

# Актуелне измене у документима од значаја за рад акредитованих тела

*Обележавање Светског дана акредитације и  
Дана акредитације у Републици Србији*

**28.06.2022.**



ATC Акредитационо тело Србије

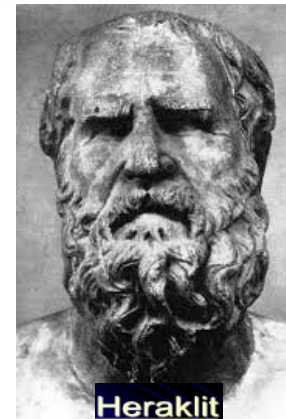
*Милица Јовчић, помоћник директора*

# Промене



Све се мења.

Промене су сталне.



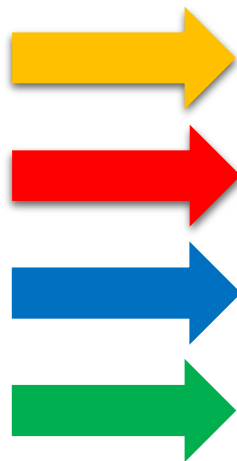
**Проблем није промена сама по себи, јер ће се промена догодити - проблем је, пре, неспособност да се носи са променама када до њих дође.**



# Значај информисаности и обрада информација



Информације



Обрада информација



Неинформисаност кошта.

Значај ефикасне и ефективне обраде информација.

**Радити на прави начин, радећи праве ствари**



# Документа која садрже захтеве за стицање и одржавање акредитације



Листа  
докумената



Нивои  
докумената



# EA MLA Документа – ниво 1

Документа у коме су дати **захтеви за акредитациона тела** (EN ISO/IEC 17011, Уредба Европског парламента и Савета број 765/2008 којом се прописују захтеви за акредитацију и тржишни надзор у вези са трговањем производима (Уредба 765/2008), и тамо где је применљиво додатни захтеви из EA обавезујућих докумената и у IAF и/или ILAC документима које је EA одобрио као обавезујућа.

ISO/IEC 17011:2017

ATC		Листа налаза		ATC-PR12-003	
Ознака предмета:		Датум:			
Редни број/иницијали оцењивача и техничке експерте из стране које је издати у складу са основним и/или другим захтевима	Захтев референтног документа	Неусаглашеност/ забринутост	<div style="border: 2px solid blue; border-radius: 50%; padding: 5px;">                     -Анализа разлога и узрока (корективне) мере                      -Предлог корекције и/или (корективне) мере                      -Доказ о спроведеним корекцијама и/или (корективним) мерама                      -Рок за отклањање забринутости                 </div>	- Прикладност предложене корекције и/или корективне мере - Начин верификације отклонености утврђене неусаглашености (оценом достижности доказа и/или напредности исправљања)	Верификација отклонености неусаглашености (неусаглашеност отклонена/ неусаглашеност није отклонена) са навођењем објективног доказа и/или информација о реализацији напредног оцењивања (у зависности од тога шта је применљиво)
(1)*	(2)*	(3)*	(4)*	(5)*	(6)*
НЕУСАГЛАШЕНОСТИ:					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ЗАБРИНУТОСТИ:					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\* (1), (2), (3), (5), (6) – попуњава тим за оцењивање, (4) – попуњава ТОУ

**У примени од 28.03.2022.**

ТОУ: Усаглашавање докумената система менаџмента !



## EA MLA Документа Ниво 2

### Активности оцењивања усаглашености

(a) еталонирање

(b) испитивање (+ мед. испитивања)

