NSTRUCTIONS FOR COMPLETING EXCEL SPREADSHEETS FOR THE NOMINATION OF REFERENCE MATERIALS AND REFERENCE MEASUREMENT METHODS/PROCEDURES FOR THE JCTLM DATABASE

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Introduction

The procedure for nominating higher-order reference materials and reference measurement methods/procedures is described in the document JCTLM DBWG-P-02A available from the BIPM website at: https://www.bipm.org/en/committees/cc/wg/jctlm-dbwg.html#manual.

According to this procedure, producers of reference materials and developers/owners of reference measurement methods/procedures nominate materials and measurement methods/procedures by completing the appropriate nomination spreadsheet (Microsoft Excel) form: the Reference Material Nomination Form (DBWG-P-02A-F-01) and the Reference Measurement Method/Procedure Nomination Form (DBWG-P-02A-F-02).

Section 1 describes the format and the content of the fields to be filled in by a producer of reference materials that nominates reference materials to be included in JCTLM List I, List II, or List III. List I, List II, and List III materials are defined in the JCTLM preamble (https://www.bipm.org/utils/common/pdf/JCTLM/Preamble.pdf.

Section 2 describes the format and the content of the fields to be filled in by a developer/owner of reference measurement methods/procedures that nominates reference measurement methods/procedures to be included in the JCTLM List I.

A number of fields are for the use of the JCTLM Database Working Group Review Teams or the JCTLM Secretariat, and these are clearly indicated.

1. Format and content of the Excel spreadsheet for the nomination(s) of reference materials (RMs)

Table 1: Description of the fields in the Reference Material Nomination Form (DBWG-P-02A-F-01), version 10, January 2017.

Column	Column Heading	Column Content: Format / Description
Column A	Unique Nomination Number	A unique identification number for the reference material being nominated is supplied by the JCTLM Secretariat. See also section 3.5.2.
Column B	Date Nomination Filed	Enter the date on which the nomination form is filled in.

Analyte / Parameter		
Column C	Analyte Category	List one analyte category from Table 3, section 3.1.
Column D	Analyte Name	Enter the name of the analyte for which the submission is being made.
Column E	IUPAC/IFCC Number	A unique identification code using the IUPAC/IFCC coding system is to be attributed to the specified analyte by the JCTLM Secretariat; e.g. CAS7440-70-2 for Calcium; EC1.1.1.27 for Lactate dehydrogenase (LDH). The IUPAC/IFCC code will allow the identification of all data entries within the database that are synonymous with a chosen analyte.
Column F	List I or II or III?	DBWG Review Team will enter 'List I' or 'List II' or 'List III' to state whether this reference material is a List I or List II or List III reference material. List I, List II and List III are defined in the JCTLM preamble document available from the following address: https://www.bipm.org/utils/common/pdf/JCTLM/Preamble.pdf.

Basis for traceability claim		
Column G	1) Traceable to SI ; 2) Procedurally-defined (if so, name/cite the procedure); 3) Traceable to an international (WHO or other) standard (If so name the standard)	State the basis for traceability for the reference material being submitted as appropriate: 1) Enter "SI" if the reference material is traceable to the SI; or 2) Enter the name or the reference of the procedure the reference material is traceable to; or 3) Enter the name of the international standard the reference material is traceable to.

Matrix description		
Column H	Matrix Category	List one matrix category from Table 4, section 3.2.
Column I	Actual Matrix	State the actual matrix of the reference material (as described in its certificate / supporting documentation); e.g. human serum; fresh, frozen or lyophilized.

Information on the reference material (RM)		
Column J	Identifier / Number	State the identification code of the reference material; e.g. SRM 911c.
Column K	Name	State the name of the reference material.
Column L	Expiry Date	Enter the date on which the certified value is no longer guaranteed for the nominated reference material. Note that the reference material being submitted, if approved for listing in the database, is expected to be available for at least 18 months after posting
Column M	Certifying organization	Enter the acronym / name of the certifying organisation of the reference material.
Column N	Quantity	Enter a quantity being measured; See examples in Table 5, section

		3.3.
Range of Analyte Certified / Assigned Value and Unit Use the three fields below to describe the full range of the certified/assigned values and unit for a given measurand. This option is given as certain RM producers include several components (in one purchasable product) each with a different certified value of the given measurand. In the case where one value is certified/assigned, this value is to be entered in both 'From' and 'To' fields.		
Column O	From	Minimum range value.
Column P	To	Maximum range value.
Column Q	Unit	Unit in which the value is expressed.

