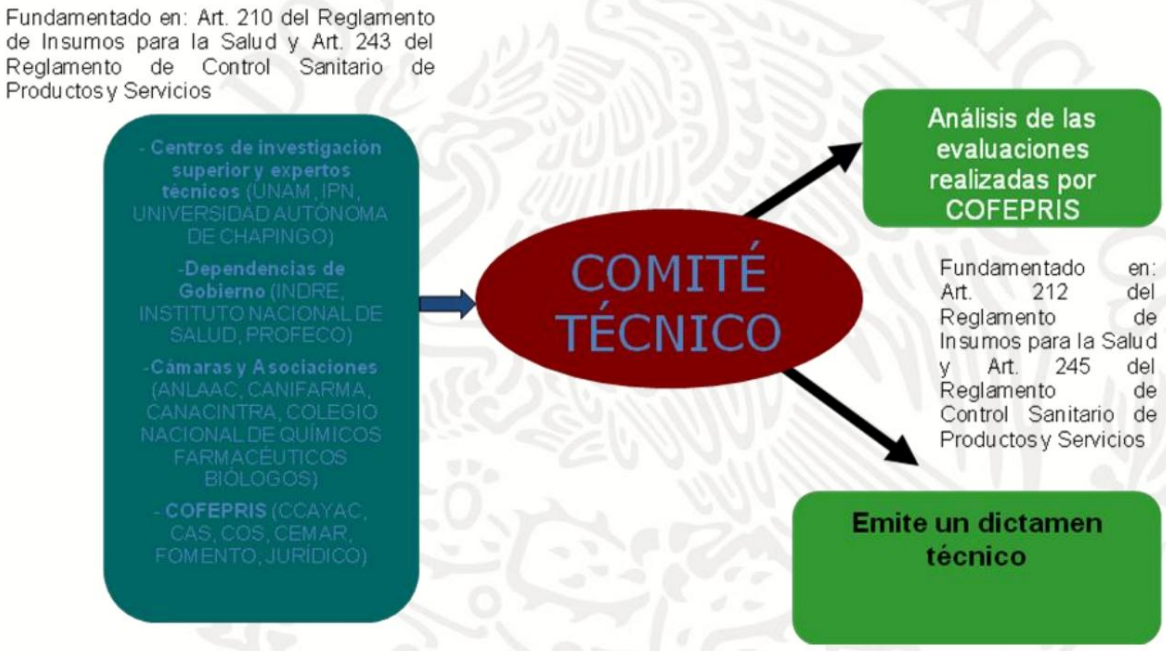
Following the verification visit or after receiving evidence of the implementation of corrective actions, as the case may be, the procedure is submitted to the Technical Committee of Authorized Third Parties so that it may issue its technical opinion and decide whether or not to approve the procedure.

The opinion of the Technical Committee of Authorized Third Parties is sent to the Health Authorization Commission for resolution and issuance of the corresponding document.

WHEN DOES THE AUTHORIZED THIRD PARTY TECHNICAL COMMITTEE MEET?

The Authorized Third Party Technical Committee meets once a month, and the Committee's meeting dates are available at the following link:
http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

WHO MAKES UP THE AUTHORIZED THIRD PARTY TECHNICAL COMMITTEE?



WHAT IS THE VALIDITY OF THE AUTHORIZATION?

The Authorization is valid for 2 years

WHEN SHOULD THE APPLICATION FOR EXTENSION OF THE VALIDITY OF THE AUTHORIZATION (RENEWAL) BE SUBMITTED?

According to the Regulations on Sanitary Control of Products and Services, the application must be submitted 1 month before the expiration of the Authorization.

WHAT DOCUMENTATION SHOULD BE SUBMITTED WITH THE APPLICATION FOR EXTENSION OF THE VALIDITY OF THE AUTHORIZATION (RENEWAL)?

1.- Application and payment format:
Authorization, certificate and visit form duly completed and preferably filled out by machine.
http://www.cofepris.gob.mx/TyS/Paginas/Formatos.aspx

Proof of payment of e5cinco rights. http://201.147.97.100:82/jsp/AGFPD/jspDPA/principalDPAJsp.jsp

Note: In the case of public higher education institutions, they are exempt from paying fees (section II of article 195-C of the Federal Fees Law).

