

FACTORY INSPECTION RECOGNITION AND COORDINATION BETWEEN THE NCBs

This document is applicable to be used for any product category

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IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components

Factory Inspection Coordination & Monitoring between the NCBs

(Edited extract of Report from the CB-FCS Special Meeting held on 2010-04-28/29 in Geneva, Switzerland)

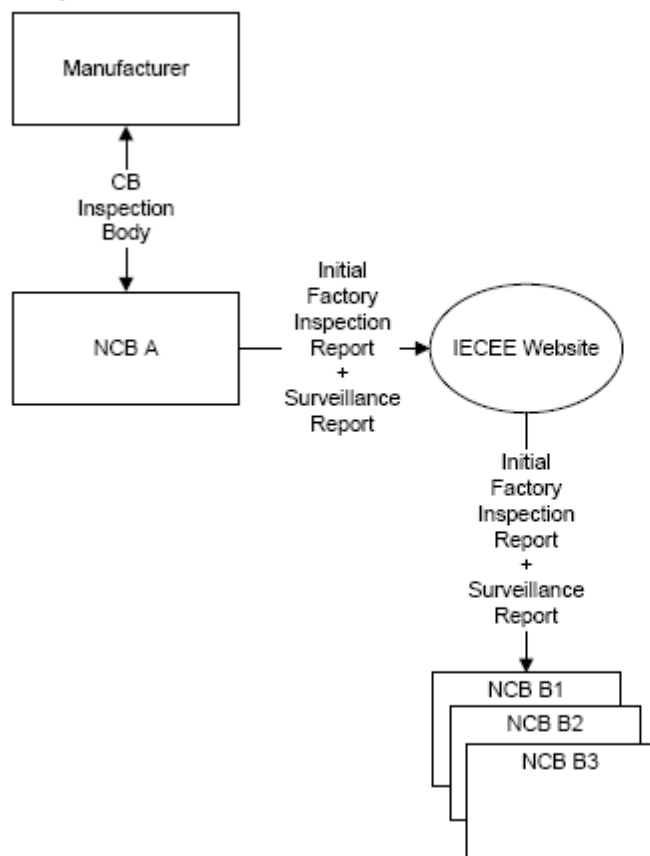
Following the presentation of the result of the Working Session-Group 2 (convened by Vladimir Filiac, EZU), some discussion arose around the meaning of IFI (Initial Factory Inspection) and it was recognized that some NCBs may have in their certification program two Initial Factory Inspections, i.e. one to assess the facilities, assembly line and Quality Management System of the Factory, followed by a second Initial Factory Inspection to assess the production of the certified product.

From the ensuing discussion it was agreed to assign the IECEE FIC to undertake this issue in the final development of the Factory Inspection Procedures and clarify/detail the existing models of Initial Factory Inspections.

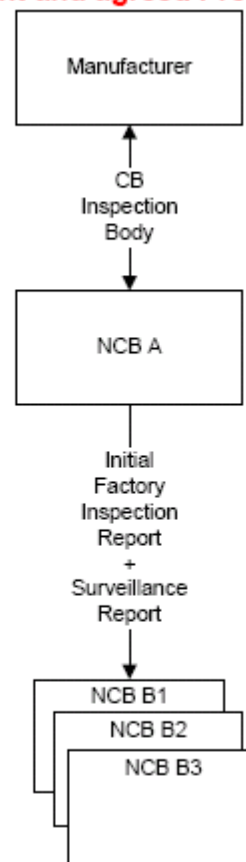
Group 2 further proposed that to optimize the flow of exchange and consultation of Initial Factory Inspection and Surveillance Reports by the Member NCBs, such reports could be posted into a specific area of the IECEE Web Site as a centralized Data Base.

In spite of expression of sympathy and for the sake of launching the simplified CB-FCS as soon as approved by the CMC it was agreed that the exchange of Initial Factory Inspection and Surveillance Reports will continue to be processed between the NCB "A" and the NCB "B1", "B2", "B3", etc...

Proposed Process



Present and agreed Process





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General principles and process of the Multilateral Agreement related to subcontracting and acceptance of Factory Inspection

0. General Principles

This Agreement details the principles and process to be followed by the Signatories of this Agreement when undertaking factory inspections on behalf of each other.