(c) контролисање

(d) сертификација производа

(e) сертификација система менаџмента

(f) сертификација особа

(g) валидација и верификација

(h) ПТ провајдери

(i) произвођачи референтних материјала

(j) биобанкинг

## EA MLA Документа Ниво 3

### Стандарди који садрже опште захтеве за ТОУ

(a) EN ISO/IEC 17025

(b)1 EN ISO/IEC 17025, (b)2 EN ISO 15189

(c) EN ISO/IEC 17020

(d) EN ISO/IEC 17065

(e) EN ISO/IEC 17021-1

(f) EN ISO/IEC 17024

(g)1 EN ISO/IEC 17029, (g)2 EN ISO 14065

(h) EN ISO/IEC 17043

(i) EN ISO 17034

(j) EN ISO 20387

# EA MLA Документа – ниво 3 праћење стстуса измена

## LIFE CYCLE

### PREVIOUSLY

WITHDRAWN  
**ISO/IEC GUIDE 43-1:1997**

WITHDRAWN  
**ISO/IEC GUIDE 43-2:1997**

### NOW

PUBLISHED  
**ISO/IEC 17043:2010**

A standard is reviewed every 5 years  
Stage: 90.92 (To be revised) ~

### WILL BE REPLACED BY

UNDER DEVELOPMENT  
**ISO/IEC DIS 17043**

The screenshot shows the ISO website interface for the draft international standard ISO/IEC DIS 17043. The search bar at the top contains the text "ISO/IEC DIS 17043(en)". The main heading of the page is "DRAFT INTERNATIONAL STANDARD ISO/IEC DIS 17043". Below the heading, it specifies "ISO/CASCO" and "Secretariat: ISO". The voting schedule is listed as "Voting begins on: 2022-04-27" and "Voting terminates on: 2022-07-20". On the left side, there is a "Table of contents" section with a list of sections including Foreword, Introduction, Scope, Normative references, Terms and definitions, General requirements, Impartiality, Confidentiality, Structural requirements, Resource requirements, Personnel, Facilities and environmental conditions, Externally provided products and services, Process requirements, and Establishing, contracting and operating a proficiency testing provider.

2022

Транзициони периоди, начини поступања.



ATC

Акредитационо тело Србије

# EA MLA Документа – ниво 3 праћење стстуса измена

## LIFE CYCLE

### PREVIOUSLY

PUBLISHED  
ISO 15189:2012



### NOW

UNDER DEVELOPMENT  
ISO/DIS 15189

Stage: 40.99 ^

00 10 20 30 40 Enquiry ^ 50 60 90 95

40.00 2021-08-17  
DIS registered

40.20 2021-10-19  
DIS ballot initiated: 12 weeks

40.60 2022-01-12  
Close of voting



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2022

#### Table of contents

- Foreword
- Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 General requirements
  - 4.1 Impartiality
  - 4.2 Confidentiality
  - 4.3 Requirements regarding patient
- 5 Structural and governance requirem
  - 5.1 Legal entity
  - 5.2 Laboratory director
  - 5.3 Laboratory activities
  - 5.4 Structure and authority
  - 5.5 Objectives and policies
  - 5.6 Risk management
- 6 Resource requirements
  - 6.1 General
  - 6.2 Personnel
  - 6.3 Facilities and environmental co

#### Tables

Available in: EN FR



#### Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This fourth edition cancels and replaces the third edition ISO 15189:2012, which has been technically revised.



# EA MLA Документа – ниво 4

Садрже критеријуме који су допуна онима садржаним у стандардима нивоа 3.  
Применљиви искључиво уз ниво 3.

## Примери:

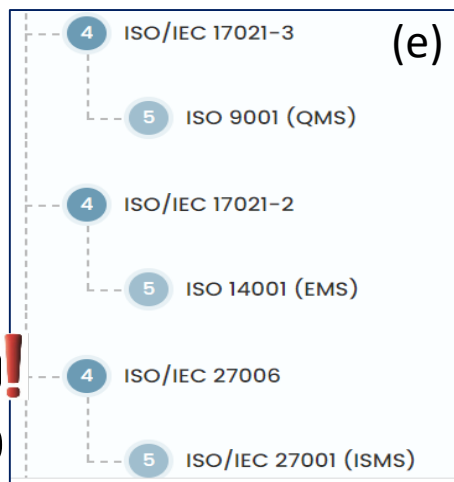
SRPS CEN/TS 15675 (b)1 –повучен (мај 2019/ новембар 2020)

ISO 22870 (b)2

ISO/IEC 27006 (e)

ISO/TS 22003 (2022)!

ISO/IEC TS 17021-10



Извод из:

<https://iaf.nu/en/scopes/>

## Напомене у обимима акредитације:

Сертификационо тело је  
акредитовано према захтевима  
стандарда SRPS ISO/IEC 17021-1:2015  
и стандарда SRPS ISO/IEC 27006:2017,  
**ISO/IEC 27006:2015/Amd.1:2020**

## Транзициони периоди

(где су дефинисани), **начини поступања**



АТС

Акредитационо тело Србије


# EA MLA Документа – ниво 5

## Обим акредитације.

Стандарди или друга нормативна документа која користи ТОУ да би спровело поступак оцењивања усаглашености.