Range of expanded uncertainty for analyte certified/assigned value In the case where only one value of the expanded uncertainty is stated, this value is to be entered in both 'From' and 'To' fields.		
Column R	From	Minimum range value of the expanded uncertainty.
Column S	To	Maximum range value of the expanded uncertainty.
Column T	Unit	Enter '%' or the unit in which the expanded uncertainty is expressed.
Column U	Level of confidence (%)	e.g. Enter '95%' to indicate the level of confidence for the expanded uncertainty.

Compliance with the requirements of paragraph 4, 5 and 6 of the ISO 15194:2009(E) Use the eight fields below to declare whether or not the reference material being nominated is fully compliant with the items listed in ISO 15194, and to reference the supporting documentation. Use the template included in the nomination folder to describe how compliance is met for all requirements listed in ISO 15194. (see section 3.8) Please note that any supporting documentation must be provided in English in order to be considered by the review team.		
Is the reference material compliant with all requirements of paragraph 4 (format of properties) of ISO 15194?		
Column V	The attached spreadsheet must be completed to demonstrate how compliance is met for all requirements of paragraph 4	Enter "Yes" or "No" to indicate if the reference material being submitted is compliant with all requirements of paragraph 4 of ISO 15194. For each nominated material a new compliance template must be completed, and the reference number given must be recorded in this cell.
Is the reference material compliant with all requirements of paragraph 5 (properties, production and characterization) of ISO 15194 ?		
Column W	Is production and characterization performed in full compliance with ISO Guide 34 and 35? The attached spreadsheet must be completed to demonstrate how compliance is met for all requirements of paragraph 5	Enter "Yes" or "No" to indicate if the reference material being submitted was produced and characterized in full compliance with Guide 34 and 35. For each nominated material a new compliance template must be completed, and the reference number given must be recorded in this cell.

Column X	Provide reference to publication on commutability study	Indicate whether or not the commutability assessment of the reference material is available and consistent with its intended use statement. Enter the reference for the commutability study of the reference material being submitted. **!** The .PDF file of the publication cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete). Please note that the reference for the commutability study will be published in the JCTLM Database website.

Is supporting documentation compliant with all requirements of ISO 15194 paragraph 6?		
Column Y	Is the label compliant with all requirements of ISO 15194 paragraph 6.2?	Enter “Yes” or “No” as appropriate
Column Z	Does the Certificate include the items specified in ISO Guide 31? State name of file containing the provided certificate	Indicate whether or not the Certificate includes the items specified in ISO Guide 31 **!** The .PDF file of the file cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AA	State name of file containing the provided certification report, or documentation including all information appropriate to a certification report	**!** The .PDF file of the file cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AB	Have you enclosed any additionnal information for compliance with paragraph 6.4? (If so state file name for any additionnal information for compliance)	**!** The .PDF file of the file cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AC	The attached spreadsheet must be completed to demonstrate how compliance is met for all requirements of paragraph 6	For each nominated material a new compliance template must be completed, and the reference number given must be recorded in this cell.

CRM information for publication in the JCTLM DB The information entered in the three fields below will be published in the JCTLM Database website.		
Column AD	Hyperlink to Comparability Final Report of extent-of equivalence studies among listed RMs	Enter the title of the Final Report of extent-of-equivalence study among listed RMs, which included this reference material (see section 3.6); or Leave cell empty. **!** The .PDF file of the document cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete)
Column AE	Other relevant publications	List citation and/or reference and/or URL for one or several publications for the nominated reference material; or Leave cell empty. Examples of publications: Certification: Jpn. J. JCCLS, 2002, 17, 2. Method used for certification: Jpn. J. Clin. Chem., 1990, 19, 209-227. General information document: Jpn. J. Clin. Chem., 2000, 29, 77-92 **!** The .PDF file of the publication(s) cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete)
Column AF	Comments	Enter one or several comments for the reference material being nominated; or Leave cell empty.

