Office for Product Safety & Standards

Guidelines on the appointment of UK Conformity Assessment Bodies

Requirements for conformity assessment bodies certifying for the GB and NI market from 1 January 2021

Guidance

January 2021

Contents

Guidance

1. Introduction

1.1 These guidelines describe the general requirements for the assessment and appointment by the Office for Product Safety and Standards of Approved Bodies for the GB market and/or UK Notified Bodies for the NI market under the Regulations listed below as they apply in Great Britain or Northern Ireland, respectively. For other legislated areas, please refer to guidance from the lead departments.

- Pressure Equipment (Safety) Regulations 2016
- Simple Pressure Vessels (Safety) Regulations 2016
- Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016
- Lifts Regulations 2016
- Measuring Instruments Regulations 2016
- Non-automatic Weighing Instruments Regulations 2016
- Electromagnetic Compatibility Regulations 2016
- Radio Equipment Regulations 2017
- Recreational Craft Regulations 2017
- Pyrotechnic Articles (Safety) Regulations 2015
- The Explosives Regulations 2014 (Amendment) Regulations 2016
- Personal Protective Equipment Regulation (2016/425)
- Radio Equipment Regulations 2017
- Supply of Machinery Regulations 2008
- The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001
- Toys (Safety) Regulations 2011
- Regulation (EU) 2016/426 and the Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018

1.2 These guidelines apply to all conformity assessment bodies (CABs) applying for approval from 1 January 2021 for each set of Regulations above with the exception of weights and measures authorities approved under module F within the Non-Automatic Weighing Machines Instruments and the Measuring Instruments Regulations.

1.3 From 1 January 2021 UK conformity assessment bodies will no longer be able to carry out mandatory conformity assessment for products being placed on the EU market unless agreed in negotiations. The UK Government is putting in place a domestic legal framework that will allow UK conformity assessment bodies to continue operating for most products being placed on the GB market and the NI market. The new UK legal framework and requirements for becoming a UK appointed conformity assessment (CAB) body for the GB or NI markets will be broadly the same as they are now.

Read guidance on conformity assessment bodies: change of status from 1 January 2021.

1.4 Most conformity assessment bodies in the UK will automatically have their status converted under the new UK framework. UK-based notified bodies will become UK approved bodies. UK-based notified bodies who become approved bodies will keep the same 4-digit identification number as they have now. UK approved bodies will still be able to act as notified bodies for the Northern Ireland market from 1 January 2021 subject to the NI Protocol.

Read guidance on moving manufactured goods from Great Britain to Northern Ireland.

Northern Ireland

1.5 Under the Northern Ireland Protocol, the UK can continue to appoint UK-based CABs as Notified Bodies for assessment against EU product regulation for placing products on the market in NI. The criteria for approval will be the same as for the appointment of Approved Bodies although the CAB must be competent to assess the requirements set out in EU legislation. Where a UK based Notified Body is used, the product may only be placed on the Northern Ireland market and not on the market of an EEA state.

1.6 There are also arrangements for Northern Ireland's unfettered access to the rest of the UK that apply here, which means that products valid for sale in Northern Ireland can also be placed on the Great Britain market.

Read guidance on placing manufactured goods on the market in Great Britain from 1 January 2021.

If a UK based Notified Body is used, then where the legislation requires the CE marking to be affixed this must be accompanied by the UKNI marking (sometimes referred to as the UK(NI) marking or indication).

Read the guidance on UK(NI) marking.

1.7 For pyrotechnics, the Product Safety and Metrology etc. (Amendment etc.)(UK(NI) Indication)(EU Exit) Regulations 2020, provide that a third-party CAB can also be established in a country outside of the UK but will still be required to meet the necessary requirements for appointment as an Approved Body for the GB market and/or UK Notified Body for the NI market, although there are particular rules unique to CABs for pyrotechnic articles that allow these CABs to use subcontractors or subsidiaries to meet the requirement of being capable of carrying out conformity assessment activities; they do not have to meet this requirement themselves. Any conformity assessment body, wherever they are based geographically, interested in applying to become an Approved Body for pyrotechnics should contact Kevin Belson, the UKAS Technical Manager at kevin.belson@ukas.com and Maggie Slinger in OPSS at maggie.slinger@beis.gov.uk.

1.8 For the period 1 January 2021 to 31 December 2021, pyrotechnic articles and other products covered by this guidance that are currently recognised in the EU, may continue to be conformity assessed for CE marking by existing notified bodies.

1.9 The Regulations apply to those products that fall within the definitions of each set of Regulations.

1.10 The conformity assessment procedures are set out in each set of Regulations.

1.11 Some of the conformity assessment procedures will require the involvement of third-party CABs.

1.12 In the United Kingdom, the CABs are appointed by the Secretary of State in accordance with the relevant Regulations. These third-party bodies, once assessed for their competence and appointed by the Secretary of State, are then listed on the UK Market of Conformity Assessment Bodies (UKMCAB) database and become "Approved Bodies" and/or "UK Notified Bodies" for the purposes of carrying out conformity assessment of products for either the GB or NI markets, respectively.