Нпр. **испитне методе, ISO 9001, ISO 14001...**

Акцент на обезбеђењу последњих валидних верзија.



ОБИМ АКРЕДИТАЦИЈЕ  
*Scope of Accreditation*

**Транзициони периоди (да ли су и где дефинисани), начини поступања.**



ISO/IEC 27001:202X

IAF MD X:202X Transition Requirements



# EA-INF/01 садржи и

## 2.6 APPLICATION DOCUMENTS FOR CONFORMITY ASSESSMENTS BODIES (CABs)

*Documents used by Conformity Assessment Bodies providing technical or scientific guidance for the application of standards.*

The documents of this category can be either:

Mandatory (M) or Guidance (G) or Informative (INF) or Technical/Advisory (TA)

### 2.6.1 Laboratories - ISO/IEC 17025 / ISO 15189

Reference	Classification	Title	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
EA-4/02 (rev.03)	Mandatory	Evaluation of the Uncertainty of Measurement in calibration	Apr 2022		LC	X
EA-4/09 G (rev.03)	Guidance	Accreditation for sensory testing laboratories	June 2022	June 2023	LC	

## ...EA-INF/01 садржи и

### *EA-INF/01 • List of EA Publications and International Documents*

EA-4/14 INF (rev.00)	Informative	Selection and Use of Reference Materials	Feb 2003	LC	
EA-4/15 G (rev.01)	Guidance	Accreditation for Non-Destructive Testing	Withdrawn May 2019	LC	
EA-4/16 G (rev.00)	Guidance	EA Guidelines on the Expression of Uncertainty in Quantitative testing	Withdrawn March 2021	LC	
EA-4/17 M (rev.01)	Mandatory	Description of scopes of accreditation for medical laboratories	Feb 2022	LC	X
EA-4/18 G (rev.01)	Guidance	Guidance on the level and frequency of proficiency testing participation	Nov 2021	LC	
EA-4/21 INF (rev.00-2)	Informative	Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation	March 2018  (republished in July 2019 for editorial updates)	LC	
EA- 4/23 INF (EX - INF/13) (rev01)	Informative	The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2005	Oct 2019	LC	

## ...EA-INF/01 садржи и

### 2.6.2 Inspection Bodies - ISO/IEC 17020

Reference	Classification	Title	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
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14<sup>th</sup> June 2022\_rev123

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# ...EA-INF/01 садржи и

EA-INF/01 • List of EA Publications and International Documents

## 2.6.3 Certification Bodies ISO/IEC 17065 - Products

Reference	Classification	Title	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
EA-6/02 M (rev.03)	Mandatory	EA Guidelines on the use of ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834	Jan 2022	Jan 2023	CC	X
EA-6/04 M (rev.00)	Mandatory	EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites	Withdrawn May 2022		CC	X

## 2.6.4 Certification Bodies - ISO/IEC 17021-1 - Management Systems

Reference	Classification	Title	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
EA-7/04 M (rev.03)	Mandatory	Legal Compliance as a part of accredited ISO 14001: 2004 certification	May 2017		CC	X

## 2.6.5 Verification Bodies - ISO 14065 - GHG

Reference	Classification	Title	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
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# Као и документа других међународних организација

## 3 INTERNATIONAL DOCUMENTS APPLICABLE TO EA, EA MEMBERS AND EA MLA SIGNATORIES

### 3.1 ILAC DOCUMENTS (all ILAC documents are available under <http://ilac.org/publications-and-resources/>)

#### 3.1.1 ILAC POLICY DOCUMENTS (P-SERIES)

Reference	Title	Applicable to EA as Region	Applicable to all	Applicable to the EA members signatories to ILAC/IAF	Date of publication	Date end transition (blank if not applicable)	Owner *	Peer evaluation
ILAC-P5	ILAC Mutual Recognition Arrangement (Arrangement)			X	May 2019		MAC	X
ILAC-P8	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies		X		March 2019	March 2020	HHC	X
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities		X		June 2014		LC	X
ILAC-P10	ILAC Policy on Metrological Traceability of Measurement Results		X		July 2020	July 2021	LC	X
ILAC-P12	Harmonisation of ILAC Work with the Regions	X			April 2009		EX	
ILAC-P14	ILAC Policy for Measurement Uncertainty in Calibration		X		Sept 2020	March 2021	LC	X
ILAC-P15	Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies		X		May 2020	Nov 2021	IC	X

