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	Version Date: 2019-03-06	Effective Date: 2019-03-06
Title: REPs User Account Management		Project Manager: Michael Chan

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[Mandatory]

1. Purpose/Policy

The purpose of this document is to define policies and procedures for user account management of the Regulatory Exchange Platform – secure (REPs) Medical Device Single Audit Program (MDSAP) module.

2. Scope

This procedure applies to all users of the MDSAP module in REPs.

3. Definitions/Acronyms

REPs – Regulatory Exchange Platform – secure

AO – Auditing Organization

RA – Regulatory Authority

PAHO – Pan American Health Organization

4. Authorities/Responsibilities

Auditing Organizations:

Designate a person(s) to serve as the roles of the AO Official Contact Person, AO Submitter and AO Client Manager role in REPs.

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AO Official Contact Person:

Responsible for determining their auditing organization's users, user roles and for submitting account change requests.

Regulatory Authorities:

Designate a person(s) to serve as a RA Approver, RA Master List Manager and REPs Account Manager

REPs Account Manager(s):

Responsible for determining their RA's users, user roles and for submitting account change requests. Also, responsible for reviewing and approving account requests from AOs.

PAHO:

Responsible for implementing approved user account requests.

5. Procedures

AO User Accounts

1. Access to REPs is subject to the following Terms of Use:

This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

2. REPs user accounts are authorized per individual user only. No guest, anonymous, group or temporary accounts are permitted.
3. Each AO's Primary Contact is responsible for determining, maintaining and managing their organization's user accounts and roles.
4. User account change requests for creating, modifying, and deactivating accounts must be submitted by the AO Official Contact Person to reps@paho.org. Account change requests will be routed for review and approval to a REPs Account Manager.

When submitting an account change request, the request must contain

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the following information for each user(s):

- a. First and last name
- b. Email address
- c. The user role(s) desired

5. **AO User Roles and Descriptions**

- a. **AO Submitter** - Creates and submits audit report packages. Can add documents to audit report packages and make modifications to audit report packages.
- b. **AO Client Manager** - Creates new facility requests to be added to the Master List. Can create facility modification and withdrawal requests. Can generate Master List report of all facilities.
- c. **AO Read-Only** – View and search AO’s Master List of facilities and audit report packages.

Note: Users may have multiple roles

6. In the event where a user is no longer an employee of the AO or no longer requires access to REPs, the AO Primary Contact must notify PAHO by submitting an account deactivation request to reps@paho.org within 5 days.
7. User accounts that have been inactive for 90 days will be automatically deactivated by the system.
8. The AO Official Contact Person is required to review their AO’s user list semi-annually to determine if their users’ access is still valid. This user list will be provided by the RAs for review.

RA User Accounts

9. REPs user accounts are authorized per individual user only. No guest, anonymous, group or temporary accounts are permitted.
10. Each RAs respective REPs Account Manager is responsible for determining, maintaining and managing their organization’s user accounts and roles.
11. The REPs Account Manager is responsible for approving and submitting

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account change requests to PAHO using the Account Update Request form located in the REPs PAHO folder in Box.

12. RA User Roles and Descriptions

- a. **RA Master List Manager** - Approves facility creation, modification and withdrawal requests. Can create, modify and deactivate facilities in the Master List.
- b. **RA Approver Role** – Reviews submitted audit report packages and can add a final classification to audit report packages. Can change the submission status of an audit report package.
- c. **RA Read-Only** – Can view all facilities in the Master List and view all audit reports packages.

13. In the event where a user is no longer an employee of the RA or no longer requires access to REPs, the respective RA REPS Account Manager must submit an account deactivation to request using the Account Update Request form in the REPs PAHO folder in Box within 5 days.

14. User accounts that have been inactive for 90 days will be automatically deactivated by the system.

15. REPs Account Managers must review their RA's user list semi-annually to determine if the user's access is still valid.

6 Forms

N/A

7 Reference Documents

- REP-MDSAP User Guide

8 Document History

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VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2019-03-06	Initial Release	Michael Chan

Version 001
Approval

Approved: ON FILE Date: 2019-03-07
CHAIR, MDSAP RAC