Contact information for publication in the JCTLM DB The RM producer's contact information entered in the fields below will be published in the JCTLM database website.		
Column AG	Producer acronym	Enter the acronym of the producer.
Column AH	Producer name	Enter the full name of the producer.
Column AI	Country	Enter the country ISO code (ISO 3166-1-alpha-2 code elements) as referenced in http://www.iso.org/iso/iso_3166_code_lists For example, enter "JP" for Japan
Column AJ to AM	Website, email, phone and fax number	Enter a contact web, email, phone and fax for the RM producer.

Contact information for additional details (for review process) Use the following fields to enter the contact details of the person who has submitted the nomination file, so that they may be contacted if additional information is requested by the JCTLM Review Team. This information will not be published on the JCTLM DB website.		
Column AN to AP	Name, email address and phone number	Enter contact details as appropriate.

Information from the JCTLM DBWG Review Team The following fields are to be filled in by the JCTLM DBWG Review Team; this information will not be returned in the JCTLM database website.		
Column AQ	Additional Reviewer Comments	Comments for review committee use.
Column AR	Recommended for publication in JCTLM Lists?	'Yes' or 'No' is to be entered by the JCTLM RT. See section 3.5.1

Information for JCTLM Secretariat use The following fields are to be filled in by the JCTLM Secretariat; this information will not be returned on the JCTLM website.		
Column AS	Review document for review committee use	The name of the compliance demonstration spreadsheet completed by the RM producer is to be entered by the JCTLM Secretariat.
Column AT	Review Word document (to be forwarded to the RM producer)	The identifier of the review report is to be entered by the JCTLM Secretariat. This document will be forwarded to the RM producer after the completion of the review and approval processes.
Column AU	Manufacturer comment (in case of delisting)	Comment from the producer of the RM stating the reasons for removal of the RM from the lists published on the JCTLM website is to be entered by the JCTLM Secretariat. This comment will be published in a separate document (.PDF) containing all entries that have been delisted from the JCTLM database.
Column AV	Manufacturer comment	Comment from the producer of the RM published in the JCTLM website lists. This comment will be published in the JCTLM website.

2. Format and content of the Excel spreadsheet for the nomination(s) of reference measurement methods/procedures (RMM/Ps)

Table 1: Description of the fields in the Reference Measurement Methods/Procedures Form (DBWG-P-02A-F-02), version 10, January 2017.

Column	Column Heading	Column Content : Format / Description
Column A	Unique Nomination Number	A unique identification number for the reference measurement method/procedure being nominated is to be supplied by the JCTLM Secretariat. See also section 3.5.2.
Column B	Date Nomination Filed	Enter the date on which the nomination form is filled in.

Analyte / Parameter		
Column C	Analyte Category	List one analyte category from Table 3, section 3.1.
Column D	Analyte Name	List the name of the analyte for which the submission is being made.
Column E	IUPAC/IFCC Number	A unique identification code using the IUPAC/IFCC coding system is to be attributed to the specified analyte by the JCTLM Secretariat; e.g. CAS7440-70-2 for Calcium; EC1.1.1.27 for Lactate dehydrogenase (LDH). The IUPAC/IFCC code will allow the identification of all data entries within the database that are synonymous with a chosen analyte.

Traceability		
Column F	Method capable of traceability of analyte to SI or defined procedure?	Enter either “SI” in the case where the measurand is traceable to SI units, or “Procedurally-defined” and name/cite the procedure.