# ...Као и документа других међународних организација

## 3.3.3 IAF MANDATORY DOCUMENTS (MD-SERIES)

Note: Due to the COVID-19 Pandemic, the transition periods of all IAF Mandatory Documents have been extended for six months

Reference	Title	Applicable to EA as Region	Applicable to all	Applicable to the EA members signatories to ILAC/IAF	Date of publication	Date end transition (blank if not applicable)	Owner	Peer evaluation
IAF MD 1	Audit and Certification of a Management System Operated by a Multi-Site Organization		X		Jan 2018		CC	X
IAF MD 2	Transfer of Accredited Certification of Management Systems		X		June 2017		CC	X
IAF MD 4	Use of information and Communication Technology (ICT) for auditing/ assessment purposes		X		July 2018		CC	X



## ...Као и документа других међународних организација

IAF MD 5	Determination of audit time of quality, environmental, and occupational health & safety management systems	X		May 2019	Application from 7 <sup>th</sup> May 2020	CC	X
IAF MD 6	Application of ISO 14065:2013		X	March 2014		CC	X
IAF MD 7	Harmonization of Sanctions		X	Sept 2010		CC	X
IAF MD 8	Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)	X		June 2020	Application from 30 <sup>th</sup> November 2020	CC	X
IAF MD 9	Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)	X		Feb 2022	Application from 1 <sup>st</sup> February 2023	CC	X
IAF MD 11	IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (Issue 2)	X		Jan 2019	Application from 17 <sup>th</sup> January 2020	CC	X

## ...Као и документа других међународних организација

IAF MD 12	Assessment of Certification Activities for Cross-Frontier Accreditation	X	Jan 2016	CC	X
IAF MD 13	Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)	X	Dec 2020	CC	X
IAF MD 14	Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)	X	June 2014	CC	X
IAF MD 15	IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance	X	July 2014	CC	X
IAF MD 16	Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies	X	Jan 2015	CC	X
IAF MD 17	Witnessing Activities for the Accreditation of Management Systems Certification Bodies	X	May 2019	Application from 7 <sup>th</sup> May 2020 CC	X



# ...Као и документа других међународних организација

## EA-INF/01 • List of EA Publications and International Documents

IAF MD 20	Generic Competence for AB Assessors: Application to ISO/IEC 17011		X	May 2016		HHC	X
IAF MD 21	Requirements for the Migration to ISO 45001:2018 from OHSAS 18001:2007	X		Feb 2022	Application from March 2018	CC	X
IAF MD 22	Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)			May 2019	Application from 7 <sup>th</sup> May 2020	CC	X
IAF MD 23	Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies	X		May 2018		CC	X
IAF MD 24	Transition Requirements for ISO 50003:2021	X		Dec 2021		CC	X
IAF MD 25	Criteria for Evaluation of Conformity Assessment Schemes	X		Jan 2022	Application from 7 <sup>th</sup> January 2024	CC/HHC	X

# Корисно је погледати и

## *EA-INF/01 • List of EA Publications and International Documents*

EA-2/13 S1 M (rev.00)	Mandatory	Supplement 1 to EA-2/13, Interpretation of Terminology used in clause 5.1 of EA-2/13	Withdrawn included in EA-2/13 above		HHC	X
EA-2/15 M (rev.01)	Mandatory	EA Requirements for the Accreditation of Flexible Scopes	April 2019	April 2020	HHC	X
EA-2/17 M (rev.04)	Mandatory	EA Document on Accreditation for Notification purposes	April 2020	April 2023	HHC	X
EA-2/18 INF (rev.00)	Informative	Guidelines for Accreditation Bodies on the content of the scopes of accreditation for proficiency testing providers	Withdrawn January 2022		LC	
EA-2/19 INF (rev.01)	Informative	List of risks for accreditation processes and operation of national accreditation bodies	May 2022		HHC	
EA-2/20 G (rev.00)	Guidance	Consultancy, and the Independence of Conformity Assessment Bodies	April 2020	April 2021	HHC	
EA-3/01 M (rev.05)	Mandatory	EA conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status	June 2021		HHC	X

