

# IECEE OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Factory Surveillance Body Assessment Report

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IECEE-PAC/ /

(\*Note: Document identification should be: "IAR" for Initial Assessment Report, EAR for Extension of Scope Assessment, "FAR" for Follow-up Assessment Report or "RAR" for Re-assessment Report and RLAR for Re-Location Assessment Report in IECEE-PAC/XXX/\*)

**Factory Surveillance Body**

Fill in with complete Legal Entity name of the Factory Surveillance Body and country of domicile.

**Date of assessment: yyyy-mm-dd**

The aim of ~~this~~ these notes in orange colour is document is to provide guidance for Assessors undertaking Factory Surveillance Body assessments and completing form OD-4006 Factory Surveillance Body Assessment Report. The notes are to be deleted by the assessor when completing the report.



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The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

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## FOREWORD

### Scope

To be determined.

### Document Owner

CFS

### History of changes

<u>Revision</u> Date	Brief summary of changes
2016-06-01	The following sub-clauses have been updated: 1.1, 1.6, 1.8, 2.1 to 2.3, 3.3 to 3., 4.5, 7, 9, Annex 1A, Annex 2 The following sub-clauses have been deleted: 1.5, 6 and Annex 1B.
<u>2018-01-24</u>	<u>The guidance information from OD-G-4006 edition 2.0 has been incorporated and marked orange.</u> <u>Aligned with OD-2004 and OD-2005</u> <u>The following sub clauses were modified: 1.8, 3.3, 3.4, Annex 3</u>

Effective date	<del>Target revision</del> <u>Next maintenance due</u> date
<del>2016-06-01</del> <u>2018-01-24</u> <del>2016-06-05</del>	<del>2019-06-01</del> <u>2021-06-05</u>



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## 1 Object and field of assessment

### 1.1 Object

Scope of Accreditation: Is the accreditation body accredited scope held by the FSB equal/greater or smaller than the applied IECEE scope?

Assessment covering	IECEE Assessment	Joint Assessment	Accreditation Body	Scope of Accreditation
Initial Assessment	<input type="checkbox"/>	<input type="checkbox"/>	N/A	
Extension of Scope	<input type="checkbox"/>	<input type="checkbox"/>		
Re-Assessment	<input type="checkbox"/>	<input type="checkbox"/>		
Follow-up Assessment	<input type="checkbox"/>	<input type="checkbox"/>		
Re-Location Assessment	<input type="checkbox"/>	<input type="checkbox"/>		

### 1.2 Product Categories

#### 1.2.1 Product Categories covered by the re-assessment

Please cross (X) as appropriate and refer to Annex 1 for a complete list of the scope of the assessment containing details of the relevant Product Category, Program/Scheme, NCB and relevant experience.

BATT	CABL	CAP	CONT	E3	ELVH	EMC	HOUS	HSTS	INDA	INST	LITE
<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"/>
MEAS	MED	MISC	OFF	POW	PROT	PV	SAFE	TOOL	TOYS	TRON	ITAV
<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 checked="" type="checkbox"/>

#### 1.2.2 Product Categories covered by the initial/scope extension assessment

Please cross (X) as appropriate and refer to Annex 1 for a complete list of the scope of the assessment containing details of the relevant Product Category, Program/Scheme, NCB and relevant experience.

BATT	CABL	CAP	CONT	E3	ELVH	EMC	HOUS	HSTS	INDA	INST	LITE
<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"/>
MEAS	MED	MISC	OFF	POW	PROT	PV	SAFE	TOOL	TOYS	TRON	ITAV
<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 checked="" type="checkbox"/>

### 1.3 Previous Assessment Report

Previous Assessment Report Number	IECEE-PAC/ /
Previous Assessment Date	yyyy-mm-dd



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**1.4 FSB Organization structure**

Please cross (X) to indicate if the FSB assessed is a part of a NCB and/or a CBTL, or if the FSB is an independent organization having a contract with one (or more) NCB's. Cross "Other" only when applicable and specify.

<input type="checkbox"/> Part of NCB	<input type="checkbox"/> Part of CBTL
<input type="checkbox"/> Independent FSB	<input type="checkbox"/> Other (specify)

**4.4.1.5 Complete legal entity name and address of the Factory Surveillance Body**

Legal Entity Name	
Address	
Contact Person	
Email	
Tel	
Mobile	
Fax	
Website	

**4.5.1.6 Members of the Assessment Team**

Assessor Country: Country of residence to be listed

	Name	Organization	Country
Lead Assessor			
Assessor			
Assessor			
Assessor			

**1.7 Place(s) and date(s) of Assessment**

If multiple buildings include addresses of both, such as: ABC Factory Surveillance Body in City A together with DEF Factory Surveillance Body in City D.