1.13 The letter of appointment will specify the scope of products within the Regulations which an Approved Body for the GB market and/or UK Notified Body for the NI market is authorised to assess. The Secretary of State for Business, Energy and Industrial Strategy is responsible for publishing the appointments and the scope of their approved activities. Existing Notified Bodies prior to 1 January 2021 will automatically become Approved Bodies for the GB market and/or UK Notified Bodies for the NI without pre-approval on 1 January 2021.

2. Criteria, Application and Appointment

2.1 An organisation wishing to be appointed will need to meet the requirements set out in the relevant regulations (an example can be found in Appendix II to this document).

2.2 Applicants should apply for accreditation by the United Kingdom Accreditation Service (UKAS) which is the recommended route. If an alternative route is used, the applicant must provide evidence to demonstrate it is justified, equivalent to accreditation, and demonstrates that it meets the requirements (see paragraph 3.5).

2.3 It should be noted that appointments are not automatic as the Secretary of State may have regard to any matter considered relevant and set further conditions the CAB must meet. Reference should also be made to paragraph 3.13 regarding insurance arrangements.

2.4 For the accredited route, UKAS, the UK's national accreditation body, has been appointed by the Secretary of State to carry out assessment of eligibility of applicants. Any other body offering 'accreditation' services in the UK will not be recognised. All applicants may make an application for accreditation to UKAS which will undertake an assessment of the applicant against the minimum requirements of the relevant regulations and (where applicable) the relevant standard(s) (see paragraph 3.4) to ensure that the applicant complies with the requirements.

2.5 Applications should be submitted using the relevant UKAS form (AC1 to AC4), dependent upon the standard against which accreditation is required.

2.6 To be eligible for appointment as an Approved Body for the GB market / UK Notified Body for the NI market for the purposes of the relevant Regulations, an applicant must be a legal entity in the United Kingdom (with the exception of pyrotechnic articles). However, CABs located outside the UK may be able to gain approval if a Mutual Recognition Agreement exists with the UK although they will need to approach the accreditation body in their territory.

2.7 An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment procedures for which it seeks approval. As part of the accreditation process, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services. Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to grant or withhold certification, the applicant will be required to have procedures for achieving consistency.

2.8 The scope of appointments will be defined by reference to the specific products covered by the relevant Regulations and applicants should indicate the conformity assessment procedure, activities and particular product(s) in respect of which they wish to be appointed.

2.9 Relevant standards are produced to demonstrate a presumption of conformity with the relevant essential requirements as set out in each Regulations. Under the appropriate conformity assessment procedures, applicants must be able to examine or inspect against the essential requirements and other relevant provisions directly. They will also need to be able to inspect against the relevant standards and relate these to the essential requirements.

2.10 UKAS will quote and charge applicants against its standard scales of charges for its accreditation activities. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.11 At the same time as it submits its application to UKAS, the applicant should inform the Department. This will provide the Secretary of State with advance notice of the intention to apply for appointment.

2.12 Once UKAS has completed its assessment, it will issue an accreditation certificate and schedule to the applicant if the requirements have been met.

2.13 The applicant should then submit an application for appointment to the Department to approvedbodies@beis.gov.uk. The application should describe the conformity assessment procedures, activities and the products for which the applicant wishes to be appointed and should be accompanied by the accreditation certificate, schedule, final assessment report issued by UKAS and evidence of the applicant's insurance cover (see paragraph 3.13).

2.14 The Secretary of State may request further information from UKAS about the applicant's accreditation, as required. The Secretary of State will then make a decision on appointment on the basis of all of the evidence. If satisfied that the applicant is fit for appointment under the Regulations, the Secretary of State will issue a letter of appointment subject to acceptance of conditions.

2.15 The precise terms of appointment will be set out in the individual letters of appointment, but they will include conditions that the applicant agrees:

- to take part in co-ordination activities at UK level;
- to undergo surveillance annually or at whatever intervals are thought appropriate by the Secretary of State (for newly appointed Approved Bodies for the GB market / UK Notified Bodies for the NI market may be required to undergo an initial surveillance after six months); and
- to undergo a full reassessment every four years; or at whatever intervals are thought appropriate by the Secretary of State.

2.16 Once the body provides its acceptance of the conditions of the letter of appointment, the Secretary of State will issue an identification number, the appointment will be confirmed and details entered on the UK Market CAB (UKMCAB) database.

