

Application Form for Integrated Assessment of Testing Laboratories

ISSUE NO.: 01 AMENDMENT NO.: 00

ISSUE DATE: 01-01-2018 AMENDMENT DATE: 01-01-2018

AMENDMENT SHEET

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Information & Instructions for completing an Application Form for applying towards Integrated Assessment

- Laboratories seeking Recognition/ Approval from Concerned Regulatory Body(ies)- Export Inspection Council (EIC) and World organic (www.worldorganic.us) and other commodity boards in conjunction with the accreditation in accordance with ISO/IEC 17025 by UKJAS.
- 2. Application shall be made in the prescribed form UKJAS 002 only. Separate application form shall be submitted for each discipline of testing. The application shall consist of the following:
 - Two sets of completed application forms/ discipline
 - One copy of laboratory Quality Manual/ Management system document
 - Prescribed application fees
 - Copy of UKJAS -131 duly signed.

Incomplete application fraudulent behavior, false information and concealing the information may lead to rejection of application or termination of the assessment process.

Laboratories shall fill the application form UKJAS 151 for the scope not covered under Integrated Assessment.

- 3. The applicant laboratory shall undertake to carry out its testing activities in such a way as to meet the requirement of ISO/IEC 17025, UKJAS specific criteria, other relevant requirements of UKJAS and the regulatory authorities, as applicable at all times.
- 4. Applicant laboratories are advised to ensure that the latest versions of UKJAS documents are available with them.
- The application fee and other necessary charges related to accreditation process is given in UKJAS document UKJAS 100 'General Information Brochure' UKJAS Finance and UKJAS Fee Structure' (Fee for Integrated Assessment separately). UKJAS 100 is available on UKJAS website www.ukjas.com.
- 6. Laboratories are advised to familiarize themselves with UKJAS 100 'General Information Brochure', UKJAS 127: Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for Testing Laboratories, UKJAS 216 'Procedures for Dealing with Adverse Decisions' and UKJAS 131 'Terms and Conditions for Obtaining and Maintaining Accreditation' before filling up this form.
- 7. The applicant laboratory shall provide photocopy of following appropriate document(s) in support of the legal status claimed:
 - a) Proprietorship firm (copy of Bank Passbook, PAN card)
 - b) Partnership (Copy of Registration under 1932 Act)
 - c) Company Act (Copy of Registration under 1956 Act)
 - d) Societies Registration Act (Copy of Registration under 1860 Act)
 - e) Indian Trust Registration Act
 - f) Government & international body (Copy of Government Notification/ Declaration etc.)

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- 8. The applicant laboratory shall intimate UKJAS / Concerned Regulatory Body(s) about any change in the information provided in this application such as scope applied for accreditation, personnel, location etc. within 15 days from the date of changes.
- 9. UKJAS expects applicant laboratories that are to be accredited to follow the test methods as mentioned in the current National or International standards and as stipulated by regulatory body (s). Where such methods do not exist, other validated methods are acceptable. In case laboratory uses in-house validated methods the validation data should be submitted along with the application.
- 10. The applicant laboratories must participate satisfactorily in the Proficiency Testing (PT) program conducted by APLAC or any other national or international accredited / recognized PT provider. For participation in PT, laboratories shall refer document UKJAS 163. In addition, applicant/ accredited laboratories shall also comply with the requirements of PT participation of concerned Regulatory Body as defined in UKJAS 127: Procedure for Integrated Assessment &Additional Requirements of Regulatory Body (ies) for Testing Laboratories. In cases, where formal accredited / recognized PT programmes are not available, the laboratory willfollow the requirements as defined by respective Regulatory Body's additional requirement document, also listed in UKJAS 127: Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for Testing Laboratories.
- 11. The laboratory shall also inform UKJAS in advance about any reservation with valid reason regarding appointment of Lead Assessor/ Assessor for the assessment.
 - 12. The applicant laboratory shall be given due notice of any intended changes relating to UKJAS accreditation criteria and will also be given such time, as in the opinion of UKJAS is reason to carry out the necessary changes to its policies/practices & procedure(s). The laboratory shall inform UKJAS when such changes have been completed.
 - 13. The application must be filled up carefully to provide required information in such a manner that further correspondence for seeking clarifications are not required. Particularly the scope of accreditation (para 2.2) shall be complete to indicate unambiguously:
 - a. group of products, materials or items tested
 - b. specific tests or types of tests performed
 - c. specification, standard (method) or technique used with year of publication
 - d. range of testing/limit of detection for each test (as applicable)
 - e. uncertainty of measurement (MU) for each test (wherever applicable) at a confidence probability of 95%
 - 14. The details of laboratory locations and the tests which the laboratory intends to cover vide UKJAS accreditation under Integrated Assessment must be listed clearly. The tests those are performed at site should be clearly identified in the scope of accreditation.
 - Note: Laboratory operates from different locations in the same city may apply for UKJAS accreditation as a single laboratory. The details of each location shall be explicitly mentioned in 1.1 of application form. In events where the laboratory operates from different city/ state, each laboratory shall apply separately for accreditation except those cases where safety or regulatory requirements are there for operation of the laboratory. In such cases, the laboratory shall provide the proper justification.
 - 15. The laboratory shall submit UKJAS 131 duly signed by the Chief Executive or his/her Authorized Representative to UKJAS Secretariat along with this application form. By signing UKJAS 131 the laboratory agrees to comply at all times with Terms and Conditions of UKJAS .In addition, laboratory

