1. Applicability / Revision

This Temporary Appendix (TA) to the IOSA Program Manual (IPM) is applicable to all stakeholders and parties within the IOSA Program. It may be revised over time and will be re-issued if necessary.

2. Inclusion of IPM Ed 12

The TA is issued to address the extraordinary circumstances caused by the COVID-19 pandemic, the disruption of IOSA Audit activities and resulting effects on the IOSA Registry.

The full and permanent IOSA Program Manual Edition 12 including any Temporary Revisions that were issued and that are still valid and remain in effect without limitations. This TA revises existing requirements, incorporates requirements from already issued Temporary Revisions, and introduces new rules and policies.

The following Temporary Revisions to IPM Ed 12 are incorporated in this TA and will be cancelled upon publication of this TA:

- IPM.ED12.TR2, issued 28 Apr 2020
- IPM.ED12.TR4, issued 23 Jun 2020

If a requirement in this TA is in conflict with a provision in either IPM Edition 12 or any Temporary Revision to it, this TA shall prevail to the extent of the conflicting information.

Any numeric chapter references contained in this document are to be used as follows:

- References to the full, permanent edition of the IPM are listed as a numeric chapter only (e.g. IPM 8)
- References to chapters within this TA are preceded with the letters “TA-” (e.g. IPM TA-2 for this chapter)
3. Definitions

The following terms are introduced through this TA and are defined in this chapter. These definitions supplement the definitions contained in the IATA Reference Manual for Audit Programs (IRM).

Audit phase
The Audit Phase is the part of a Remote Audit which falls between the Opening Meeting and Closing Meeting. The Audit Phase is the time during which scheduled interviews are planned for a Remote Audit.

Conformity – Active Implementation
Conformity – Active Implementation is the assessment used for provisions where an Operator has demonstrated conformity using an active implementation plan. This type of assessment is reserved for cases where an operator would be in non-conformity, however the operator has received a COVID-19 related exemption from the regulator for the same requirement.

Extended Deadline Date
The Extended Deadline Date is the date given to an Operator with a validated claim of Extenuating Circumstances for Audit Conduct, by which a renewal audit must be conducted and closed in order to retain IOSA registration.

First Remote Audit
A First Remote Audit is a Remote Audit conducted on an Operator which has never undergone a Remote Audit.

Focus Area
A Focus Area refers to an issue or area that requires the IOSA Auditor’s increased attention during an Audit. Focus Areas can be defined by IATA either for all operators, individual operators or groups of operators (e.g. based on regions, fleets, etc.).

Focus Areas can be triggered by current industry concerns, emerging risks, regional observations or information related to an operator’s reporting responsibilities in accordance with IPM 7.7. Focus Areas define specific ISARPs, groups of ISARPs, management systems, topics or other areas where an IOSA Auditor will need to increase the sample size and/or general auditing efforts.

Remote Audit
A Remote Audit is an IOSA Audit conducted without any onsite verification of evidence. The audit is conducted remotely using document and record review as well as interviews using teleconferencing technology.

Renewal Audit
A Renewal Audit, as used in this TA, can be either a full scope onsite renewal audit, or a reduced scope remote audit.

Second Remote Audit
A Second Remote Audit is a Remote Audit conducted on an Operator, which has already undergone a First Remote Audit.
4. IOSA Program Management

4.1. Standards Management

IATA shall have a process to provide for reduced scope Remote Audit checklists. Such process shall identify risk levels to IOSA provisions based on a simplified method. IOSA provisions for the reduced scope Remote Audits shall be selected based on the risk levels resulting from this method. There shall be separate checklists for the First Remote Audit and the Second Remote Audit.

4.2. Observation of Remote Audits

IATA shall have a process to observe Remote Audits in part or in full for the purpose of quality control and continuous improvement of the Audit.

(i) Whenever an Audit is performed under a Remote Audit, the IATA QA Program may oversee the IOSA remote audit process, completely or in parts, applying a combination of the different options described below:
   a. Audit to be followed remotely via communication technology;
   b. Interview Auditor(s) after the Audit is completed, with a review of the Audit results;
   c. Interview Auditor(s) to measure discipline knowledge and competence;
   d. Review of the Audit results with supporting documentation from the auditee.