2.17 Reassessment and surveillance will be carried out on behalf of the Secretary of State, by UKAS in line with usual accreditation practice and paragraph 2.15, second indent, above. A report on the reassessment and surveillance will be sent to the Secretary of State. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Secretary of State of the outcome of annual surveillance, four-yearly reassessment and any other necessary monitoring in intervening periods in order for the Secretary of State to take any necessary decisions about the continuation of the appointment. The Secretary of State may request further information about the reassessment and surveillance activities, as required. Should an existing Approved Body for the GB market / UK Notified Body for the NI market terminate its activities, files and other relevant information must be transferred as required by the regulations.

3. Meeting the criteria

Applications for Accreditation

3.1 Applicants for accreditation are required to demonstrate conformity with the requirements set out in the Regulations by being accredited to the appropriate scope of one or more of the relevant standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests.

3.2 All applicants, as part of the accreditation process, will need to meet any additional requirements set out in these guidelines which may change from time to time.

3.3 As indicated in paragraphs 2.8 and 2.13, applicants will need to state the products specified in the relevant Regulations in respect of which they wish to be appointed. The scope of accreditation and subsequent appointment will be determined by reference to the categories of product specified.

3.4 Accreditation will be carried out against the relevant preferred standard for the organisation concerned, taking into account the requirements of other relevant standards depending on the modules for which the applicant wishes to be appointed. The relevant standards, mapped against the modules, are shown in Appendix I.

Applications from non-accredited organisations

3.5 Accreditation by UKAS is the recommended route for assessment and appointment of Approved Bodies for the GB market / UK Notified Bodies for the NI market as it allows assessments to be compared like for like and judged on similar criteria. However, the legislation allows for applications via an alternative route. Applicants will need to submit evidence to the Secretary of State demonstrating that their organisation, its processes and systems meet the requirements for appointment.

3.6 Applicants should be aware of the following when considering making an application for appointment without UKAS accreditation:

- This alternative route to appointment may mean that assessments will take longer.
- It involves the use of third-party assessors appointed by the Secretary of State whose costs will have to be met by the applicant.

- Applicants using the alternative route must meet the requirements for CABs (as given in Appendix II).
- Once appointed, all approved bodies shall be required to demonstrate ongoing technical competence and compliance with relevant criteria through a programme of annual assessment by third-party assessors appointed by the Secretary of State whose costs will have to be met by the approved body.

All applicants

3.7 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the Regulations to be able to determine whether products offered for assessment satisfy the essential requirements or essential requirements and the other relevant provisions.

Conformity Assessment Standards

3.8 An applicant that can demonstrate compliance with the criteria set out in a relevant standard or part of a standard is presumed to comply with the requirements of a conformity assessment body covered by that standard, set out in the Regulations.

Management System

3.9 All applicants will need to have a Management System and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. The Management System will need to ensure that all the relevant requirements of the appropriate standards in the ISO 17000 series are met plus any further requirements for appointment and operation as an Approved Body for the GB market / UK Notified Body for the NI market.

Sub-contracting

3.10 Where an applicant wishes to sub-contract any part of the assessment process, the Management System of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the sub-contractors with the relevant requirements and to demonstrate that the sub-contractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of sub-contractors, and a list of sub-contractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.

3.11 An applicant will need to have fully documented agreements with its sub-contractors. Applicants will need to maintain a Register of all sub-contractors which may be used by the applicant. The Management System will either contain the Register or will state where the Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose. Where a subcontractor is used, the consent of the economic operator concerned to use that contractor is required. With the exception of pyrotechnic articles, if subcontractors are used, the Approved Body for the GB market / UK Notified Body for the NI market must be technically competent to manage the subcontracted activity.

3.12 An Approved Body for the GB market / UK Notified Body for the NI market will, at all times, be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the relevant regulations.

Insurance

3.13 All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted at the point at which a body makes an application to be appointed as an Approved Body for the GB market / UK Notified Body for the NI market. Thereafter, it should make available to UKAS evidence of insurance at each annual surveillance visit undertaken by UKAS.

3.14 The Secretary of State will not in relation to any case or circumstance cover an Approved Body for the GB market's / UK Notified Body for the NI market's liability.

4. Duties of Appointed Conformity Assessment Bodies

4.1 It will be the duty of an appointed CAB to assess the conformity of the products or management systems which fall within the scope of its appointment, against the requirements of the relevant Regulations. When an Approved Body for the GB market / UK Notified Body for the NI market assesses products as being in conformity, it will be required to issue the appropriate conformity assessment documentation as specified in the relevant Regulations. This would include a type examination or quality assurance certificate stating that the product or management system concerned complies with the terms of the Regulations which apply to it and has been assessed as such.

4.2 An appointed CAB will be required to maintain an up-to-date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of State or such other person as may be authorised by the Secretary of State.