In this Agreement:

- NCB“A” is defined as the NCB that carries out Initial Factory Inspections & Factory Surveillance on behalf of NCB “B1”, “B2” “B3” “B4”, etc.
- NCB”B” (if more than one NCB “B1”, “B2” “B3” “B4”, etc.) is defined as the requesting NCB that subcontracts its Initial Factory Inspections & Factory Surveillance to NCB”A”.

By signing the CB-FCS MLA the Signatory NCBs agree to conform to all requirements of IECEE 03 and in particular to maintain confidentiality in respect of all information exchanged between the NCBs.

In particular, the Signatories will not disclose any information to third parties who do not have rights to access such information, even after termination of this Agreement.

Signatories of the Agreement who violate the Factory Inspection Multilateral Agreement or conduct-s their part of the operation in an unsatisfactory way can be suspended for a stated period. Such a suspension shall be agreed upon by all the other Signatories and formally recorded.

During the validity of this Agreement the IECEE Peer Assessment Committee (PAC) shall monitor the competence, performance, integrity and confidentiality of the relevant Factory Inspection Department of the NCBs on a regular basis according to the relevant requirements of ISO/IEC Guide 65.

It is the responsibility of the IECEE to organize trainings and workshops aiming at achieving consistent techniques to carry out Initial Factory Inspections & Factory Surveillance.

It is the responsibility of the individual NCBs Signatories of this Agreement to organize training sessions to teach how to cover their “Deviations” from the IECEE Initial Factory Inspections & Factory Surveillance Procedures.

Although this Agreement is meant to cover both Initial Factory Inspections and Factory Surveillance some NCBs for particular reasons (e.g. Regulatory Requirements) could only (temporarily) adhere to Initial Factory Inspections whilst awaiting that a solution is found to also adhere to Initial accept and subcontract Factory Surveillance.

This Agreement comes into effect on the date of its signing.



1 Definitions

For the purposes of CB-FCS, the following definitions apply:

1.1 NCB “A”

- a) In the field of the IECEE System, NCB A is a National Certification Body accepted to participate in CB-FCS to which an applicant first applies to obtain a CB-FCS Certificate and a Conformity Assessment Report
- b) In the field of the CB-FCS Scheme, NCB A is the Body **Issuing** CB-FCS Certificate and a Conformity Assessment Report
- c) In the field of Factory Inspection, NCB A is also identified as the **Subcontractor** that performs factory inspection on behalf of NCB Bs.

1.2 NCB “B”

- a) In the IECEE System, NCB B is a National Certification Body accepted to participate in CB-FCS to which an applicant successively applies to be granted its certification mark, or approval, making use of the CB-FCS Certificate and Conformity Assessment Report issued by the NCB “A”.
- b) In the field of the CB-FCS Scheme NCB B is the **Recognizing** Body that grants its private mark to Applicants on the basis of CB-FCS Certificates and Conformity Assessment Reports.
- c) In the field of Factory Inspection, NCB B is also identified as the **Primary Contractor** of Factory Inspections on factories located in the country of residence of NCB A.

NOTE An application to seek CB-FCS Membership can only be made if the NCB is recognized and accepted as member of the CB Scheme as Issuing/Recognizing Body in the last three years prior to the application.

1.3 Conformity Assessment Certificate (CAC)

A CB-FCS Conformity Assessment Certificate is a document, issued by a Member NCB, used to inform other NCBs, in conjunction with the attached Conformity Assessment Report.

A Conformity Assessment Certificate is valid only when the relevant Conformity Assessment Report is attached.

1.4 Conformity Assessment Report (CAR)

The Conformity Assessment Report (OD CB-FCS 117) is a complete administrative batch of product and factory information developed by the NCB “A” and made available to the NCB “B” by the applicant. It includes the following conformity assessment details to demonstrate that the



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product/components and the factory assembly line and quality system have been fully evaluated and meet all applicable requirements:

- **for the product:**
 - a) Information including product description, product test results, observations, National Differences, etc.)
 - b) Any additional information required by NCB “Bs”.