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- shall also abide by the specific requirements set out in the document UKJAS 127; Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for Testing Laboratories.
- 16. The laboratory shall offer cooperation to UKJAS or its representative & representative from any concerned Regulatory Body(ies) in:
 - f. undertaking any check to verify testing capability of the laboratory.
 - g. the laboratory shall unambiguously provide names of all authorized signatories who are responsible for authenticity and issue of test certificates and reports.
 - h. offering access to relevant areas of the laboratory for witnessing the test being performed.
 - i. examination of all relevant documentation and records.
 - j. interaction with all relevant personnel.
- 17. The laboratory shall take all necessary actions and discharge all non- conformities raised during the assessment within the stipulated time. The same shall be verified to the satisfaction of UKJAS. The final decision on accreditation shall rest with UKJAS.
- 18. The application shall be kept confidential (until required by law) by UKJAS and information obtained during the processing of application, assessment visit and grant of accreditation shall be safeguarded and dealt with impartiality. The procedure for processing of application for accreditation is given in UKJAS 100.
- 19. The Laboratories falling under the ambit of Integrated Assessment of Regulatory Body(s), shall also abide by other UKJAS policies, requirements and Terms & conditions.

* * *

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Application Form for Accreditation/ Recognition/ Approval of Laboratory

We a		ation/ Approval/ Recognitio	n of our testing laboratory	as per details given
	First Accreditation		Renewa	al of Accreditation
	Extension of Scope			
	credited by UKJAS , please CAB ID	provide accreditation certi	ficate no. & accreditation val	idity (if applicable)
Last	Recognition/ Approval Cer	tificate No., Issuing Authori	ty & Validity (if applicable)	
	EIC	AF	PEDA / World Organic	
	FSSAI /ISO 22001	Co	ommodity Board	
	_	If Commod	lity Board, please specify	
1.1	Name of the Testing La			
Note	Telephone Noe: refer cl. 13 for details on l	Fax No aboratory locations	E-mail	
1.2		pplied under the scope of the scope of accreditation	of Accreditation , para 2.2, the test conducte	d)
	a. Permanent Facility		Yes	No
	b. Site Facility		Yes	No
	c. Mobile facility		Yes	No
	Note: for details please refer	· UKJAS -130		
1.3	Nameof Parent Organiza (if part of an organization)	tion		
	Telephone No	Fax No	E-mail	

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1.4	(Ple	gal identity of the la ease give Registrati ificate shall be enclos	on No. and name	eof establishment:- e of authority who granted	I the registration.	Copy of the
1.5	God	ods and Service Tax	(GST) Number a	long with PAN/ TAN Numb	er:-	
1.6	Ту	pe of laboratory by	service			
	Оре	en to others	partly open to	others an ir	n-house activity	
1.7	Oth	er accreditations				
	Indi e Engli		e name and addre	ess of the laboratory are to	appear on the ce	rtificate
2.		Accreditation/ Reco				
2.1	DIS	scipline of Testing f	or which accredit	ation is sought		
	•	Biological				
	•	Chemical				
2.2	(Lal	pe of Accreditation poratory seeking cerned regulatory E	accreditation fro	m UKJAS alongwith oth Format-1 &2)	recognition / ap	proval from
	SI	Group of products, materials or items tested	Specific tests performed	*Test Method / Standard against which tests are performed	Range of Testing/ Limits of detection	Uncertainty of Measurem ent (±) at Value

Note:

- 1. Laboratories performing site testing shall clearly identify the specific tests on product(s)/ material performed at site separately.
- Measurement uncertainty shall be expressed as expanded uncertainty with 95% confidence level
 Test methods and standards shall be mentioned along with the year of publication of the standard

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- 4. In case of enhancement of scope; it shall be specifically mentioned and clearly identified in the scope of accreditation
- 5. In exceptional case, where the test facility is unique in nature and is the only facility available in the country, the laboratory may use the test facility without owning it but with proper justification and agreement.
- 6. Latest test method / standard to be mentioned in the applied scope.
- 7. Laboratories having multiple locations in the same city shall clearly identify the scope for each location separately.

