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TITLE: MANAGEMENT OF OPEN LAB SOFTWARE				

1.0 PURPOSE:

To lay down the procedure for Management of Open Lab Software.

2.0 SCOPE:

This procedure is applicable for Ezchrome Elite Open Lab software.

3.0 RESPONSIBILITY:

3.1 Analyst-QC is responsible to follow this SOP.

3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

4.0 DEFINITION: Nil

5.0 PROCEDURE:

5.1 All instruments / equipments that are controlled by software and connected with computer systems shall be accessed through user account and password.

5.2 Such instruments / equipments shall be accessed by the user with user ID and password provided for them.

5.3 The Manager/in charge shall be responsible to create the new project every month.

5.4 The following **USER types (4 Levels)** are available:

5.4.1 Analyst

5.4.2 Reviewer

5.4.3 Asst. Manager / Manager / Sr. Manager

5.4.4 Administrator

5.5 The following **ROLES (6 roles)** are available in Open Lab software:

5.5.1 Everything


5.5.2 System administrator

5.5.3 Instrument administrator

5.5.4 Project administrator

5.5.5 Instrument user

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5.5.6 EZChrome analyst


5.6 Roles screen shots are mention below:

Roles	
Name	Description
› Everything	All privileges
› System Administrator	Manage users and security settings
› Instrument Administrator	Manage instruments and locations
› Project Administrator	Manage projects and project groups
› Instrument User	View and run instruments
› EZChrom Analyst	Generic Role for Laboratory Analysts

5.7 User types and allotted Role Membership as given below:

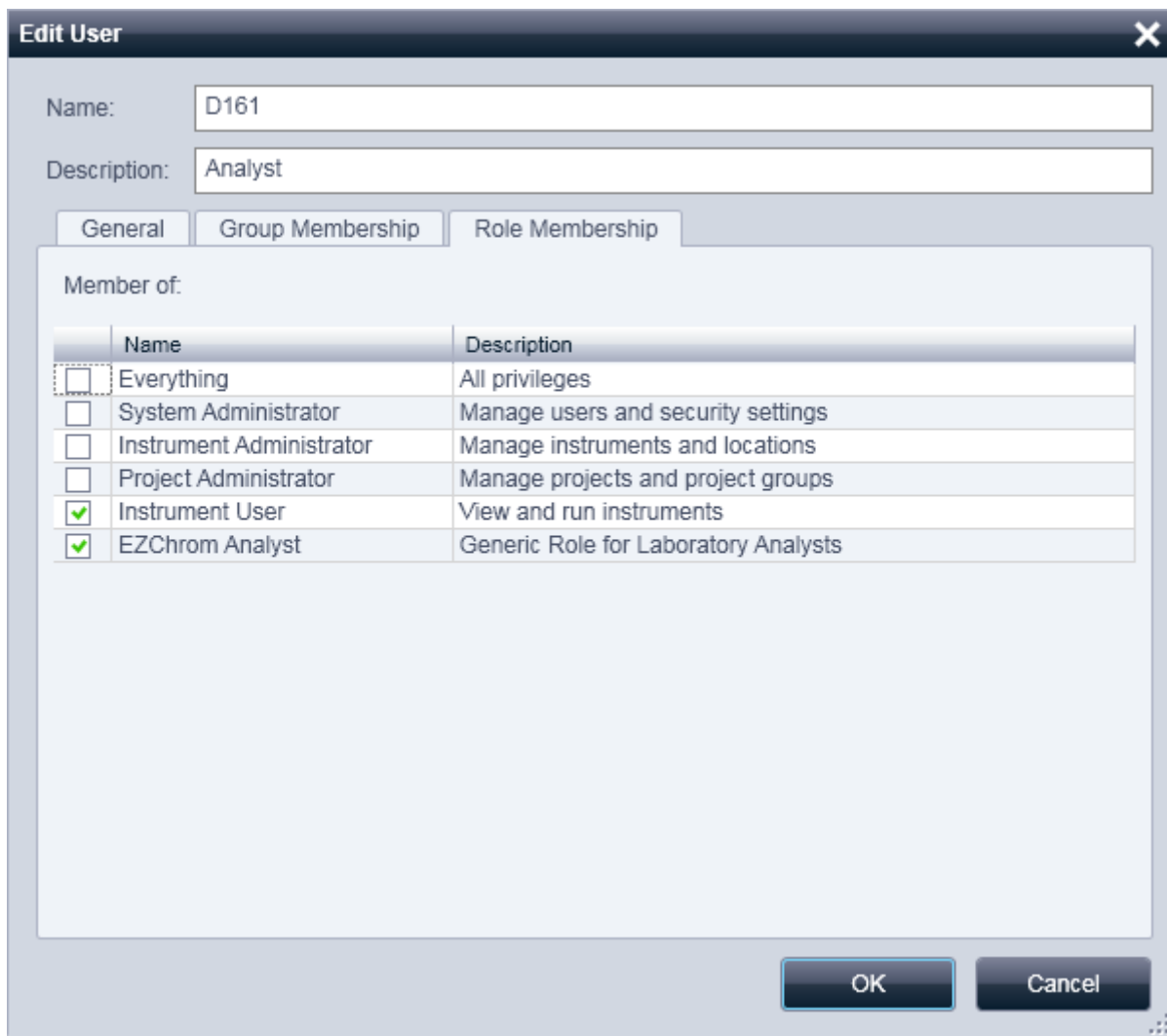
User Type	Allotted Role Membership
Analyst	Instrument User EZ Chrom Analyst
Reviewer	Project Administrator Instrument User EZ Chrom Analyst
Asst. Manager / Manager / Sr. Manager	System Administrator Instrument Administrator Project Administrator Instrument User EZ Chrom Analyst
Administrator	Everything