Main location(s)	
If applicable, other location(s)	
Date of Assessment for main location(s) and any other location(s)	yyyy-mm-dd



**4.61.8 Assessment Base**

~~IECEE 01 Basic Rules~~ [IEC CA 01 and IECEE 01-S Basic Rules](#)

~~IECEE 02 Rules of Procedure~~ ~~CB Scheme~~

[IECEE 02-2 IECEE Membership Procedures](#)

[IECEE 02-3 Peer Assessment Programme Procedures](#)

ISO/IEC 17065 Requirements for bodies certifying products, processes and services

ISO/IEC 17020 Requirements for operation of various bodies performing inspection

[OD-2006 Guidelines and Information for IECEE Assessments: Procedures and Documentation](#)

~~OD-G-4006 Guidelines for Assessors~~

The above documents are to be based upon the latest published editions

**2 Organization**

**2.1 National Certification Body undertaking the responsibility for the Factory Surveillance Body**

Indicate whether the responsible NCB was present during the assessment, and if so, by who. In the case the CB-FSB also has a contract with another NCB (or other NCBs), please specify in the Annex 4.

If there ~~are~~ is more than one NCB involved, use [Annex 4](#) NCBs undertaking the responsibility for the Factory Surveillance Body of this report for **each** additional NCB

Legal entity name	
Address	
NCB Representative present at assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Number of NCBs associated with this FSB	

	Contact person located at the NCB	NCB Representative present at assessment (if different to contact person)
Name		
Email		
Tel		
Fax		



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**2.12.2 Brief history of the Factory Surveillance Body**

Include information about the legal entity of the FSB and ownership. Reference ISO/IEC 17020/17065 as applicable. Complete this section for Initial Assessment and for other Assessments complete only with updates from the last assessment.

**2.22.3 Organization of the Factory Surveillance Body**

Include information relevant to the organization of the FSB pertaining to the operated Scheme(s) and /or programs including the interaction with its NCB.

Show/briefly describe the programs and schemes in which the FSB is active. E.g. make reference to national certification mark(s) owned, controlled or licensed by the associated NCB and for which the FSB is active at least in the course of this assessment.

If the Quality Management System is such that the Quality Manual and/or Quality Procedure include one or more organization charts then this could be attached as an appendix to the Assessment Report.

**3 Personnel Structure**

**3.1 Responsible Managers for Surveillance**

Name	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		Reporting to:
			Yes	No	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	



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**3.2 Staff involved in the Quality Management System of the Factory Surveillance Body**

Name	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		Reporting to:
			Yes	No	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

**3.3 ~~Registered~~ IECEE Registered Factory ~~Inspectors~~ Surveillance Trainer involved in Surveillance**

Number of inspectors under responsibility of the FSB and registered by the NCBS as IECEE Factory Inspector					
Name	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		Reporting to:
			Yes	No	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

**3.4 ~~Registered~~ Qualified IECEE Factory Inspectors involved in this assessment**

When the declared years of experience is low, the assessment team should make a professional judgment based upon interviews on the awareness and knowledge of the standards, witnessing of Surveillance Report review, witnessing of surveillances as well as CV information e.g. previous employments and function, training programmes completed.

Name	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		Reporting to:
			Yes	No	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	





### 3.5 Assessment of staff competence

Briefly describe how the competence was assessed e.g. interview, interview by video conference, CV check, demonstration of surveillance decisions, knowledge of the surveillance program/scheme, reviewing of the Surveillance Reports, etc.

### 3.6 Training

Briefly describe if the FSB has documented procedures for training inspectors for the FSS inspection program.

Indicate if the records of training were checked. Also provide some typical examples of the training provided by the relevant associated NCBs, if applicable.

IECEE OD- 4004 requirements for factory inspectors shall be fulfilled.

## 4 FSB Quality Management System

Briefly describe the structure and implementation of the quality system of the FSB. When applicable, describe in which way the Quality Management System is integrated in the Quality Management System of the NCB and/or CBTL and in which way the Quality Management System of the FSB complies with the requirements of ISO/IEC 17065, item 5.1.

The documentation shall comply with the requirements of ISO/IEC 17065, item 7.

Review the procedures for accepting and handling of inspection requests from other organizations and/or manufacturers. See ISO/IEC 17065, item 6.2 and ISO/IEC 17020, item 4.1.6 as a guide.

Review procedures for handling of complaints against ISO/IEC 17065, item 7.13; the control of non-conforming work against ISO/IEC 17020, item 8.7 and corrective and preventive actions against the requirements given in the items 8.7 and 8.8 of the ISO/IEC 17065 and ISO/IEC 17020.

The keeping of records shall comply with the requirements of the ISO/IEC 17065 item 8.4.