- **for the factory:**
 - a) Initial or Surveillance Factory Inspection Report as applicable.
 - b) Description of the arrangements made by NCB “A” to ensure ongoing compliance of the product with the requirements. (e.g. copy of the license).

1.5 Conformity Assessment System n°5

This system includes product testing and assessment of the involved quality system.

Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity.

This certification system includes the following:

- samples requested by the certification body (NCB),
- testing and measuring of the relevant product(s) by the testing laboratory (CBTL),
- initial factory inspection of the production process by the NCB’s Inspectorate Department,
- evaluation of the test report and initial factory inspection report by the NCB,
- decision and issuance of the IECEE CB-FCS Conformity Assessment Certificate by the NCB,
- surveillance (factory inspection) of the quality system and the production process of the factory location,
- re-testing or inspection of samples from the factory or the from the open market, or both.

NOTE The extent to which the three elements of ongoing surveillance are conducted may be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

1.6 CB Testing Laboratory (CBTL)

A testing laboratory which, after having been proposed as a candidate by an Issuing and Recognizing NCB, and which, after having been successfully assessed according to these Rules of Procedure, is accepted into CB-FCS.

NOTE An application to seek CB-FCS Membership can only be made if the CBTL is recognized and accepted to operate within the CB Scheme in the last three years prior to the application.

1.7 NCB’s Inspectorate Department

A Department of the NCB or an outsourcing subcontractor carrying out initial and factory surveillance inspection on behalf of NCB A and one or more NCB Bs.



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1.8 Factory Inspection Differences

Specific requirements in addition to the Factory Inspection Requirements OD-4004.

NOTE Those restrictive requirements that deviated from the IECEE Factory Inspection Requirements and which limit the possibility to offer the relevant product for sale in the country concerned, are also considered to be specific requirements.

1.9 Factory Inspector

A specialist of Factory Inspection appointed by its responsible NCB.

1.10 Registered Factory Peer Assessor (RFPA)

A specialist of Factory Inspection that is duly nominated by its responsible NCB and registered by the IECEE Secretariat. A RFPA has the obligation to attend the trainings and workshops as organized by the IECEE. RFPA's competence is checked and confirmed through due examinations.

1.11 Technical Reviewer

A specialist of Factory Inspection and/or other Product Categories.

1.12 Applicant

A firm or a person who applies to an NCB "A" for obtaining a CAC or to an NCB "B" for national certification or approval at the national level based on acceptance of the CAC and associated CAR issued by an NCB A.

1.13 Manufacturer

An organisation, situated at a stated location or stated locations, that carries out or controls stages in the manufacture, assessment, verification, handling and storage of a product. A Manufacturer has full responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in this regard.

1.14 Factory

The location at which the product is produced or assembled and initial and factory surveillance inspection service is established by an NCB A and/or one or more NCB B.

1.15 Operational Document (OD)

A normative document approved by the CMC and used to cover the various operations within CB-FCS. Operational Documents are used in conjunction with the Basic Rules IECEE 01 and Rules of Procedure IECEE 03.



2. Acceptance of NCBs carrying out Factory Inspections

2.1 In addition to the requirements for the acceptance of Issuing and Recognizing NCBs as detailed in the CB-FCS Rules of Procedure IECEE 03, NCBs operating in the CB-FCS Scheme shall comply with the relevant requirements pertaining to the Bodies carrying out Factory Inspections.

NCBs carrying out Factory Inspections shall not be, or be influenced by, a body that manufactures or trades in electrotechnical equipment and components. Furthermore, the NCB shall be impartial and not offer assistance or other services to the factory that may compromise the objectivity of its factory inspection activities and decisions.

2.2 The NCB's Inspection Body's general competence, efficiency, experience, and familiarity with the Factory Inspection techniques, procedures, NCB B differences as well as compliance with ISO/IEC Guide 65 and any relevant Operational Document that applies, shall be demonstrated by an on-site assessment under the IECEE Peer Assessment Program. Accreditation, if any, shall be taken into account when a reputable accreditation body has provided an accreditation service to such NCB, however the IECEE Peer Assessment shall be conducted to cover the IECEE specific requirements pertaining to the Electrotechnical Sector.