## ...Корисно је погледати и

EA-3/02	Mandatory	EA policy for the accreditation of Certification Bodies providing certification of PDO, PGI and TSG	June 2022	June 2023	CC	X
EA-3/04 G (rev.01)	Guidance	Use of Proficiency Testing as a Tool for Accreditation in Testing ( <i>with EUROLAB and EURACHEM</i> ). <i>Reinstated according to EA Resolution 2012(29)24</i>	Withdrawn November 2017		LC	
EA-3/11 M (rev.00)	Mandatory	Food Safety Management Systems – Scope of Accreditation	Withdrawn November 2017		CC	
EA-3/12 M (rev.02)	Mandatory	EA Policy for Accreditation of Organic Production Certification	March 2022	March 2023	CC	



## ...Корисно је погледати и

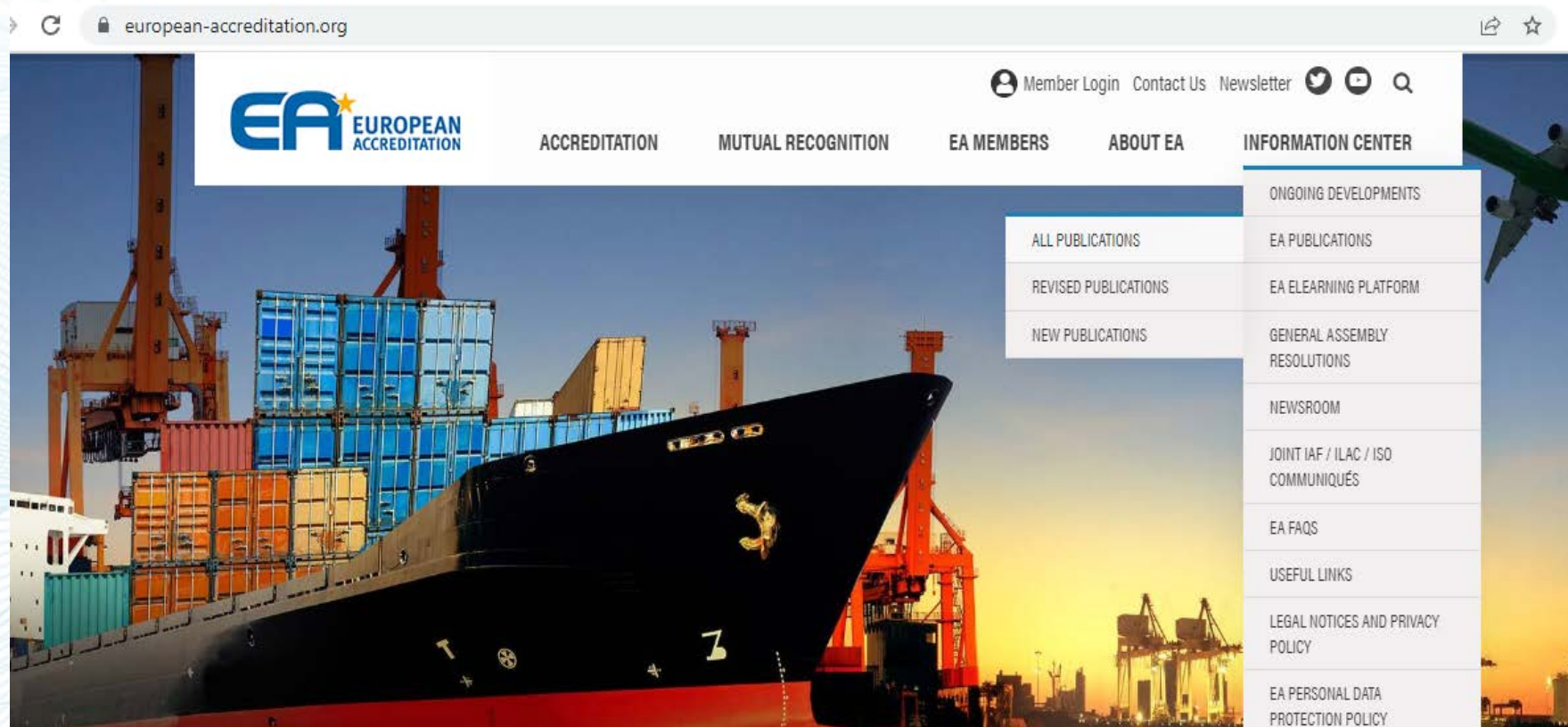
### *EA-INF/01 • List of EA Publications and International Documents*