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5.8 Allotted Role Membership given below:


5.8.1 **Analyst**



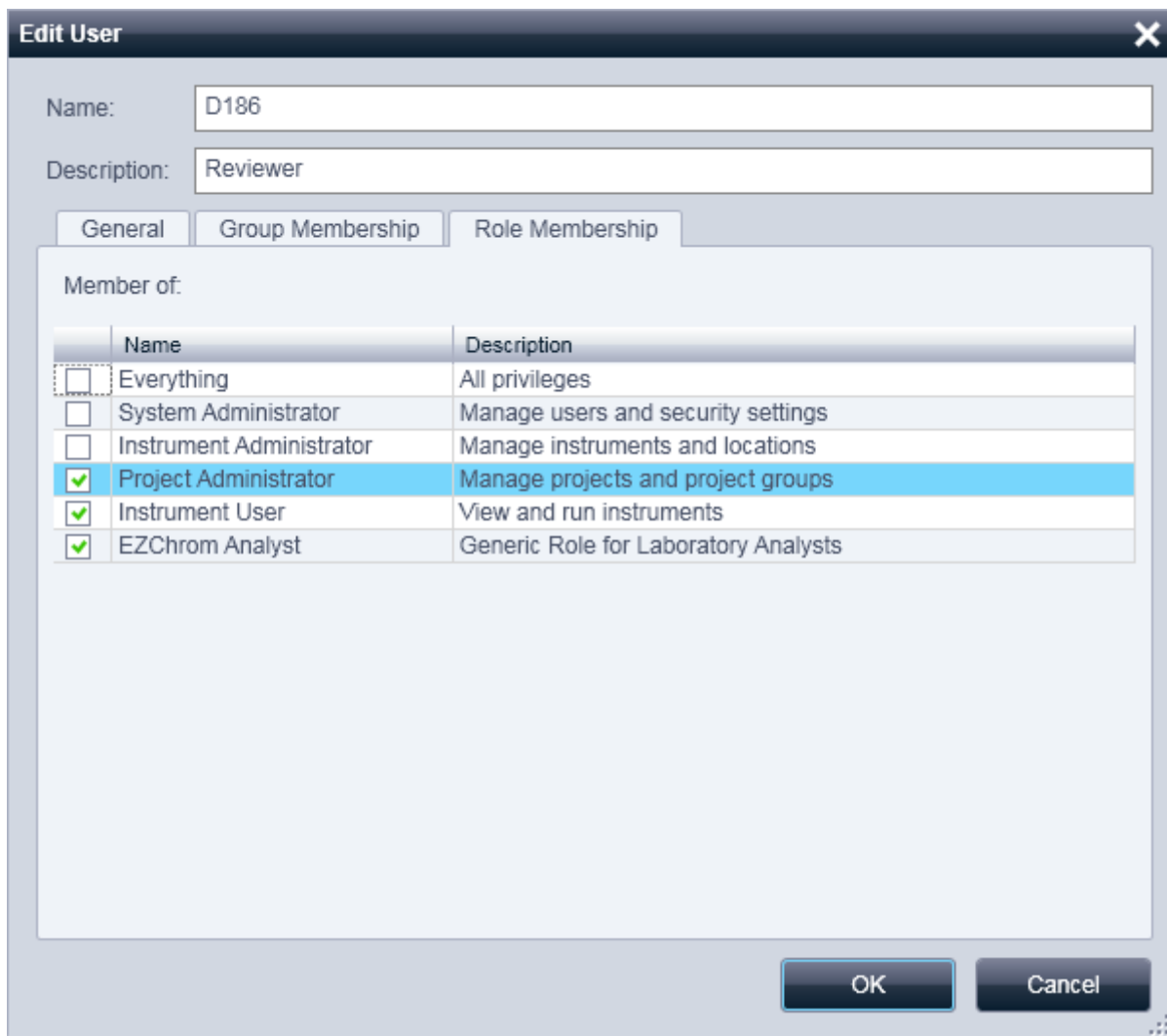
The screenshot shows a software window titled "Edit User" with a close button (X) in the top right corner. Inside the window, there are two text input fields: "Name:" with the value "D161" and "Description:" with the value "Analyst". Below these fields are three tabs: "General", "Group Membership", and "Role Membership". The "Role Membership" tab is selected. Under the heading "Member of:", there is a table with two columns: "Name" and "Description". The table contains six rows, each with a checkbox in the first column. The first row, "Everything" with description "All privileges", has a dashed border around its checkbox. The other rows are "System Administrator" (Manage users and security settings), "Instrument Administrator" (Manage instruments and locations), "Project Administrator" (Manage projects and project groups), "Instrument User" (View and run instruments), and "EZChrom Analyst" (Generic Role for Laboratory Analysts). The checkboxes for "Instrument User" and "EZChrom Analyst" are checked with green checkmarks. At the bottom right of the window are "OK" and "Cancel" buttons.