Matrix description The matrix(ces) and matrix category(ies) for which the method/procedure is applicable should be listed. This information will be posted on the JCTLM database website.		
Column G	Matrix Category 1	List one matrix category from Table 4, section 3.2.
Column H	Matrix Category 2	List a second matrix category from Table 4, section 3.2 for which the method/procedure is applicable; this within the same measurement range and expected uncertainty range stated from column T to AA for the analyte-matrix combinaison 1; or Leave cell empty.
Column I	Matrix Category 3	List a third matrix category from Table 4, section 3.2 for which the method/procedure is applicable; this within the same measurement range and expected uncertainty range stated from column T to AA for the analyte-matrix combinaison 1; or Leave cell empty.
Column J	Matrix Category 4	List a fourth matrix category from Table 4, section 3.2 for which the method/procedure is applicable; this within the same measurement range and expected uncertainty range stated from column T to AA for the analyte-matrix combinaison 1; or Leave cell empty.
Column K	Matrix Category 5	List a fifth matrix category from Table 4, section 3.2 for which the method/procedure is applicable; this within the same measurement range and expected uncertainty range stated from column T to AA for the analyte-matrix combinaison 1; or Leave cell empty.
Column L	Matrix Category 6	List a sixth matrix category from Table 4, section 3.2 for which the method/procedure is applicable; this within the same measurement

		range and expected uncertainty range stated from column T to AA for the analyte-matrix combination 1; or Leave cell empty.
Column M	Applicable Matrices	State the names (e.g. nature and physical form) of the matrix(ces) for which the measurement method/procedure is applicable; e.g. human serum; fresh, frozen or lyophilized.

Information on the reference measurement method/procedure (RMM/P)		
Column N	Identifier/Number	State the identification code of the reference measurement method/procedure that uses any number or lettering system; or Leave cell empty. (Do not leave both Column N and Column O blank) This information will be returned on the JCTLM database website.
Column O	Name	State the name of the reference measurement method/procedure or Leave cell empty. (Do not leave both Column N and column O blank) This information will be returned on the JCTLM database website.
Column P	Organization that developed/validated the method	Enter the acronym and/or name of the developer/owner of the reference measurement method/procedure being submitted
Column Q	Measurement Technique(s) Used	List the measurement technique(s) used by using acronym(s) or full name(s) of the measurement technique(s); See examples listed in Table 6, section 3.4.
Column R	Comments 1	Enter a comment*
Column S	Comments 2	Enter a comment*
Column T	Quantity	Enter a quantity being measured; See examples in Table 5, section 3.3.
Applicable method range Use the three fields below to describe the applicable measurement range of the method/procedure.		
Column U	From	Minimum range value.
Column V	To	Maximum range value.
Column W	Unit	Unit in which the value is expressed.
Method expected uncertainty range Use the four fields below to state the expected uncertainty range for the method/procedure applied. In the case where one value of the expanded uncertainty is stated rather than a range of values, this value is to be entered in both 'From' and 'To' fields.		
Column X	From	Minimum range value of the expanded uncertainty.
Column Y	To	Maximum range value of the expanded uncertainty.
Column Z	Unit	Enter %, or Unit in which the expanded uncertainty is expressed.
Column AA	Level of confidence (%)	e.g., Enter '95%' to indicate the level of confidence for the expanded uncertainty.

Method/Procedure documentation The reference or citation of the publicly available documentation indicated in the fields below will be returned on the JCTLM website.		
Column AB	Peer Reviewed Publication	Enter reference(s) for peer reviewed publication(s) with description of the method and validation data

* Comments used for review purposes only. This information will not be returned on the JCTLM Database website.

		! The .PDF file of the publication(s) cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AC	Not to be used	Not to be used
Column AD	CCQM Key Comparison Report in which the method has been used	Enter the CCQM key or pilot comparison identifier, e.g. CCQM-K## or CCQM-P##, or Leave cell empty. (Consultative Committee for Amount of Substance (CCQM)) ! If Column AE is not applicable the .PDF file of the Final Report of the comparison cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AE	Hyperlink for CCQM Key comparison report	Reference and URL of the Metrologia Technical Supplement for the CCQM key or pilot comparison (given in Column AD) will be entered by the JCTLM Secretariat (if applicable).
Column AF	Non-CCQM Interlaboratory Comparison Report	Enter a citation for the non-CCQM interlaboratory comparison report or Leave cell empty. ! If Column AG is not applicable the .PDF file of the Final Report of the comparison cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete).
Column AG	URL of non-CCQM Interlaboratory Comparison Report	Enter the URL of the report cited in column AF or Leave cell empty.