NOTE A reputable Accreditation Body (AB) is an AB well known in the market, for e.g. IAF Member accreditation bodies. In case of doubt, the IECEE Secretary will consult with the PAC to determine the level of suitability of the Accreditation Body, if different from being, for e.g. an IAF Member Accreditation Body.

2.3 The NCB's Inspection Body shall be assessed by one IECEE Registered Assessor to be appointed by the IECEE Secretariat. The IECEE Registered expert shall normally be recruited from Issuing and Recognizing NCBs that are members of the CB-FCS.

At the discretion of the IECEE Secretariat, the number of experts may be increased if justified by the size of the activities of the NCB's Inspectorate Department.

The NCB's Inspection Body shall be given the name(s) and qualification(s) of the IECEE Registered Assessor proposed to be appointed by the IECEE Secretariat.

The relevant NCB may object "for cause" (reasons to be stated) to the appointment of the IECEE Registered expert. The mandate given to the IECEE Registered Assessor shall be clearly defined and made known to the candidate.

The mandate shall include critical assessment of any specific differences from IECEE Factory Inspection Procedures as declared by Subcontracting NCB "B".

The NCB to be assessed shall express its willingness to pay the travelling and living expenses and other applicable fees arising from the assessment (See OD-2026). An estimate of these expenses and fees shall be provided to the candidate NCB in advance by the IECEE Registered Assessor and agreed to by the candidate NCB.

During the assessment, the IECEE Registered Assessor shall prepare a draft report (last edition OD-4001 Factory Inspection Report) that shall be discussed with the management of the responsible NCB.



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2.4 The confidential Factory Inspection Report, containing their findings and recommendations, shall be submitted to the IECEE Secretariat.

The "**Open Part**" of the OD-4001 Factory Inspection Report is posted on the dedicated restricted area of the IECEE Web Site for review and comment by the IECEE Members. Any comments on the OD-4001 Factory Inspection Report shall be submitted to the IECEE Secretariat within one month of the date of posting of the assessment report on the Web Site.

NOTE: The "Open Part" of the Assessment Report is composed of the OD-4001 Factory Inspection Report, and the Non-Conformity Sheets.

2.5 If the outcome of the IECEE Registered Assessor review is negative, the IECEE Secretariat may, depending on the findings, recommend to the responsible NCB:

- to put the application on hold, or
- to be subjected to a new (follow up) factory inspection.

2.6 If the outcome of the IECEE Registered Assessor review is positive, the IECEE Secretariat will notify the responsible NCB on the outcome. In between the CMC meetings, the IECEE Secretariat, on behalf of the CMC, notifies the NCB of the provisional decision. The IECEE Secretariat shall submit a final recommendation to the CMC for formal decision at its next regularly scheduled meeting.

An NCB wishing to discontinue recognizing Initial and Factory Surveillance Reports shall, via the Member Body of the IECEE, notify the Executive Secretary of the IECEE and shall indicate the date from which the discontinuation becomes effective at least one year in advance. Such a notice automatically cancels the right to operate in the CB-FCS Scheme and to issue Conformity Assessment Certificates in the field of the IECEE System. The IECEE Secretariat will post this information on the IECEE Web Site and also inform all other NCBs of the decision.

Inspection body proceeds inspection.

3. Roles and responsibilities

3.1 Role and responsibilities of NCB "B"

When acting as a Primary Contractor in the field of the CB-FCS Scheme, NCB "B" shall provide NCB "A" with a brief containing detailed written instructions related to sub-contracted Factory Location basically detailed in Sub-clauses 1.1 to 1.5 of OD-4001, also including Factory Inspection Differences (special Requirements).

NCB "B" shall also provide the frequency of the sub-contracted Factory Inspection in a calendar year.



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3.2 Role and responsibilities of NCB "A" (Inspection Body)

When acting as the Sub-Contractor of Factory Inspections on behalf of NCBs "B", NCB "A" shall administrate Factory Inspections so as to optimize time and costs.

Where the NCB "A" receives several requests for the same factory location, NCB "A" will undertake to organize inspections so as to achieve maximum economy of resource. Inspection fees shall be established by the NCBs "B" and communicated to the NCB "A" on a yearly basis.