2.- Conflict of Interest and Confidentiality Formats:
Deliverables: Required and signed forms of no conflict of interest and confidentiality (originals).

3.- Items to be extended (renewed)
Deliverables: Letter on letterhead indicating the category to be extended (renewed) as an Authorized Third Party, signed by the legal representative of the organization (original)

In the case of testing laboratories, you must additionally indicate the analytical framework, according to the following:

Bibliographic Reference	Determination
NOM-092-SSA1-1994. Assets and services. Account method of aerobic bacteria on plate	Method for the Accounting of aerobic bacteria in plaque

In the case of verification units, you must indicate the items you wish to extend (renew) and the personnel proposed as verifiers for each of these.

4.- Legal identity of the natural or legal person
If the organization has made changes to its articles of incorporation, these must be sent along with the application.

5.- Quality Manual, Organization Manual and Procedures Manual
These should only be entered if there have been significant changes to the quality management system.

Note: Updates are not considered significant changes.

6.- Responsibility
Deliverables: Letter on letterhead indicating responsibility for all activities carried out within the organization and by the technical staff and for the results issued, signed by the legal representative of the organization. (original)

WHAT IS THE EVALUATION PROCESS FOR EXTENDING THE VALIDITY OF THE AUTHORIZATION (RENEWAL)?

The evaluation process is the same as that described in the previous points, depending on the area.

IF YOU WANT TO EXPAND THE ANALYTICAL FRAMEWORK OR THE ITEMS AS A VERIFICATION UNIT OR INTERCHANGEABILITY UNIT, WHAT DOCUMENTS SHOULD BE ENTERED?

1.- Application and payment format:
Authorization, certificate and visit form duly completed and preferably filled out by machine.
http://www.cofepris.gob.mx/TyS/Paginas/Formatos.aspx

Proof of payment of e5cinco rights. http://201.147.97.100:82/jsp/AGFPD/jspDPA/principalDPAJsp.jsp

Note: In the case of public higher education institutions, they are exempt from paying fees (section II of article 195-C of the Federal Fees Law).

2.- Conflict of Interest and Confidentiality Formats:
Deliverables: Required and signed forms of no conflict of interest and confidentiality (originals).

3.- Areas to expand
Deliverables: Letter on letterhead indicating the area to be expanded as an Authorized Third Party, signed by the legal representative of the organization (original)

In the case of testing laboratories, you must additionally indicate the analytical framework, according to the following:

Bibliographic Reference	Determination
NOM-092-SSA1-1994. Assets and Method services. Account method of aerobic bacteria on plate	for the Accounting of aerobic bacteria in plaque

In the case of verification units, you must indicate the areas you wish to expand and the personnel proposed as verifiers for each of these.

In the case of interchangeability units, the pilot study carried out for the item to be expanded must be entered.

4.- Legal identity of the natural or legal person

If the organization has made changes to the articles of incorporation for the items to be expanded, these must be sent along with the application.

5.- Quality Manual, Organization Manual and Procedures Manual

Only those that were modified by the expansion, as well as the procedures related to the new items, should be entered.

6.- Responsibility

Deliverables: Letter on letterhead indicating responsibility for all activities carried out within the organization and by the technical staff and for the results issued, signed by the legal representative of the organization. (original)

ARE THERE ANY CRITERIA OR GUIDELINES FOR THE REQUIREMENTS?

Currently on the COFEPRIS page in the procedures and services section in the Third Parties section Authorized, the following is published:

- Validation Criteria for Physicochemical Methods
- Criteria for Validation of Microbiological Methods
- Verification Unit Evaluation Guide
- Interchangeability Units Evaluation Guide
  - or Analytical Unit
  - or Clinical Unit
  - or Dissolution Profiles Analytical Unit
- Testing Labs Evaluation Guide
- Application criteria of the NMX-EC-17025-IMNC-2006 standard

- Application criteria of the NMX-EC-17020-IMNC-2000 standard
- Calls to act as Authorized Third Parties
- List of Authorized Third Parties
    - o Verification Units o
    - Interchangeability Units o Testing
    - Laboratories
- Confidentiality and Non-Conflict of Interest Formats

It can be seen at the following link: http://www.cofepris.gob.mx/TyS/Paginas/Terceros-Autorizados.aspx

Update date: March 2013