4.3 An appointed CAB will be required to inform the Secretary of State and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status, ownership, location, key personnel, technical competence, facilities etc.

4.4 An appointed CAB must exercise management control of the process, have technical capability and carry out its final assessment functions within the jurisdiction of the United Kingdom. It may conduct technical activities, or have technical activities conducted on its behalf, outside the jurisdiction of the United Kingdom.

4.5 An appointed CAB should ensure that it does not unreasonably restrict the access to its services by manufacturers of products within the scope of the Regulations. It must not place undue financial or other conditions upon such manufacturers. The procedures under which an Approved Body for the GB market / UK Notified Body for the NI market operates must be administered in an independent, impartial and non-discriminatory manner.

4.6 An example of the operation obligations of Conformity Assessment Bodies as set out in the legislation is provided at Appendix III.

5. Misuse of Certificates and Approved Body Identification Numbers

5.1 The Approved Body for the GB market / UK Notified Body for the NI market should set out its policy and procedure for controlling the use of its certificates and identification numbers in its Management System.

5.2 The Secretary of State will deal with incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

5.3 An Approved Body for the GB market / UK Notified Body for the NI market will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within its Management System.

6. Use of UKAS Symbols

6.1 An Approved Body for the GB market / UK Notified Body for the NI market may make reference to UKAS Accreditation or include the relevant National Accreditation Symbol on certificates issued by UKAS.

6.2 Certificates bearing an accreditation symbol must comply with the requirements:

- of the relevant conformity assessment body standard against which accreditation is held (e.g. ISO/IEC 17020 etc);
- for notification and in the BEIS conditions of use; and
- any other requirements specified by UKAS.

Read guidance on the national accreditation logo and symbols: conditions for use.

7. Contact Points

Contact addresses are:

Department for Business, Energy and Industrial Strategy,

1 Victoria Street, London, SW1H 0ET

Tel: 020-7215 5000

Email: approvedbodies@beis.gov.uk

Kevin Belson – UKAS Technical Manager (or your usual assessment manager),

United Kingdom Accreditation Service,

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR

Tel: +44 (0) 1784 429000

Email: kevin.belson@ukas.com

8. Sources of relevant documents

Copies of the Regulations may be obtained from:

The Stationery Office Limited, PO Box 29, Norwich, NR3 1GN

Phone: +44 (0)333 202 5070Fax: +44 (0)333 202 5080

Email: book.orders@tso.co.uk

Web: www.tso.co.uk/bookshop

Or from the UK Legislation website: legislation.gov.uk.

Information on the ISO 17000 series of standards and other standards is available from:

BSI British Standards, 389 Chiswick High Road, London, W4 4AL

Tel: 0845 086 9001 Fax: 0208-996 7001

Email: cservices@bsigroup.com

Web: http://www.bsigroup.com

Appendix I

NB: This table covers the applicable standard for each module - there are exceptions for certain regulations and there are other designations rather than the standard modules. For more information see www.ukas.com

Module	Applicable Standard
A1, A2	ISO/IEC 17020
B	ISO/IEC 17065
C	ISO/IEC 17065 / 17020
C1, C2	ISO/IEC 17065
D, D1	ISO/IEC 17065
E, E1	ISO/IEC 17065
F, F1	ISO/IEC 17065
G	ISO/IEC 17065
H	ISO/IEC 17021-1
H1	ISO/IEC 17065

Appendix II: Requirements relating to Conformity Assessment Bodies

Note: this is an example, some legislation may have different requirements, so you should check the relevant provision in the specific Regulations.

1. For the purposes of appointment, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under UK law and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

   A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.
4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

   A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

   Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be competent to technically manage all the conformity assessment tasks assigned to it and in relation to which it has been appointed, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

   At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

   (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks

   (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities

   (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

   A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

   (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been appointed

   (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments

   (c) appropriate knowledge and understanding of the essential health and safety requirements set out in the applicable designated standards, and the legislation

   (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out

8. The impartiality of the conformity assessment bodies, their top-level management, and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

   The remuneration of the top-level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by UK government in accordance with national law, or UK government itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks or any provision of national law giving effect to it. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of the relevant standardisation activities.

Appendix III: Operational Obligations of Appointed Approved Bodies for the GB market / UK Notified Bodies for the NI market

1. Appointed Approved Bodies for the GB market / UK Notified Bodies for the NI market shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant Regulations.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the requirements of the Regulations.
3. Where an appointed CAB finds that the essential health and safety requirements set out in the relevant Regulations or corresponding relevant standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.
4. Where, in the course of the monitoring of conformity following the issue of a certificate, an appointed CAB finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
5. Where corrective measures are not taken or do not have the required effect, the appointed CAB shall restrict, suspend or withdraw any certificates, as appropriate.

This publication is available at https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: OPSS.enquiries@beis.gov.uk

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