2.2.1 Scope for Recognition/ Approval from Concerned Regulatory Body (Format 2)

(*Lab shall fill individual format for the each concerned Regulatory Body)

SI	Categor y or Group of Substan ces	Specific Test (Param eter / Analyte) i.e actual substan ce or test paramet er like metabol ites	Name of Group / Therap eutic Classifi cation	Target product/ material / item / tissue (Matrix	Product categor y / Animal species / plants product s	MRPL / MRL / ML	Validati on protocol	Analytic al Method	Limits of detectio n (LOD) /cca	Limit of Quantifi cation (LOQ) /ccβ	Range of testing	Recove ry / Accurac y at Detectio n capabilit y, (as applica ble)	Uncerta inty of Measur ement

2.2.2 Details of scope for FSSAI recognition (Format 3)

Sr. No.	Category of food	Specific food articles	•

Note: In any case, subcontracting of parameters/ scope by laboratory is not permitted

2.2.3 Scope of Sampling:

Sr. No.	Name of Commodity/ Product group/ Matrix	Sampling procedure/ technique

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3. C	Organization						
3.1 S	Senior Management(N	ame, Designation, telephone, Fa	ax, e-mail)				
3.1.1	Chief Executive of the	e laboratory					
3.1.2	Person responsible for the management system						
3.1.3	Person responsible for	or technical operations					
3.1.4	Contact	person	for	UKJAS			

Contact person for Accounts_____

3.2 Proposed personnel for authorization of test results/ sampler

3.2.1Proposed personnel for approval of test reports
(For qualification & experience requirements for Proposed personnel for approval of test reports please refer UKJAS 165 "UKJAS 's Policies for Accreditation as per ISO/IEC 17025:2017")

SI	Laboratory/ Department/ Section	Name &Designatio n of Signatory	Qualification with Specialization	Experience in years related to present work	Relevant Training	Authorized forwhich specific area of testing	Specimen Signature

3.2.2 Authorized Sampler

3.1.5

(Lab shall fill individual format for the each concerned Regulatory Board(s))

3.2.1 Authorized sampler for the sampling

(Please refer relevant specific criteria for qualification and experience details from the concerned Regulatory Board (s))

SI.	Laboratory/	Name	Highest	Experience	Relevant	Authorized	Location	Specimen
	Department/	&Designation	Qualification		Training	forwhich		Signature
	Section	of Signatory				specific area of		
						sampling		

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3.2.3 Food Analyst (For FSSAI/ISO 22001 Recognition)

Sr.	Name	of	Whether qua	lified	Certificate	no.	and	Details	of	Training /
No.	qualification	of	under Rule 2.1.4 d	of the	year of pas	sing		Specializ	zed	trainings
	Food analyst*		Food Safety	and				attended	by F	ood analyst
			standards Rules,2	011						

^{*}If qualified food analyst is not available with laboratory, then laboratory shall appoint qualified food analyst within 1 year from the grant of accreditation/ recognition.

3.3Organization Chart

- 3.3.1.Indicate in an organization chart the operating departments of the testing laboratory for which accreditation is being sought (please append)
- 3.3.2 Indicate how the testing laboratory is related to external organizations or to its own parent organization (where applicable)

3.4 Employees

3.4.1 Details of staff

SI	Name	Designation+	Academic and Professional Qualifications*	Experience related to present work (in years)	Relevant Training

Note: Laboratory shall clearly indicate staff responsible for Site testing Laboratory operating in shifts shall clearly identify the staff working in shifts * Please clearly indicate the area of specialization

4. Equipment and Reference Materials/ Reference standards

4.1 List of equipment / reference standards available

SI	Name of equip ment	Model / type/ year of make	Recei pt Date	Range and accuracy	Date Placed in service	Purpo se/ Scope	Recovery and Accuracy	Last date of Calibrati on	* Due date of Calibration	**Cali brated by	Whether personnel trained/ authorized for the purpose

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4.2 Detail of Equipment Repair and Maintenance