Compliant with other mandatory elements of ISO 15193?		
Column AH	Other means of validation used?	Enter a comment as appropriate*
Column AI	Adopted by professional organization? (If so state the organization name)	Enter a comment as appropriate*
Column AJ	Not to be used	Not to be used
Column AK	No known patent issues?	Enter a comment as appropriate*
Column AL	Not to be used	Not to be used
Column AM	Do the method instructions contain all the required items? The attached spreadsheet must be completed to demonstrate how compliance is met for all requirements of paragraph 4 appropriate spreadsheet.	Enter “Yes” or “No” as appropriate. For each nominated method a new compliance template must be completed, and the reference number given must be recorded in this cell.

* Comments used for review purposes only. This information will not be returned on the JCTLM Database website.

Column AN	Additional comments	Enter a comment* or Leave cell empty

Contact information for additional details (for review process) Use the following fields to enter the contact details of the person who has submitted the nomination file, so that they may be contacted if additional information is required by the JCTLM DBWG Review Team. This information will not be returned in the JCTLM database website.		
Column AO to AQ	Name, email address and phone number	Enter contact details as appropriate.

Information to be published via the JCTLM-DB		
Column AR	Comment(s) to be published via the JCTLM database website	Enter a comment as appropriate or Leave cell empty
Column AS	Hyperlink to Final Report of extent-of-equivalence studies among listed RMM/Ps	Enter the title of the Final Report of extent-of-equivalence study among listed RMM/Ps, which included this reference measurement method/procedure (see section 3.7) or leave cell empty. **!** The .PDF file of the document cited here must be submitted together with the completed nomination file in order to facilitate the review process. (If not included this would render the nomination form incomplete)

Information from the JCTLM DBWG Review Team The following fields are to be filled in by the JCTLM DBWG Review Team; this information will not be returned in the JCTLM database website.		
Column AT	Does Reference Method value assignment approach meet traceability requirements of IVDD industry and regulatory community?	Comments for review committee use.
Column AU	Additional reviewer comments	Comments for review committee use.
Column AV	Recommended for publication in JCTLM List?	'Yes' or 'No' is to be entered. See section 3.5.1

Information for JCTLM Secretariat use The following fields are to be filled in by the JCTLM Secretariat; this information will not be returned on the JCTLM website.		
Column AW	Review document for review committee use	The name of the compliance demonstration spreadsheet completed by the RMM/P developer/owner is to be entered by the JCTLM Secretariat.

* Comments used for review purposes only. This information will not be returned on the JCTLM Database website.

Column AX	Review Word document (to be forwarded to the RMP developer/owner)	The identifier of the review report is to be entered by the JCTLM Secretariat. This document will be forwarded to the RMM/P nominator after the completion of the review and approval processes.
Column AY	Owner/Developer comment (in case of delisting)	Comment from the owner/developer of the RMM/P stating the reasons for removal of the RMM/P from the lists published on the JCTLM database website; it is to be entered by the JCTLM Secretariat. This comment will be published in a separate document (.PDF) containing all entries that have been delisted from the JCTLM database.
Column AZ	Review team name	The name of the JCTLM DB WG Review Team that has carried out the review is to be entered.

3. Data contained into the RMs and RMM/Ps files

3.1 Analyte Category

Table 3 gives the list of the analyte categories that can be entered in the corresponding field of the nomination file by the nominating organization. The list can be extended to cover other categories as requested by JCTLM Database WG.

Analyte Category	
0	Blood Cell Counting
1	Blood gases
2	Blood groupings
3	Coagulation factors
4	Drugs
5	Electrolytes
6	Enzymes
7	Metabolites and substrates
8	Microbial serology
9	Non-electrolyte metals
10	Non-peptides hormones
11	Nucleic acids
12	Proteins
13	Vitamins and micronutrients
14	Other

Table 3: List of the Analyte Categories

3.2 Matrix Category

Table 4 gives the list of the matrix categories that can be entered in the corresponding field of the nomination file by the nominating organization. The list can be extended to cover other categories as requested by JCTLM Database WG.