	Name	Description
<input type="checkbox"/>	Everything	All privileges
<input type="checkbox"/>	System Administrator	Manage users and security settings
<input type="checkbox"/>	Instrument Administrator	Manage instruments and locations
<input type="checkbox"/>	Project Administrator	Manage projects and project groups
<input checked="" type="checkbox"/>	Instrument User	View and run instruments
<input checked="" type="checkbox"/>	EZChrom Analyst	Generic Role for Laboratory Analysts

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5.8.2 Reviewer



Edit User

Name:

Description:


General Group Membership Role Membership

Member of:

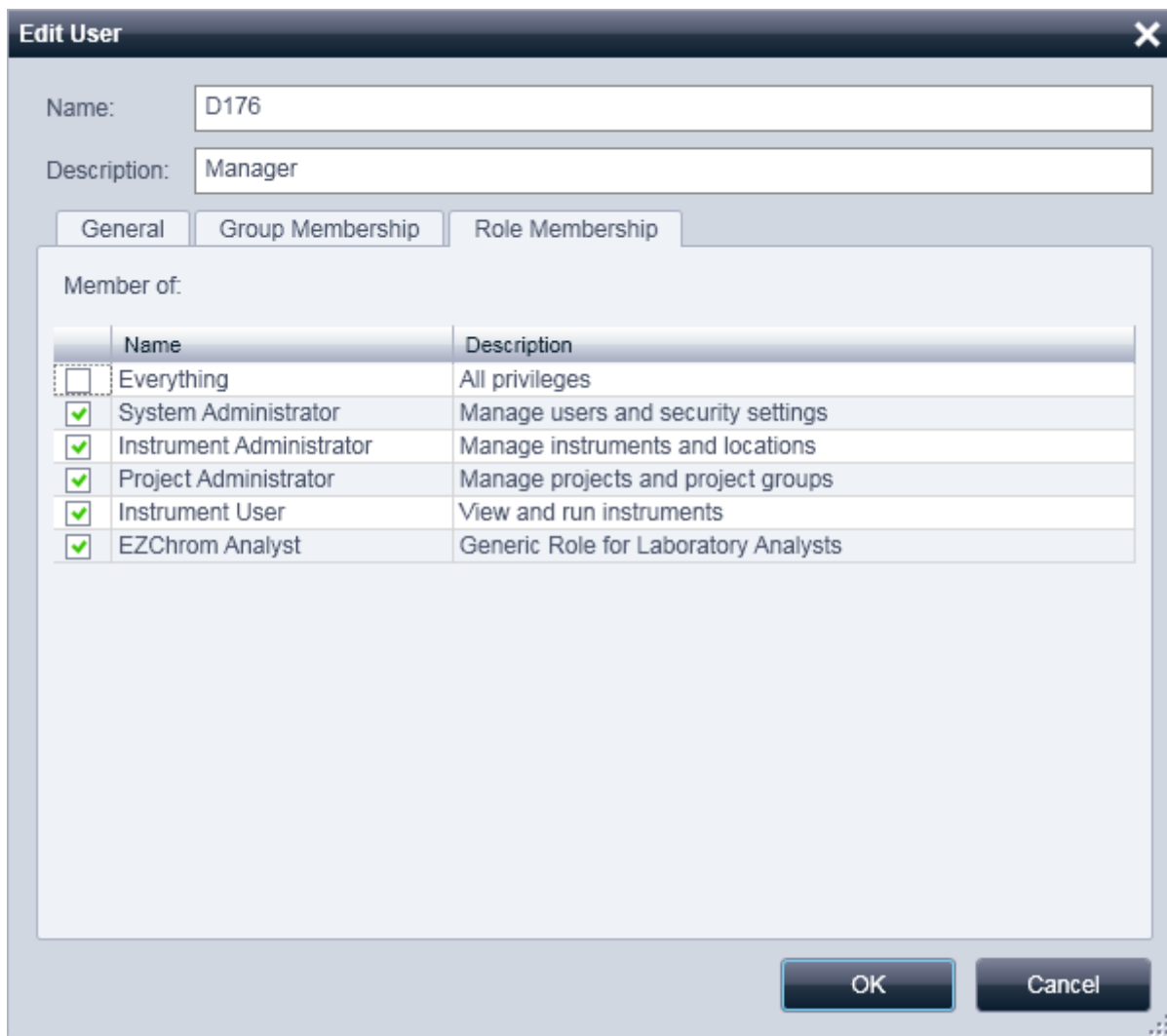
	Name	Description
<input type="checkbox"/>	Everything	All privileges
<input type="checkbox"/>	System Administrator	Manage users and security settings
<input type="checkbox"/>	Instrument Administrator	Manage instruments and locations
<input checked="" type="checkbox"/>	Project Administrator	Manage projects and project groups
<input checked="" type="checkbox"/>	Instrument User	View and run instruments
<input checked="" type="checkbox"/>	EZChrom Analyst	Generic Role for Laboratory Analysts

OK Cancel

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5.8.3 Asst. Manager / Manager / Sr. Manager



Edit User

Name:

Description:


General Group Membership **Role Membership**

Member of:

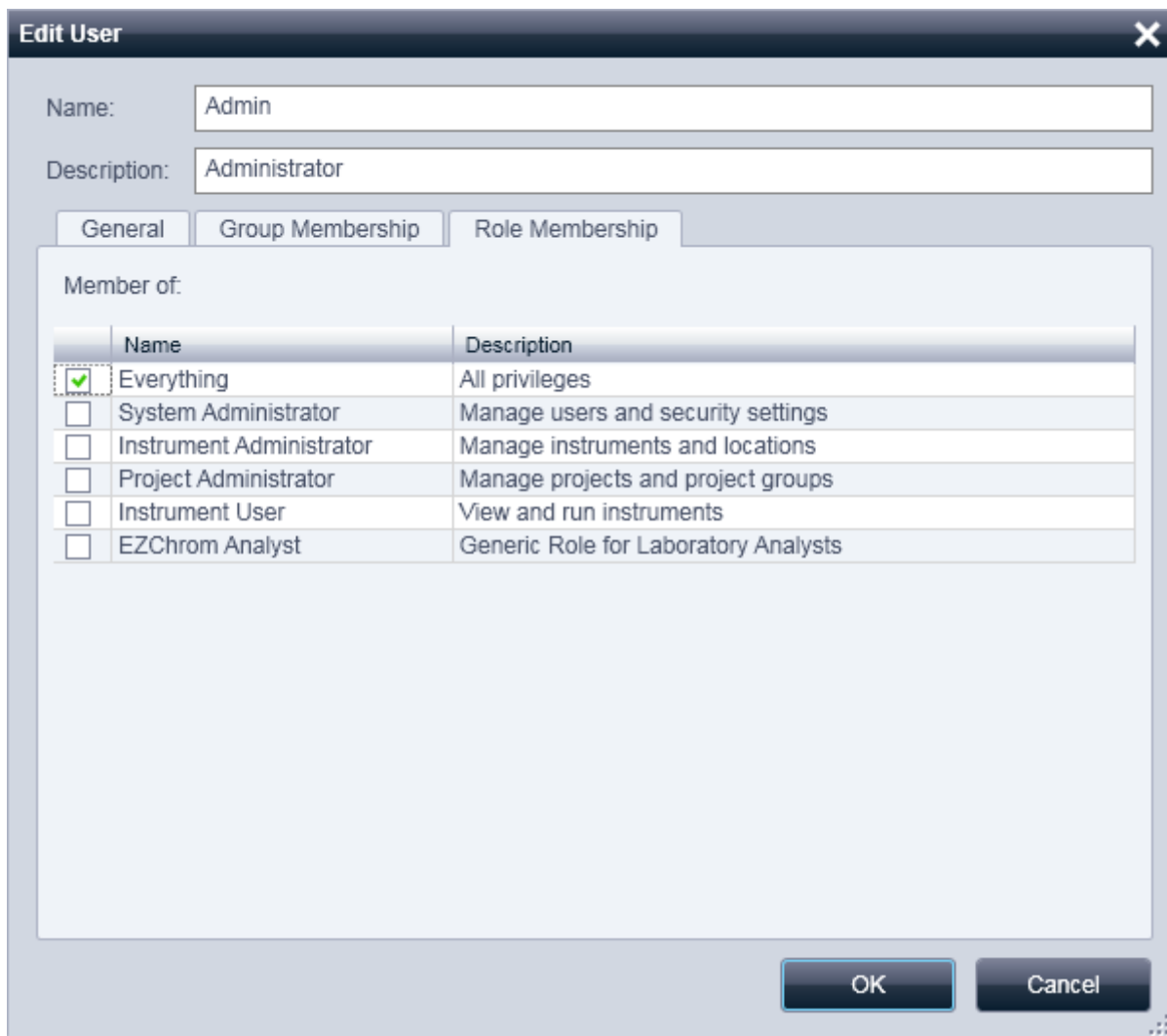
	Name	Description
<input type="checkbox"/>	Everything	All privileges
<input checked="" type="checkbox"/>	System Administrator	Manage users and security settings
<input checked="" type="checkbox"/>	Instrument Administrator	Manage instruments and locations
<input checked="" type="checkbox"/>	Project Administrator	Manage projects and project groups
<input checked="" type="checkbox"/>	Instrument User	View and run instruments
<input checked="" type="checkbox"/>	EZChrom Analyst	Generic Role for Laboratory Analysts

OK Cancel

	Prepared by	Reviewed by	Approved by
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5.8.4 Administrator



Edit User

Name: Admin

Description: Administrator


General Group Membership Role Membership

Member of:

	Name	Description
<input checked="" type="checkbox"/>	Everything	All privileges
<input type="checkbox"/>	System Administrator	Manage users and security settings
<input type="checkbox"/>	Instrument Administrator	Manage instruments and locations
<input type="checkbox"/>	Project Administrator	Manage projects and project groups
<input type="checkbox"/>	Instrument User	View and run instruments
<input type="checkbox"/>	EZChrom Analyst	Generic Role for Laboratory Analysts

OK Cancel


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5.9 Users privileges as given below:


<i>Privilege</i>	<i>Analyst</i>	<i>Reviewer</i>	<i>Manager</i>	<i>Admin</i>
View instrument or location	✓	✓	✓	✓
Manage instrument or location	✓	✓	✓	✓
Manage instrument or location access	✓	✓	✓	✓
Run instrument	✓	✓	✓	✓
Service instrument	✓	✓	✓	✓
View project or project group	✓	✓	✓	✓
Manage project or project group	✓	✓	✓	✓
Edit content of project	✓	✓	✓	✓
Manage project or project group access	✓	✓	✓	✓
Manage printers	✓	✓	✓	✓
Edit activity log properties	×	×	×	✓
Create administrative reports	✓	✓	✓	✓
Manage system components	✓	✓	✓	✓
Manage security	✓	✓	✓	✓
Manage instrument controllers	✓	✓		✓
Unlock and locked UI	×	×	×	✓
E- Signature Sign Data Files	×	×	×	✓
E- Signature Revoke	×	×	×	✓
Save method	✓	✓	✓	✓
Edit method properties	✓	✓	✓	✓
Open method	✓	✓	✓	✓
Instrument Setup	×	✓	✓	✓
Integration Events	✓	✓	✓	✓
Peaks Groups	✓	✓	✓	✓
Advanced Parameters	✓	✓	✓	✓
Custom Reports	✓	✓	✓	✓
System Suitability	✓	✓	✓	✓
Review Calibration	✓	✓	✓	✓
Calibrate	✓	✓	✓	✓
Edit Running Method	✓	✓	✓	✓
Update Master Method	✓	✓	✓	✓
Save Data	✓	✓	✓	✓