After each Factory Inspection NCB "A" will provide NCBs "B" with the:

- a) common Factory Inspection Report - OD-4001,
- b) relevant non-conformities by using the Non-Conforming Sheet included in the Factory Inspection Report,
- c) specific non-conformities related to Factory Inspection Differences only to the Primary-Contractor (NCB "B").

Unless a specific Agreement is signed between NCB "A" and NCB "B", it is the responsibility of the Primary-Contractor (NCB "B") to directly invoice the Inspection Fees to the manufacturer or the Holder (Applicant) of the Licence/Certificate

Note: Inspection Fees could be part of a separate Agreement between NCB "A" and NCBs "B".

If the Inspection Fees Agreement between NCB "A" and NCB "B" is so that the invoicing is done by the NCB "A", in case of lack of payment by the manufacturer, NCB "B" guarantees payment for the inspection services provided by NCB "A".

3.3 Archives and confidentiality of Factory Inspection Reports

NCB "A" (Inspection Body) shall be so organized to properly centralize and archive Factory Inspection Reports so as to be able to provide the relevant NCBs "B" due information over the Factory Inspections carried out and their results upon follow up request by the Primary-Contractor NCB "B". Unless otherwise specified in a formal way by the Primary-Contractor NCB "B", Factory Inspection Reports shall not be disclosed or disseminated to anyone else but the Primary Contractor NCB "B" and the relevant authorized contact person at the Factory Location.

3.4 Competence and registration of Factory Inspectors

It is the responsibility of the relevant IECEE NCBs to ensure that their operating Inspection Bodies have the necessary background competence and skill to act as Inspectors.

It is also the responsibility of the relevant IECEE NCBs to nominate Inspectors that will be acting as IECEE Registered Inspectors once they will get the necessary training provided by the IECEE System.

It is the responsibility of the IECEE FIC to prepare the necessary Training Programs for future IECEE Registered Inspectors, in order to achieve a uniform understanding of the Factory Inspection Procedure.

For the Specific Requirements deviating from the IECEE Factory Inspection Procedure, it is the responsibility of the relevant NCBs to provide the specific Training Programs and the Instructor that will be providing the specific training.



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The IECEE System will fund the costs related to the trainings and workshops pertaining to the IECEE Factory Inspection Procedure whereby the costs related to the specific NCBs Training Programs will be at the charge of the relevant NCBs.

3.5 Registration of Factory Peer Assessors

Registered Factory Inspectors are entitled to also apply to be registered Factory Peer Assessors. Specific Trainings will be dispensed by the IECEE to qualify Registered Factory Peer Assessors. Likewise IECEE Lead Assessors and Technical Assessors, once registered as Factory Peer Assessors can be assigned to carry out Peer Assessments to the relevant NCB's Inspection Bodies for acceptance and continued acceptance to operate in the IECEE System and more particularly in the IECEE CB-FCS Scheme.

3.6 Peer Assessment of NCB's Inspection Bodies

For NCBs Signatories of the CB-FCS MLA, if already accepted to operate in the CB Scheme, the acceptance to operate in the IECEE CB-FCS Scheme will entail an Initial stand alone Assessment of the NCB's Inspection Body by one Registered Factory Peer Assessors.

For NCBs Signatories of the CB-FCS MLA already accepted to operate in the CB-FCS Scheme, the assessment of the NCB's Inspection Body will take place during the on-going Re-Assessment Program. In which case a Registered Factory Peer Assessors will be appointed in addition to the regular Assessment Team, composed by one Lead Assessor and one Technical Assessor.

Likewise for NCBs and CBTLs, the IECEE Secretariat will keep the records of the Peer Assessment Program pertaining to the NCB's Inspection Bodies granting their competence to operate in the field of Factory Inspections against the relevant clauses of ISO/IEC Guide 65 and the IECEE Factory Inspections Rules and Procedures.

3.7 Matrix of the CB FCS Full Certification Scheme Multilateral Agreement

The CB-FCS Full Certification Scheme Multilateral Agreement will be centralized by the IECEE Secretariat, using a matrix of NCBs to define each and every agreement between NCBs, see example in the attached excel file.