S	Name of equipment, Make, Mode	Date of Out of order/ out of service	Detail of repair/maintenance	Date of back in service	Remark

4.3 List of reference materials available

SI	Name of reference material/ strain/ culture	Source	Date of expiry/ Calibration validity	Traceability

^{*} The laboratory to decide the calibration interval based on ISO 10012 or IAF-AB-A2401

Note-: For traceability in measurement, refer UKJAS policy document UKJAS 142

Internal Audit and Management Review

5 1	Data /a	chedule	of loot	Intornal	Audit.
วา	IJATA /S	cneaille.	กราสรรา	internai	Allait. =

5.1.1 Whether all requirements of ISO/IEC 17025 covering all activities of laboratory have been audited at least once in last one year YES/NO

5 2	Dato	of la	et Ma	nanan	nont	review:
J.Z	Date	UI IAS	ot ivia	IIautii	ICIIL	ieview.

6. Complaints/Disputes (Details of last 03 Years)

SI	Name of the client	Nature of complaint/dispute	Whether resolved in favor of Laboratory/Client	Brief of the action taken for resolving the complaint	Latest status (if not resolved yet)

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^{**} Please mention name of calibration agency. In case the equipment is calibrated in-house, same needs to be clearly indicated under this column.

7. Proficiency Testing

Participation in PT / any other Inter Laboratory Comparison (for details and requirements please refer to ISO/IEC 17043, UKJAS 163)

SI	Product/ Material	Details of Test(s)	Date of Testing	Nodal Laboratory/ PT Provider (Accreditation Body/ Country)	Performance in terms of Z score / other criteria	Corrective Action Taken (if any)
				, , , , , , , , , , , , , , , , , , , ,		

3. A	Application Fees
	pplication fees* (Rs.)
DE	O / At par Cheque** number
	nformation regarding the groups applied for accreditation in each discipline. Refer relevant specific criteria for more details o oups.
	All payments made through Cheques or Demand Draft shall be made in favor of ' UKJAS Accreditation Pvt Ltd' payable umbai.
No	te: Kindly make all kind of payments preferably through the 'Payment Gateway' available on UKJAS website (www.UKJAS.com)
9.	Declaration by the laboratory
9.3 9.4	We declare that: - We are familiar with the terms and conditions of maintaining accreditation (UKJAS 131), which enclosed and will abide by them. We agree to comply fully with ISO/IEC 17025 for the accreditation of testing laboratory. We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment verification visit (if any), surveillance and reassessment irrespective of the result. We agree to co-operate with the assessment team appointed by UKJAS for examination of a relevant documents by them and their visits to those parts of the laboratory that are part of the scop of accreditation. We agree to comply with the requirements of concerned Regulatory Body(s)as per the applied scope. has provide
	consultancy for preparing towards UKJAS accreditation. (Information regarding any individual organization who provided consultancy (if any) for UKJAS accreditation shall be declared) No adverse action has been initiated / taken against the laboratory in the past. (If yes, please provide the details with present status) All information provided in this application is true.
	Signature of laboratory head/ Laboratory director
	Name & Designation
	Date & Place

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9. Application Form - Check List

SI.	Information / details provided as part of application	Availability
1.	Two copies of application in each discipline (eg. Chemical/ Biological)	
2.	One copy of Quality Manual/Management system document (latest issue) according to ISO/IEC 17025	
3.	 Application fees a) Information on total groups applied for accreditation b) Estimated applicable fees as per UKJAS 100 c) Demand Draft / At Par Cheque in favor of 'UKJAS Accreditation Pvt Ltd' & details of payment made through Payment Gateway of UKJAS . 	
4.	Copy of Legal Identity (Registration Details of the Laboratory)	
5.	Goods and Service Tax (GST) Number along with PAN/TAN Number	
6.	Scope of Accreditation / Recognition as per Format-1 & Format-2	
7.	Details of Senior Management with Designation and Contact Details	
8.	List of staff, proposed Authorized Signatory (ies) & Authorized Sampler (s)	
9.	Organization Chart enclosed	
10.	List of Equipments, its repair & maintenance details / Reference Material used with details of Traceability	
11.	Details of PT/ILC participation	
12.	Dates of Internal Audit and Management Review	
13.	Details of Complaints/ disputes of last 03 years	
14.	Declaration about the Consultant (if any)	
15.	Signed copy of UKJAS 131 (latest issue)	

Verified the above details and confirmed the availability of all required documents/ details as part of application form.

Signature of laboratory head/ Laboratory director	
Name & Designation	
Date & Place	

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