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<i>Privilege</i>	<i>Analyst</i>	<i>Reviewer</i>	<i>Manager</i>	<i>Admin</i>
Open Data	✓	✓	✓	✓
Edit Properties	✓	✓	✓	✓
Manual Integration Fixes	✓	✓	✓	✓
Open Sequence	✓	✓	✓	✓
Sequence Save	✓	✓	✓	✓
Process Sequence	✓	✓	✓	✓
Sequence Properties	✓	✓	✓	✓
Edit Any Running Sequence	✓	✓	✓	✓
Edit Own Running Sequence	✓	✓	✓	✓
Open Sample Prep	✓	✓	✓	✓
Save Sample Prep	✓	✓	✓	✓
Edit Sample Prep Properties	✓	✓	✓	✓
Edit Running Sample Prep	✓	✓	✓	✓
Update Master Sample Prep	✓	✓	✓	✓
Preview Run	✓	✓	✓	✓
Single Run	✓	✓	✓	✓
Sequence Run	✓	✓	✓	✓
Print Setup	✓	✓	✓	✓
Manual Control (idle only)	✓	✓	✓	✓
Manual Control	✓	✓	✓	✓
Monitor All Data	✓	✓	✓	✓
Abort Any Run	×	×	×	✓
Add Standard Report Template	✓	✓	✓	✓
Open Advanced/Intelligent Report	✓	✓	✓	✓
Save Advanced/ Intelligent Report	✓	✓	✓	✓
Lock/ unlock report template items	✓	✓	✓	✓

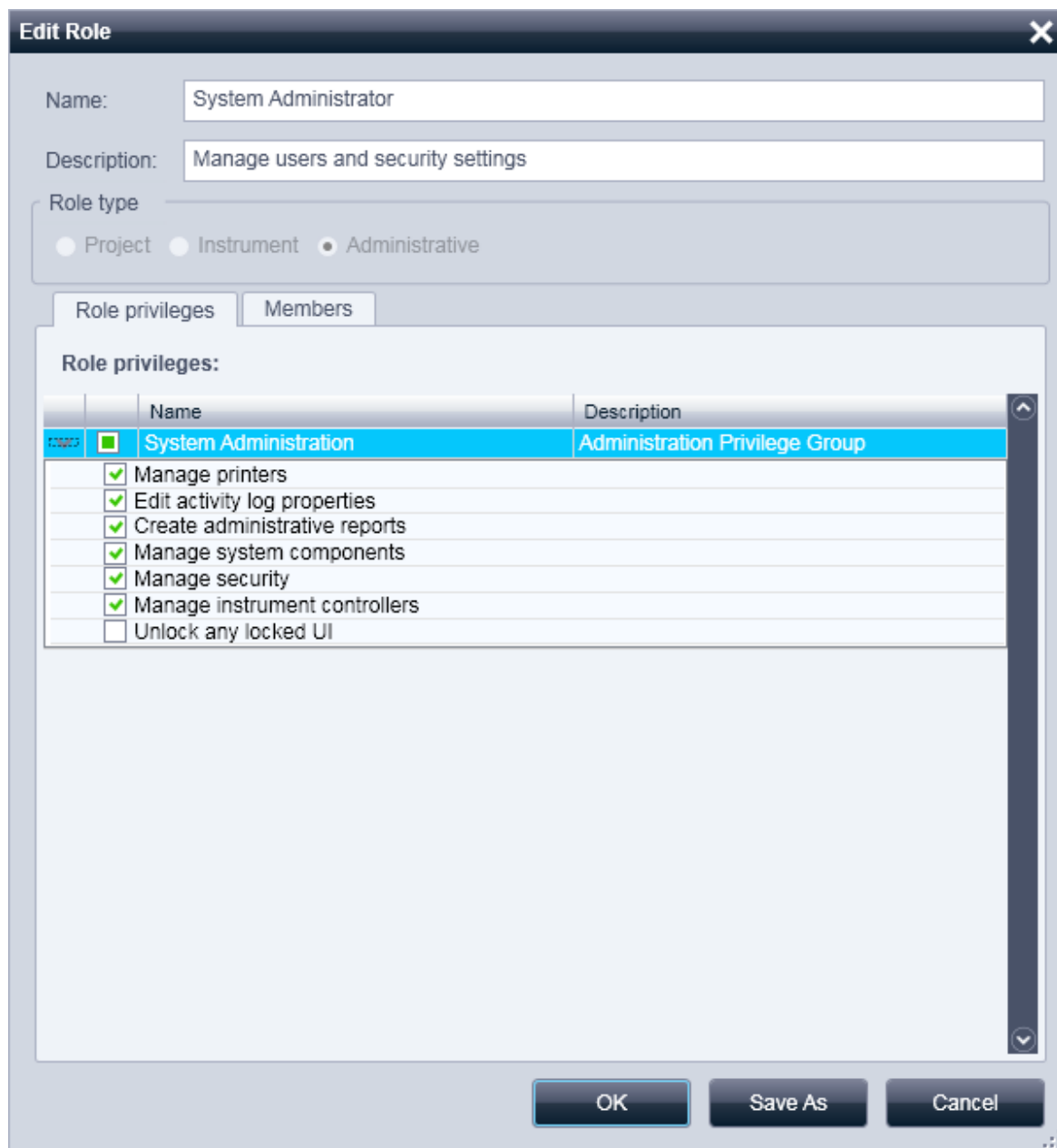
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5.9.1 Everything privileges:

All privileges

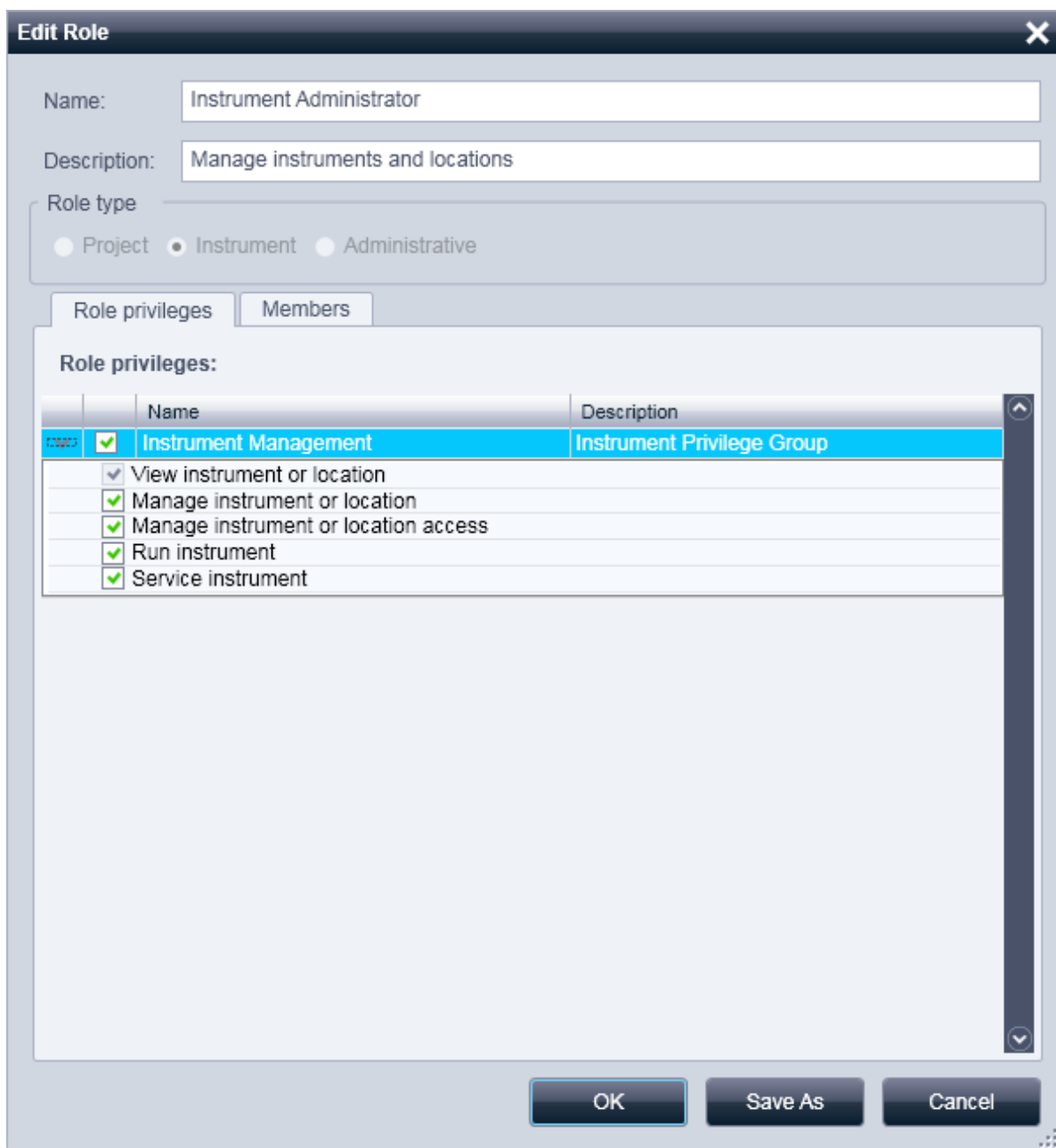
5.9.2 System administrator privileges:



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5.9.3 Instrument administrator privileges:



Edit Role

Name: Instrument Administrator

Description: Manage instruments and locations

Role type

☐ Project ☒ Instrument ☐ Administrative


Role privileges Members

Role privileges:


	Name	Description
<input checked="" type="checkbox"/>	Instrument Management	Instrument Privilege Group
<input checked="" type="checkbox"/>	View instrument or location	
<input checked="" type="checkbox"/>	Manage instrument or location	
<input checked="" type="checkbox"/>	Manage instrument or location access	
<input checked="" type="checkbox"/>	Run instrument	
<input checked="" type="checkbox"/>	Service instrument	