(ii) During the selection of the activities to be evaluated by IATA QA Program, the following elements can be considered to determine the scope of the oversight: Auditor performance, AO performance, the Operator’s previous IARs and incident/accident reports, new standards, specific disciplines, etc.

(iii) IATA shall obtain access to related information or documentation from the AO and the Operator prior to, during or after any announced or unannounced observation and/or evaluation.

4.3. Focus Areas

IATA may, at its discretion, identify Focus Areas for an individual operator, multiple operators or all operators. Focus Areas shall be communicated to the AOs through Alerts or direct communication to the AO for audit specific Focus Areas. Focus Areas shall be:

(i) Defined based on objective information and data;
(ii) Selected based on specific policies and criteria;
(iii) Limited to the scope of the ISM;
(iv) Accompanied by instructions for IOSA Auditors;
(v) Communicated to the AOs at least 7 days prior to any applicable Audit; and
(vi) Of temporary nature.
5. Operator Responsibilities

5.1. Audit Preparation

If an Operator is undergoing a Remote Audit, the Operator shall support the preparation of the Remote Audit. This shall include, but not be limited to:

(i) Timely communication and coordination with the AO to ensure all required activities can be accomplished;
(ii) Assisting the AO in the scheduling of calls;
(iii) Provision of all required manuals and documentation at least fourteen (14) days prior to the opening meeting of the audit. All manuals and documents shall be supplied using the method agreed on with the AO;
(iv) Ensuring reliable internet connectivity during the entire audit phase to enable interviews using video-conferencing technology;
(v) Participation in at least one trial and/or preparatory activity sufficient time prior to the opening meeting to test the video-conferencing technology;
(vi) Any further assistance and collaboration necessary to successfully prepare for the audit.

5.2. Audit Conduct

If an Operator is undergoing a Remote Audit, the Operator shall support and ensure the successful completion of such Remote Audit. This shall include:

(i) Ensuring the availability of teleconferencing capabilities during the whole period from Opening Meeting to Closing Meeting as agreed on with the AO during the planning and preparation;
(ii) Ensuring designated interview partners have sufficient knowledge in the English language to conduct an interview or have translators/interpreters available;
(iii) Support all planned and non-planned activities to the extent possible to support the Auditors in gathering all required evidence;
(iv) Providing all relevant evidence as requested by the Auditors in a timely manner;
(v) Making available randomly selected operational personnel, as required by each Auditor, and to the extent possible, for sampling purposes;
(vi) Providing up to date-controlled documentation and records, if they have changed between the initial submission and the audit phase.
5.3. Operator Questionnaire

An Operator currently on the IOSA registry shall submit the Operator Questionnaire (SAR.F23) as follows:

(i) As required by, and on a frequency specified in this TA or as specified in form SAR.F23;
(ii) Fourteen (14) days prior to a Registration Renewal Audit;
(iii) Anytime there is a significant change compared to the most recent submission.

Note: A significant change is any change in operations (such as policies, fleet(s), authorizations) or in the organization, which has the potential to significantly affect operational safety and which pertains to questions in form SAR.F23.
6. IOSA Registration

6.1. IOSA Registry

An Operator is added or retained on the IOSA Registry under the following conditions:

(i) An Operator has fulfilled all eligibility requirements as outlined in IPM 7; or
(ii) An Operator has a validated claim of Extenuating Circumstances for Audit Conduct; or
(iii) An Operator has completed a full scope onsite Renewal Audit or a reduced scope Remote Audit and is completing corrective actions within the deadlines specified in IPM TA-7.4.1.

6.2. Audit Report Validity

An Audit for a renewal of an existing registration shall have a limited period of validity and shall expire as an instrument for IOSA registration at 23:59 local time, at the location of the Operator, as follows:

(i) For an Audit of an Operator without a validated claim of Extenuating Circumstances for Audit Conduct, on the date exactly two hundred ten (210) consecutive days following the last IOSA registration expiry date;
(ii) For a Remote Audit, while an Operator is under a validated claim of Extenuating Circumstances for Audit Conduct, on the date exactly two hundred ten (210) consecutive days following the Extended Deadline Date;
(iii) For a full scope onsite Renewal Audit, while an Operator is under a validated claim of Extenuating Circumstances for Audit Conduct, on the date exactly three hundred (300) consecutive days following the onsite closing meeting date.