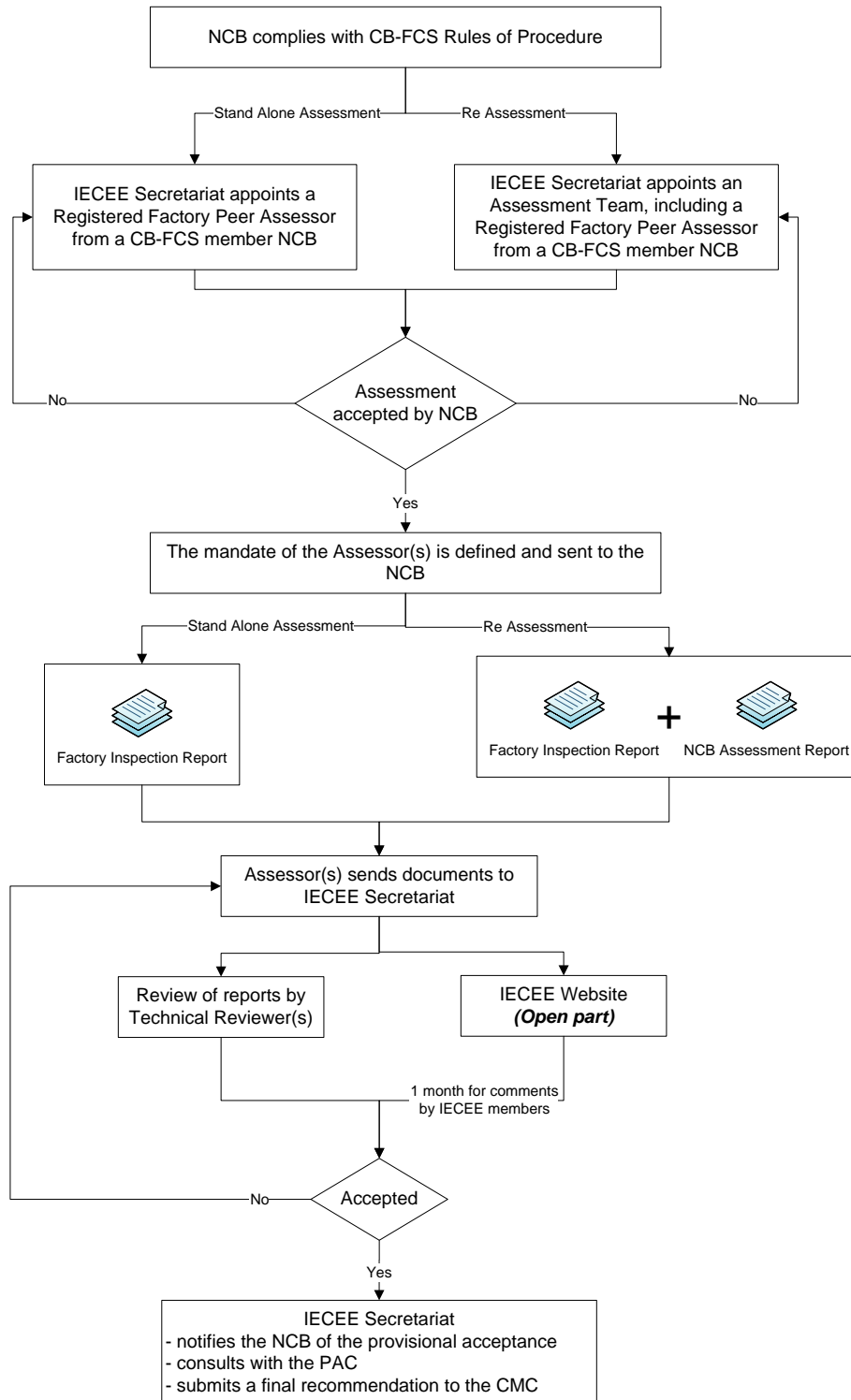
Some NCBs will recognize the Initial Factory Inspection ONLY, so there will be a choice when entering data in the matrix to follow-up the agreement:

The matrix will be divided in two parts

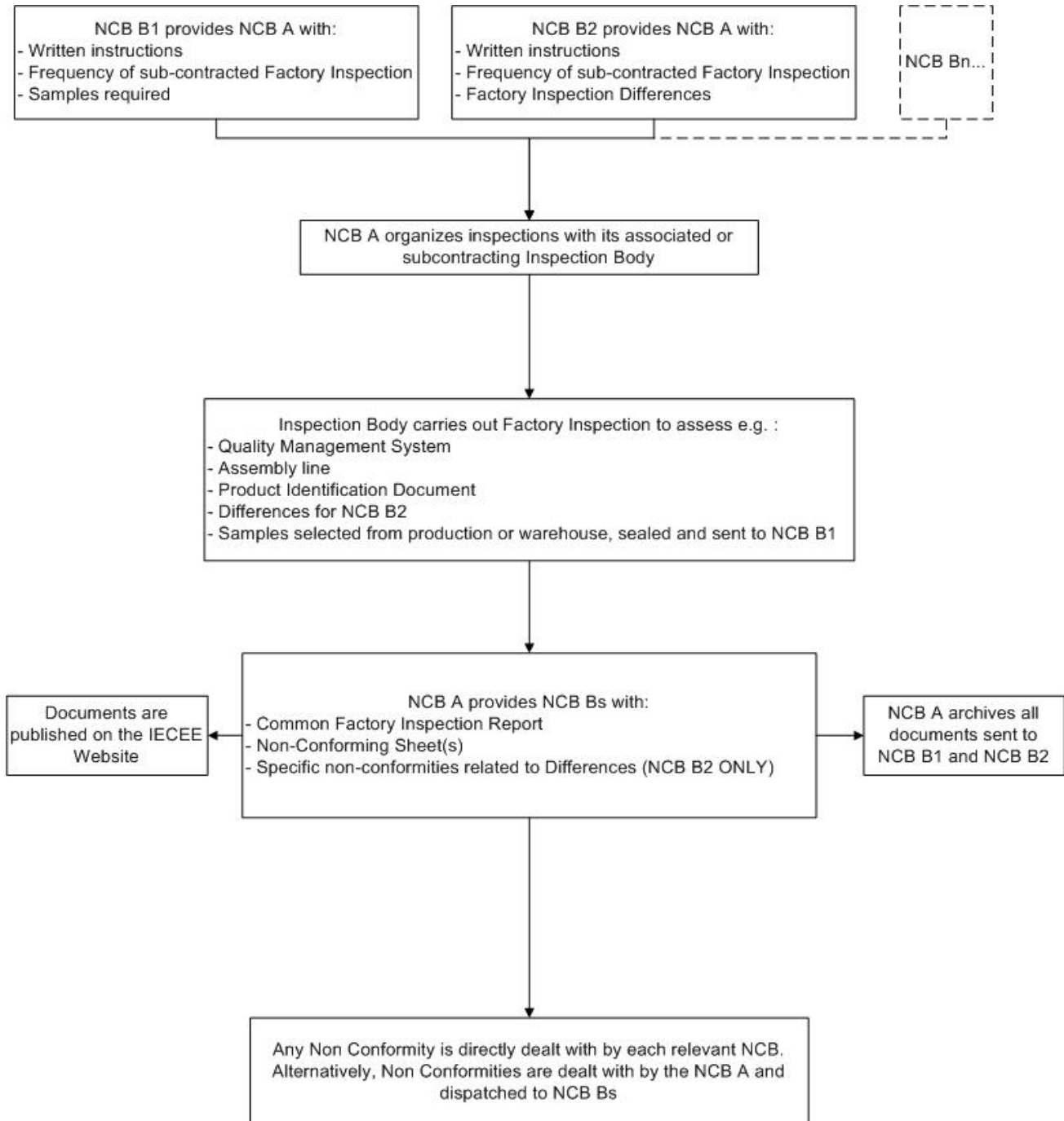
- Left bottom half = Acceptance of Initial Factory Inspection
- Top right half = Acceptance of Initial Factory Inspection + Factory Inspection (Surveillance)



Acceptance of NCBs carrying out Factory Inspections Process Flowchart



Peer Assessment Process Flowchart



NOTE In this flowchart, NCB B1, B2 and Bn are examples to outline the different options