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Internal audits and management review shall be in conformity with the requirements of the ISO/IEC 17065, items 8.5 and 8.6. State whether reports from external/internal audits, management reviews and corrective action processes have been reviewed and other relevant items from ISO/IEC 17065.

Additionally the Rules of Procedure of the relevant IECEE Schemes should be assessed in order to verify that they are duly included in the quality management system and implemented in practise and effectively. This assessment may include, but is not limited to, e.g. Operational Documents, CTL Decisions, CFS decisions, process of document control and provision to use the appropriate IEC Standards etc.

Structure of the Quality System
Document control
Review of requests, tenders and contracts
Complaints
Control of non-conforming work



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Corrective action
Preventive action
Control of records
Internal audits
Management reviews
IECEE Rules of Procedure and Guidance
IECEE Operational Documents



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CTL and CFS Decisions
Use of appropriate IEC standards
Current decisions

**5 Critical Technical Procedures^**

Briefly describe the presence and appropriateness of procedures for sample selection and handling as well as handling of Product Identification Document (PID), if applicable for activities of this body.

Sampling: Procedures shall be in compliance with the requirements of ISO/IEC 17020, item 7.2

Sampling
Handling of test items
Handling of Product Identification Document (PID)



## 6 Void

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## 7 Surveillance reports reviewed during the assessment

Check the validity and completeness of Surveillance Reports, e.g. correct annexes used, proper signatures and verdicts etc.

Check if Surveillance Reports show that requirements for testing on site are in compliance with the requirements/Standard.

Surveillance Reports from surveillance schemes similar to the FSS may be referenced.

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## 8 Number of Non-Conformity Reports issued

Number of NCRs appended	
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## 9 Recommendations of the Assessment Team

This assessment has been a sampling exercise and thus every aspect of the Factory Surveillance Body's activities has not been covered. It does not follow, therefore, that non-conformances do not exist in areas where none have been reported in this assessment report.

Standard recommendations:

1. The Assessment Team recommends <b>acceptance</b> of the assessed organization.	<input type="checkbox"/>
2. The Assessment Team recommends <b>acceptance</b> of the assessed organization <b>subject to clearance</b> of the outstanding Non-conformity Reports as appropriate.	<input type="checkbox"/>
3. The Assessment Team recommends that the acceptance of the assessed organization is <b>postponed</b> until a further <b>follow-up assessment</b> is carried out and is found satisfactory.	<input type="checkbox"/>
4. Other, please specify using similar terminology	<input type="checkbox"/>

### 9.1 Additional Information



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### 10 Signatures of the Assessment Team

Date: yyyy-mm-dd

	Printed name	Signature
Lead Assessor		
Assessor		
Assessor		
Assessor		

### 11 Acknowledgement by the assessed organization

- We acknowledge and agree with the content of the Assessment Report.
- We acknowledge the content of the Assessment Report and we disagree for the following reasons:

Date: yyyy-mm-dd

	Printed name / Organization	Signature
FSB Representative		
NCB Representative		
NCB Representative		
NCB Representative		



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## Annex 1

### Declaration of Surveillance Experience

Please cross (X) as appropriate the accepted/not accepted Product Category as well as program/Scheme and NCB.)

Surveillance reports from inspection programs/schemes similar to the FSS may be taken into consideration.

	Program/Scheme	NCB	Number of Surveillance Reports issued during the last three years	Assessment Team acceptance	
				Yes	No
				<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"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

Note: For the organization's full scope please see the IECEE Website





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## Annex 2 Organization Chart

If the quality management system is such that the Quality Manual and/or Quality Procedure include one or more organization charts then this could be attached in this Annex. The Assessment Team shall not request the assessed organization to draft a dedicated organization chart simply for the purpose of completing this Annex or clarifying the information provided in the body of this report.



### Annex 3 “Independence and impartiality” including “Commercial consultancy”

[This Annex to OD-4006 \(Annex 3\) applies to all Factory Surveillance Bodies not already assessed against it. Note: If this Annex has been completed at least once and the organization is accredited according to ISO/IEC 17065, this Annex does not have to be completed again, except for clause 0. If the FSB is not accredited, this Annex needs to be completed during each Assessment.](#)