Should corrective action in accordance with the accepted Corrective Action Plan (CAP) not be implemented by the Operator, verified by the AO, and the IAR approved by IATA prior to the above expiry dates, the Audit becomes invalid as a means for the Operator to renew or re-instate the IOSA registration.

Note: The IAR must be submitted to IATA at least 15 calendar days before audit expiration to allow sufficient time for approval.

6.3. Registration Period

The IOSA registration period shall be as detailed below and, if not successfully renewed, expire at 23:59 local time on the expiry date at the location of the Operator as specified on the AOC.

(i) For a full scope onsite Renewal Audit, the registration period shall be twenty-four (24) months;
(ii) For a Remote Audit, the registration period shall be twelve (12) months.
6.4. Registration Renewal

An IOSA registered Operator shall have such registration renewed when all findings resulting from a Renewal Audit, if any, have been closed in accordance with applicable provisions contained in this TA.

The period of renewed registration for a current IOSA Operator shall become effective on the date as specified below:

(i) For an Audit conducted without a validated claim of Extenuating Circumstances for Audit Conduct, on the date the current IOSA registration expires;
(ii) For an audit conducted while under a claim of Extenuating Circumstances for Audit Conduct, on the date the current IOSA registration expires, or the date of the Closing Meeting, whichever is later;
(iii) For an Audit conducted on an Operator in accordance with TA-6.11, on the date of the closing meeting of the Audit conducted in accordance with TA-6.11.2.

Such renewed registration shall expire as defined in IPM TA-6.3. The exact time of such expiry shall be 23:59 local time on the expiry date at the location of the Operator as specified on the AOC.

6.5. Registration Removal

An Operator shall be removed from the IOSA Registry under the following conditions, unless the Operator has been suspended in accordance with IPM TA-6.11:

(i) A Renewal Audit has not been conducted prior to the current expiration date, and a Claim for Extenuating Circumstances for Audit Conduct has not been validated;
(ii) A Renewal Audit has not been conducted prior to the Extended Deadline Date, for any Operator with a validated claim of Extenuating Circumstances for Audit Conduct;
(iii) A Renewal Audit has been conducted, but Findings, if any, have not been closed in accordance with the rules outlined in this Temporary Appendix, notwithstanding any claims for Extenuating Circumstances in accordance with IPM 7.5.6.

6.6. Registration Reinstatement

An operator that:

(i) Has been removed from the IOSA Registry in accordance with IPM TA-6.5 (i) or (ii), shall undergo an initial registration Audit;
(ii) Has been removed from the IOSA Registry in accordance with IPM TA-6.5 (iii), shall be reinstated to the IOSA Registry if all Findings have been closed and the IAR approved within a maximum period of one hundred twenty (120) calendar days following the registration removal.
6.7. Registration Expiry Dates

IOSA Registration expiry dates are based on standard registration periods. A registration expiry date shall only be updated upon the successful conduct of a full scope onsite Renewal Audit or a Reduced Scope Remote Audit, and subsequent closure of such Audit, including IAR approval.

6.8. Annotations

In addition to the regular annotations contained in IPM Table 7.1, the following annotations are introduced temporarily.

<table>
<thead>
<tr>
<th>Description</th>
<th>Annotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Operator is under a validated claim of Extenuating Circumstances for Audit Conduct.</td>
<td>“The registration renewal audit could not be conducted due to Extenuating Circumstances related to and/or caused by the COVID-19 pandemic. The Operator will remain on the registry until dd mmm yyyy.”</td>
</tr>
<tr>
<td>The Operator’s registration date has expired, and the Operator is under the extended finding closure period.</td>
<td>“The Operator underwent a registration renewal audit and is under an extended finding closure period. The Operator will remain on the registry until dd mmm yyyy.”</td>
</tr>
<tr>
<td>The Operator is using the active implementation option for addressing non-conformities related to regulatory exemptions.</td>
<td>“The IOSA Audit Report contains Active Implementation associated with regulatory exemptions related with COVID-19.”</td>
</tr>
<tr>
<td>The Operator is suspended from the registry in accordance with IPM TA-6.11. During the period of suspension, the operator does not enjoy registration status. Upon successful completion of all steps required in TA-6.11, the suspension will be lifted and registration status re-instated.</td>
<td>“Registration has been suspended until dd mmm yyyy.”</td>
</tr>
</tbody>
</table>
6.9. Operator Questionnaire

6.9.1 Submission of Questionnaire

An IOSA registered Operator, which is not under a validated claim of Extenuating Circumstances for Audit Conduct, during the period starting 01 July 2020 and until further notice, shall submit to IATA a completed operator questionnaire (Form SAR.F23), and re-submit this form every sixty (60) days or whenever there is a significant change compared to the most recent submission. The initial submission shall be made within ten (10) calendar days of the above effective date, and re-submission shall subsequently be made every sixty calendar (60) days.