Matrix Category	
1	High-purity material
2	Calibration solution
3	Whole blood
4	Blood serum
5	Blood plasma
6	Urine
7	Other

Table 4: List of the Matrix Categories

3.3 Quantity

Table 5 gives some examples of quantities that can be entered into the corresponding field of the nomination file by the nominating organization.

Quantity
Mass concentration
Volume concentration
Amount-of-substance fraction
Mass fraction
Volume fraction
Amount-of-substance content
Volume content
Amount of substance ratio

Mass ratio Volume ratio

Table 5: List of the quantities

3.4 Measurement techniques

Table 6 gives some examples of measurement techniques that can be entered into the corresponding field of the nomination file by the nominating organization. The list can be extended to cover other measurement techniques.

	Measurement principles or techniques
1	atomic absorption spectrophotometry
2	coulometry
3	flame emission spectrophotometry
4	gravimetry
5	high performance liquid chromatography
6	inductively coupled plasma atomic emission spectroscopy
7	inductively coupled plasma mass spectrometry
8	instrumental neutron activation analysis
9	ion chromatography
10	isotope dilution mass spectrometry
11	liquid chromatography mass spectrometry
12	turbidimetry
13	radiochemical neutron activation analysis
14	spectrophotometry
15	turbidimetry
16	ultracentrifugation/spectrophotometry
17	enzymatic
18	flow cytometry

Table 6: List of the measurement techniques

3.5 Recommended for publication in the JCTLM Database

3.5.1 – Information on each nominated reference material and reference measurement method/procedure fully reviewed by the corresponding review team of the Database Working Group is entered into the database. However, only those that are recommended for publication (column AR, section 1 and column AV, section 2) will appear on the lists published in the JCTLM website. If the field 'Recommended for publication' is left blank the reference material and the reference measurement method/procedure will not appear on the JCTLM website.

3.5.2 - In the case where a RM or a RMM/P is not recommended for publication in the JCTLM Database after being nominated and fully reviewed, and is subsequently re-nominated, the code (Unique Identifier Number, column A) is to be modified with the addition of a character (i.e. letter); e.g. if the RM was identified by 1104 for its first nomination, it could be identified by 1104A for its second nomination.

3.6 Hyperlink to Final Report of extent-of-equivalence studies among listed RMs

The Final Report of the extent-of-equivalence study among listed RMs (column AD, section 1) is to be published on the JCTLM Database website for all RMs involved in the study, via a hyperlink. The Final Report is saved by the JCTLM Secretariat in the appropriate local directory. If the Final Report is received after the publication of the RMs in the JCTLM-Lists, the hyperlink will be entered automatically by the JCTLM Secretariat for each of the RMs involved in the extent-of-equivalence study.

3.7 Hyperlink to Final Report of extent-of-equivalence studies among listed RMM/Ps

The Final Report of the extent-of-equivalence study among listed RMM/Ps (column AS, section 2) is to be published on the JCTLM Database website for all RMM/Ps involved in the study, via a hyperlink. The Final Report is saved by the JCTLM Secretariat in the appropriate local directory. If the Final Report is received after

the publication of the RMM/Ps in the JCTLM-Lists, the hyperlink will be entered automatically by the JCTLM Secretariat for each of the RMM/Ps involved in the extent-of-equivalence study.

3.8 Compliance demonstration spreadsheets

Reference material and measurement method/procedure nomination folders include a template spreadsheet named “Compliance template”. This must be completed by the nominating organization to demonstrate how compliance is met with the requirements of ISO 15194:2009 for RM and ISO 15193:2009 for RMM/P, and the information required is as follows:

- Indicate in column C whether or not the nomination is compliant with the requirements of ISO 15194:2009 for RM and ISO 15193:2009 for RMM/P,
- Add in column D a short description on how the compliance with the requirements of ISO 15194:2009 for RM and ISO 15193:2009 for RMM/P is achieved, with a reference to the section of the documentation supporting the submission. Alternatively, the compliance description can be submitted as a separate supporting document summarizing how compliance is met with references in the compliance spreadsheet.

One spreadsheet should be used for each reference material or reference measurement method/procedure being nominated. If not provided this would render the nomination incomplete.