<b>0. Compliance with ISO/IEC 17065</b>	<b>Yes</b>	<b>No</b>
<u>The FSB has a valid accreditation to ISO/IEC 17065.</u>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1. General Operating Procedure</b>	<b>Yes</b>	<b>No</b>
Does the Body have a documented procedure for independence and impartiality that as a minimum includes the following while carrying out conformity assessment activities: a) to be objective, b) to identify, avoid, mitigate and manage conflicts of interest, and c) to ensure independence, so as to increase the amount of trust, confidence and value that those activities have in the market place	<input type="checkbox"/>	<input type="checkbox"/>
Document title:	Document number:	
<b>2. Reference Document</b>	<b>Yes</b>	<b>No</b>
<u>Does the Body have access to ISO/IEC 17065:2012 and in particular Sub-clause 5.2 Mechanism for safeguarding impartiality, “Management of Impartiality?”</u> <del>Does the Body have access to ISO/IEC 17065 and in particular Sub-clause 4.2</del>	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body have access to ISO/IEC 17020:2012 and in particular Sub-clause 4.1	<input type="checkbox"/>	<input type="checkbox"/>
<b>3. Knowledge, training and decision making</b>	<b>Yes</b>	<b>No</b>
Does the Body’s staff have knowledge of the basic concepts of independence and impartiality?	<input type="checkbox"/>	<input type="checkbox"/>
Were the training records of the Body’s staff checked?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body’s selected staff have sufficient knowledge in the principles of independence and impartiality to provide initial training and retraining to other staff?	<input type="checkbox"/>	<input type="checkbox"/>
Names of person(s):		
Were examples of training programs of the Body’s staff reviewed and found to be sufficient?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body’s staff select and make pass/fail decisions taking the principles of independence and impartiality into account?	<input type="checkbox"/>	<input type="checkbox"/>
Are the Body’s decisions based on objective evidence of conformity (or nonconformity) obtained by the Body’s staff?	<input type="checkbox"/>	<input type="checkbox"/>
Are the Body’s decisions influenced by other interests or parties?	<input type="checkbox"/>	<input type="checkbox"/>



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<b>4. Documentation and Implementation</b>	<b>Yes</b>	<b>No</b>
Does the Body have documented and implemented (on an on-going basis) sufficient procedures to ensure the independence and impartiality of all staff?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body have documented and implemented (on an on-going basis) sufficient procedures to ensure that the remuneration of staff is free from pressures and inducements and is not dependent on the number, outcome of the result of their activities?  Note: It is recognized that the source of revenue of the Body is its customers paying for its services and that this is a potential threat to independence and impartiality.	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body have documented sufficient procedures for the identification, review, resolution and prevention of conflict of interest (including “commercial consultancy”) where conflicts of interest are suspected or proven (including subcontracted personnel) and does the Body keep records of such reviews and decisions?	<input type="checkbox"/>	<input type="checkbox"/>

<b>5. Marketing and advertising materials</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
Do the Body’s marketing materials give the impression that “commercial consultancy” activities are offered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the Body linked to an organization that provides “commercial” consultancy services?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a documented policy/procedure to ensure that there is an effective separation between all conformity assessment activities and consultancy services?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body’s surveillance staff participate in “commercial consultancy”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>6. Staff declarations</b>	<b>Yes</b>	<b>No</b>
Does the Body require all staff acting on its behalf to declare any potential conflict of interest?	<input type="checkbox"/>	<input type="checkbox"/>

<b>7. Compliance</b>	<b>Yes</b>	<b>No</b>
Does the Body comply with all the above independence and impartiality principles on an ongoing basis?  Note: If the answer is NO a Non-Conformity Report must be issued	<input type="checkbox"/>	<input type="checkbox"/>



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#### Annex 4      NCBs undertaking the responsibility for the Factory Surveillance Body

The NCB, on which behalf the CB-FSB is assessed, is to be specified under item 2.1 of the OD-4006.

In the case the CB-FSB also has a contract with another NCB (or other NCBs), please specify

Legal entity name	
Address	
NCB Representative present at assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Number of NCBs associated with this FSB	

	Contact person located at the NCB	NCB Representative present at assessment (if different to contact person)
Name		
Email		
Tel		
Fax		

Legal entity name	
Address	
NCB Representative present at assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Number of NCBs associated with this FSB	

	Contact person located at the NCB	NCB Representative present at assessment (if different to contact person)
Name		
Email		
Tel		
Fax		



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### Non-Conformity Reports

<b>Non-conformity Report No</b>	/	<b>Date</b>	YYYY-MM-DD
Categories concerned			
Clause / Sub-clause of Non-Conformity			
Non-conformity description			
Lead Assessor		Management representative	
Signature and printed name		Signature, printed name and title	
Root cause of non-conformity			
Proposed Corrective action(s)			



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Implementation date	Management representative
YYYY-MM-DD	Signature, printed name, title and date
<b>Proposed Corrective Action(s) acceptance</b>	
Acceptance, no further verification required	<input type="checkbox"/>
Acceptance, further verification of implementation is required, <u>without</u> on-site follow-up assessment	<input type="checkbox"/>
Acceptance, further verification of implementation is required, <u>with</u> on-site follow-up assessment	<input type="checkbox"/>
Lead Assessor (Signature, printed name and date)	
<b>Implementation verified and final clearance provided by Lead Assessor</b>	
Lead Assessor signature, printed name and date	

**INTERNATIONAL  
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COMMISSION**

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