Note. Any information reported through form SAR.F23, which falls within the scope of IPM 7.7.1, will be considered as reported by the Operator and does not need to be reported separately.

6.9.2 Failure to Submit

Failure to submit form SAR.F23 as required in IPM TA-6.9.1 may result in the temporary suspension of the Operator, until successful submission of the form.

6.10. Extenuating Circumstances for Audit Conduct

6.10.1 Eligibility

If an Operator is unable to undergo or complete a Renewal Audit prior to the current expiration date, the Operator may submit a claim of Extenuating Circumstances for Audit Conduct. The validity of a claim of Extenuating Circumstances shall be determined by IATA, based on internal criteria and circumstances which may justify such a claim. As a minimum, an Operator must fulfil the following conditions:

(i) The Operator is IOSA registered;
(ii) The Operator’s registration expiration date is within 150 days of the date of making a claim of Extenuating Circumstances for Audit Conduct;
(iii) The Operator is not able to undergo or complete a Renewal Audit due to conditions and limitations related to and/or caused by the COVID-19 pandemic;
(iv) An updated SAR.F23 form is submitted to IATA together with the claim of Extenuating Circumstances for Audit Conduct.

Note: Effective 1 Aug 2020, claims will only be processed if an Operator has temporarily ceased operations at the time of making a claim.

Note: Effective 1 May 2021, claims for Extenuating Circumstances for Audit Conduct will no longer be accepted.

6.10.2 Extension Period

Should a claim of Extenuating Circumstances for Audit Conduct be validated by IATA, the Operator will remain on the IOSA registry for a period of one hundred and eighty (180) calendar days following the current expiration date. The current expiration date will remain unchanged until a Renewal Audit has been conducted, successfully closed, and the IAR approved.
The following annotation shall be placed on the Operator’s registration until the Renewal Audit has been conducted, successfully closed, and the IAR approved: “The registration renewal audit could not be conducted due to Extenuating Circumstances related to and/or caused by the COVID-19 pandemic. The Operator will remain on the registry until dd mmm yyyy.” During this period, the Operator enjoys full registration status.

Note: If an Operator’s validity of the Claim of Extenuating Circumstances for Audit Conduct expires before 30 April 2021, such validity shall be extended until 30 April 2021.

6.10.3 Operator Questionnaire
An Operator with a validated claim of Extenuating Circumstances for Audit Conduct shall submit an up-to-date status report using form SAR.F23 provided by IATA every sixty (60) days or whenever there is a significant change compared to the most recent submission. Failure to provide and update this report may result in invalidation of the Extenuating Circumstances claim. The form will be made available to parties authorized by the Operator.

6.11. Operators not operating

6.11.1 Suspension
Effective 1 May 2021, if an Operator has temporarily ceased operations and cannot undergo a Registration Renewal Audit, such Operator shall be suspended from the IOSA Registry on the Registration Expiry date or the Extenuating Circumstances Deadline Date, whichever is applicable. Such suspension has the following conditions:

(i) An annotation is added to the Operator’s registration;
(ii) The registration expiry date remains unchanged;
(iii) The maximum suspension period is limited to ninety (90) calendar days, following which the Operator is removed from the IOSA Registry.

6.11.2 Renewal Audit
An Operator suspended in accordance with TA-6.11.1 shall undergo an onsite Registration Renewal Audit or a Reduced Scope Remote Audit within a maximum period of ninety (90) calendar days of the current Expiry date or the Extenuating Circumstances Deadline Date, whichever is applicable. If an Audit does not take place within ninety (90) calendar days, the Operator shall be removed from the Registry.

6.11.3 Closure period for findings
An Operator undergoing an Audit in accordance with TA-6.11.2 shall close all findings resulting from such Audit within a maximum period of 150 calendar days following the Closing Meeting. The Operator shall be removed from the Registry, should the Operator not close all findings within this period.