EA-3/13 M (rev.00)	Mandatory	EA Document on the Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems	Withdrawn May 2018	CC	
EA-4/20 G (rev.01)	Guidance	Guidance for the assessment of laboratories against EN ISO 15189 and EN ISO 22870 Point-of Care Testing (POCT)	May 2021	LC	
EA-4/22 G (rev.00)	Guidance	EA Guidance on Accreditation of Pesticide Residues Analysis in Food and Feed	Nov 2018	LC	
EA-5/02 INF (rev.03)	Informative	Guidance on the application of ISO/IEC 17020 in vehicle inspection	April 2021	IC	
EA-6/03 M (rev.05)	Mandatory	EA document for accreditation of Verification Bodies for the purpose of EU ETS Directive	June 2022	CC	X



# Корисни линкови

## <https://european-accreditation.org/>



The screenshot shows the website [european-accreditation.org](https://european-accreditation.org/). The main navigation menu includes: ACCREDITATION, MUTUAL RECOGNITION, EA MEMBERS, ABOUT EA, and INFORMATION CENTER. The INFORMATION CENTER dropdown menu is open, listing the following items:

- ONGOING DEVELOPMENTS
- EA PUBLICATIONS
- EA ELEARNING PLATFORM
- GENERAL ASSEMBLY RESOLUTIONS
- NEWSROOM
- JOINT IAF / ILAC / ISO COMMUNIQUÉS
- EA FAQs
- USEFUL LINKS
- LEGAL NOTICES AND PRIVACY POLICY
- EA PERSONAL DATA PROTECTION POLICY

Additional links in the top right corner include Member Login, Contact Us, Newsletter, and social media icons for Twitter, YouTube, and a search icon.

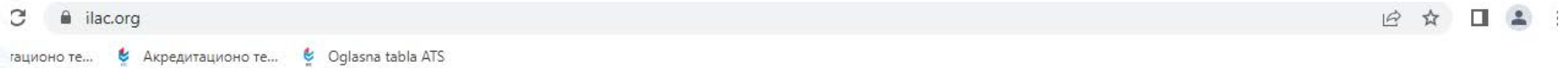


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Акредитационо тело Србије

# Корисни линкови

## <https://ilac.org/>



Welcome Guest

Search



»About ILAC »ILAC MRA and Signatories »ILAC Membership »Publications »News and Events »Contact Us »Members Area

- Deutsch
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- Tiếng Việt
- Türkçe
- Беларуская
- монгол хэлээр
- русский
- עברית
- دري
- عربي
- فارسي
- हिंदी
- ไทย
- မြန်မာ
- 中文

**Facts & Figures**

107 ILAC MRA signatory accreditation bodies

81,760 accredited laboratories

12,200 accredited inspection bodies

560 accredited proficiency testing providers

200 accredited reference material providers



**SIGNATORY SEARCH**  
ILAC MRA signatories and  
accredited facilities



**CERTIFICATES & REPORTS**



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ATC Акредитационо тело Србије



# Корисни линкови

## <https://iaf.nu/>

iaf.nu/en/scopes/

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COVID-19



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## Scopes

Currently there are five main scopes: Management Systems Certification, Product Certification, Certification, Validation and Verification, and Validation and Verification.

A main scope means certificates are 'equally reliable' because the conformity assessment bodies conform to the same standard. The combination of a Level 2 activity and the Level 3 relevant normative document is called a main scope of the MLA.

A sub-scope means the certificates are 'equivalent' because the management systems

/en/scopes/#



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<https://www.iso.org/home.html>

<https://iss.rs/>



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# Важност праћења законске регулативе



Опрема под  
притиском

Радиоактивност

Земљиште

...



# Праћење и прилагођавање променама

Где се сада налазимо



Где желимо да будемо



# ХВАЛА НА ПАЖЊИ

Акредитационо тело Србије

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