6.11.4 Lifting of suspension
The suspension in accordance with TA-6.11.1 shall be removed upon successful closure of the Audit in accordance with TA-6.11.3. The renewed registration period shall be in accordance with TA-6.3 and shall be based on the Closing Meeting date of the Audit performed in accordance with TA-6.11.2.
7. Audit Program

7.1. Audit Planning

7.1.1 Planning Process

The AO shall have a planning process to support the conduct of a Remote Audit and to ensure the objectives of the Remote Audit are achieved. Such planning process shall take into consideration:

(i) Availability of reliable internet connectivity;
(ii) Availability of tools to support teleconferences;
(iii) Availability of file sharing platforms or other accepted means to receive documentation;
(iv) Location of auditee and auditors during the Audit;
(v) Language of the auditors, auditee and related documentation;
(vi) Observation of audits by IATA in accordance with IPM TA-4.2.

7.1.2 Auditor Days

The AO shall ensure an Audit of a single Operator is planned for a minimum of:

(i) Thirty (30) auditor days for a regular onsite Audit as outlined in IPM 8.2.5;
(ii) Ten (10) auditor days for a reduced scope First Remote Audit;
(iii) Seventeen (17) auditor days for a reduced scope Second Remote Audit.

7.1.3 IOSA Preparation Visit (IPV)

The AO shall have a process to conduct an IOSA Preparation Visit (IPV) at the discretion of the Operator and in accordance with requirements outlined in IPM Ed 12. If an Operator is planning to undergo a Remote Audit, the IPV shall be delivered remotely using video conferencing technology.

7.1.4 Consecutive Audits

When conducting an Audit, the AO shall ensure that it has not conducted the previous Audit of that Operator, even in such a scenario where the Operator may have not closed that previous Audit. AO shall ensure that no Auditor who has participated in the previous Audit of the Operator (e.g. an Auditor working for multiple AOs) is part of the team that will perform the upcoming Audit. For the purpose of this restriction, Reduced Scope Remote Audits are considered as a previous Audit.

Note: An AO may conduct an Audit of an Operator for which it has conducted the previous Audit, provided no other AO is able to conduct the Audit of the Operator, and the Operator has provided sufficient evidence of refusal to IATA by the remaining AOs.
7.2. Audit Preparation

The AO shall have a process to ensure each Auditor prepares for a Remote Audit. Such preparation shall include:

(i) Review of all relevant documents submitted by the Operator;
(ii) Review of the previous IAR;
(iii) Review of the Operator Questionnaires (SAR.F23), if available;
(iv) Review of country-specific exemptions granted by Authorities as published in the ICAO CCRD website and/or provided by the Operator;
(v) Assessment of documentation using controlled documentation submitted by the Operator;
(vi) Establishment of detailed interview questions and strategies for each Auditor for the interviews, as outlined in the IAH.

7.3. Conducting the Audit

7.3.1 Opening and Closing Meeting

The AO shall ensure the Audit is started with an opening meeting and concluded with a closing meeting. Opening and closing meetings shall:

(i) be conducted using teleconferencing methods for Remote Audits;
(ii) be open to management and staff of the Operator;
(iii) be conducted by the designated Lead Auditor;
(iv) be presented using a standard presentation format;
(v) contain the items listed in the IAH.

7.3.2 Using the Checklist

The AO shall ensure Auditors are using the correct checklist for the Audit as follows:

(i) The full IOSA checklist for a full scope onsite Renewal Audit;
(ii) The reduced scope IOSA Remote Audit checklist for a First Remote Audit;
(iii) The reduced scope IOSA Remote Audit 2 checklist for a Second Remote Audit.

7.3.3 Gathering Evidence

The AO shall ensure Auditors, during a Remote Audit, are gathering necessary evidence to assess conformity with all provisions contained in the IOSA checklist. Such gathering of information shall be accomplished as described in the IAH and shall include the following:

(i) Review of controlled documentation provided by the Operator prior to the Opening Meeting;
(ii) Review of records provided by the Operator prior to the Opening Meeting;
(iii) Interviews and review of evidence and documentation during the Audit Phase.
7.3.4 Assessing Regulatory Exemptions

The AO shall ensure Auditors identify temporary regulatory exemptions from applicable regulations granted to an Operator by the Authority and shall ensure Auditors:

(i) Verify the validity of such temporary exemption using procedures outlined in the IAH;
(ii) Assess the corresponding provision as Conformity – Active Implementation;
(iii) Document the existence of such regulatory exemption in the Audit Software as outlined in the IAH;
(iv) Verify that the Operator’s projected conformity with the IOSA provision will be within a maximum time frame of one hundred eighty (180) days following the deadline to close any findings, or within the time frame allowed by the Authority, whichever is less.

7.3.5 Audit Duration

The AO shall ensure a Remote Audit, once the Opening Meeting has taken place, is not interrupted by more than one business day without interviews and is concluded within 5 business days following the Opening Meeting. Exemptions to these rules can be requested from IATA by the AO in case of unforeseen circumstances.

7.3.6 Focus Areas

The AO shall ensure Auditors and the Operator are aware of Focus Areas identified by IATA and Auditors include these Focus Areas and corresponding instructions in the auditing and sampling. An Operator should be informed about the Focus Area as soon as it becomes known to the AO.

7.4. Audit Follow-up

7.4.1 Closure Period Findings

Findings resulting from a Renewal Audit, whether this was conducted as a Remote Audit or a full scope onsite Audit, shall be closed at the latest by the following deadlines:

(i) For a full scope onsite Renewal Audit, within ninety (90) calendar days following the expiry date of the current IOSA registration;
(ii) For a remote Renewal Audit, within ninety (90) calendar days following the expiry date of the current IOSA registration;
(iii) For a remote Renewal Audit conducted while under a validated claim of Extenuating Circumstances for Audit Conduct, within ninety (90) calendar days following the Operator’s EC deadline date as communicated by IATA;
(iv) For a full scope onsite Renewal Audit, conducted while under a validated claim of Extenuating Circumstances for Audit Conduct, within one hundred eighty (180) calendar days following the onsite closing meeting date.

If findings are not closed by the above deadline dates, an Operator shall be removed from the IOSA Registry in accordance with IPM TA-6.4.
7.5. Remote Audit Eligibility

7.5.1 First Remote Audit
An Operator shall be eligible for a First Remote Audit if it has never undergone a Remote Audit.

7.5.2 Second Remote Audit
A Second Remote Audit agreement shall only be executed as an amendment to a previously executed full-scope onsite Audit Agreement. An Operator that has already undergone a First Remote Audit shall not enter into an Amendment Agreement with an Audit Organization for a Second Remote Audit, unless the following conditions are fulfilled:

(i) The Operator has already undergone a First Remote Audit; and
(ii) Current government-imposed travel or entry restrictions at the Operator’s place of business do not allow an Audit Team to travel onsite, an onsite Audit would result in unreasonable additional variable cost to the Operator, or the contracted Audit Organization is unable to assemble an Audit Team for an onsite Audit; and
(iii) The Opening Meeting is planned to take place within 45 days following the execution of the Second Remote Audit Amendment Agreement.

Note: Unreasonable additional variable costs would represent costs directly related to government-imposed public health measures such as quarantine, testing, or other related requirements. Unreasonable would generally be defined as costs in excess of 10% of onsite Audit fixed fees.
8. IOSA Data Analysis

8.1. Operator Questionnaires

IATA shall provide an online Operator Questionnaire (Form SAR.F23), aimed at capturing relevant information about the Operator during the COVID-19 pandemic. Such Questionnaire shall serve the purpose of information sharing among operators and regulators.

8.2. Questionnaire Sharing

IATA shall ensure the Operator Questionnaire, as specified in IPM TA-8.1, is made available to interested parties under the same processes and limitations applicable to IARs, as specified in IPM 9.9.

8.3. Questionnaire Data Analysis

IATA at its discretion may conduct analyses of information supplied by the Operators through Operator Questionnaires (SAR.F23) as a function of its responsibility for IOSA program management and promotion of industry safety. Analyses of this information shall be accomplished for the purpose of monitoring, among other things:

(i) industry conformity with IOSA standards and recommended practices (ISARPs) for statistical safety reporting;
(ii) other IOSA program areas as necessary for quality assurance.

All data analysis shall be for statistical purposes only and shall ensure the data is always de-identified.