OK Save As Cancel

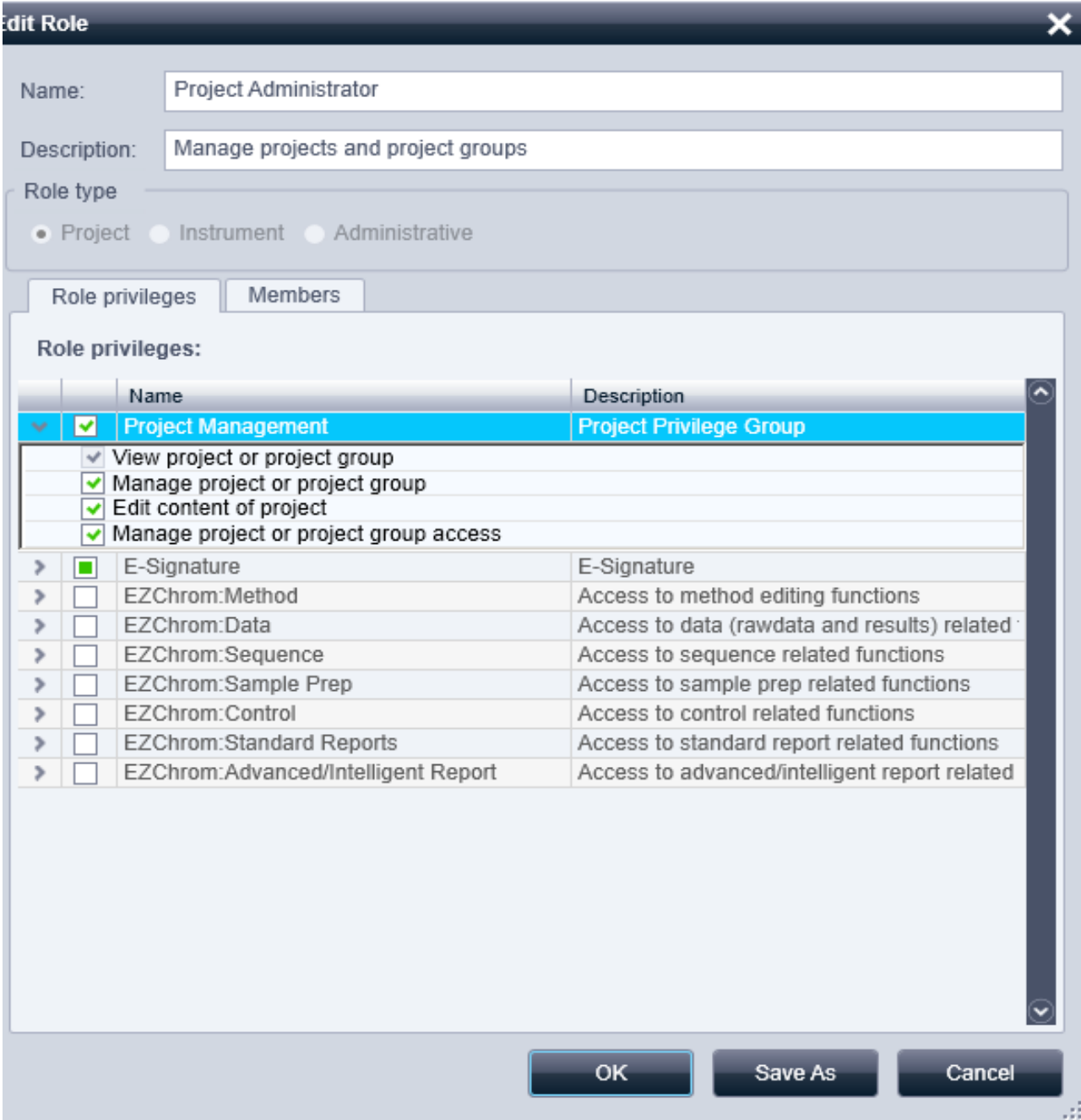
	Prepared by	Reviewed by	Approved by
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5.9.4 Project Administrator privileges:



Edit Role

Name:

Description:

Role type

☒ Project ☐ Instrument ☐ Administrative


Role privileges | Members

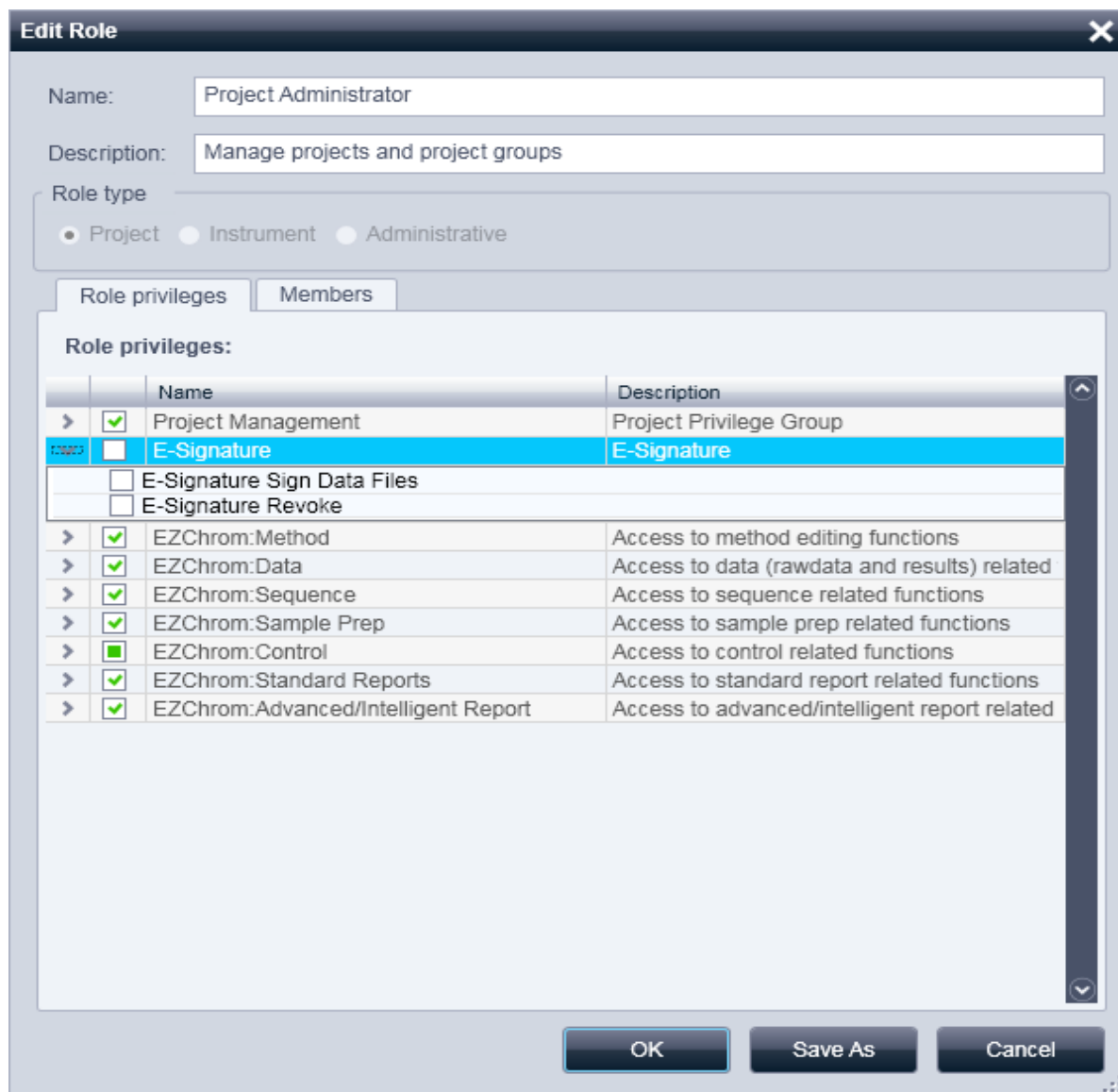
Role privileges:

	Name	Description
<input checked="" type="checkbox"/>	Project Management	Project Privilege Group
<input checked="" type="checkbox"/>	View project or project group	
<input checked="" type="checkbox"/>	Manage project or project group	
<input checked="" type="checkbox"/>	Edit content of project	
<input checked="" type="checkbox"/>	Manage project or project group access	
<input type="checkbox"/>	E-Signature	E-Signature
<input type="checkbox"/>	EZChrom:Method	Access to method editing functions
<input type="checkbox"/>	EZChrom:Data	Access to data (rawdata and results) related
<input type="checkbox"/>	EZChrom:Sequence	Access to sequence related functions
<input type="checkbox"/>	EZChrom:Sample Prep	Access to sample prep related functions
<input type="checkbox"/>	EZChrom:Control	Access to control related functions
<input type="checkbox"/>	EZChrom:Standard Reports	Access to standard report related functions
<input type="checkbox"/>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK Save As Cancel

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Edit Role

Name:

Description:

Role type: ☒ Project ☐ Instrument ☐ Administrative


Role privileges | Members

Role privileges:

	Name	Description
<input checked="" type="checkbox"/>	Project Management	Project Privilege Group
<input checked="" type="checkbox"/>	E-Signature	E-Signature
<input type="checkbox"/>	E-Signature Sign Data Files	
<input type="checkbox"/>	E-Signature Revoke	
<input checked="" type="checkbox"/>	EZChrom:Method	Access to method editing functions
<input checked="" type="checkbox"/>	EZChrom:Data	Access to data (rawdata and results) related
<input checked="" type="checkbox"/>	EZChrom:Sequence	Access to sequence related functions
<input checked="" type="checkbox"/>	EZChrom:Sample Prep	Access to sample prep related functions
<input checked="" type="checkbox"/>	EZChrom:Control	Access to control related functions
<input checked="" type="checkbox"/>	EZChrom:Standard Reports	Access to standard report related functions
<input checked="" type="checkbox"/>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK Save As Cancel

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Edit Role

Name:

Description:

Role type
☒ Project ☐ Instrument ☐ Administrative

Role privileges

Members

Role privileges:


	Name	Description
> <input checked="" type="checkbox"/>	Project Management	Project Privilege Group
> <input type="checkbox"/>	E-Signature	E-Signature
> <input checked="" type="checkbox"/>	EZChrom:Method	Access to method editing functions
> <input checked="" type="checkbox"/>	EZChrom:Data	Access to data (rawdata and results) related
> <input checked="" type="checkbox"/>	EZChrom:Sequence	Access to sequence related functions
> <input checked="" type="checkbox"/>	EZChrom:Sample Prep	Access to sample prep related functions
	<input checked="" type="checkbox"/> Open Sample Prep	
	<input checked="" type="checkbox"/> Save Sample Prep	
	<input checked="" type="checkbox"/> Edit Sample Prep Properties	
	<input checked="" type="checkbox"/> Edit Running Sample Prep	
	<input checked="" type="checkbox"/> Update Master Sample Prep	
> <input checked="" type="checkbox"/>	EZChrom:Control	Access to control related functions
> <input checked="" type="checkbox"/>	EZChrom:Standard Reports	Access to standard report related functions
> <input checked="" type="checkbox"/>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK

Save As

Cancel

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Edit Role

Name:

Project Administrator

Description:

Manage projects and project groups

Role type

☒ Project
☐ Instrument
☐ Administrative

Role privileges

Members

Role privileges:


	Name	Description
> <input checked="" type="checkbox"/>	Project Management	Project Privilege Group
> <input type="checkbox"/>	E-Signature	E-Signature
> <input checked="" type="checkbox"/>	EZChrom:Method	Access to method editing functions
> <input checked="" type="checkbox"/>	EZChrom:Data	Access to data (rawdata and results) related
> <input checked="" type="checkbox"/>	EZChrom:Sequence	Access to sequence related functions
> <input checked="" type="checkbox"/>	EZChrom:Sample Prep	Access to sample prep related functions
> <input checked="" type="checkbox"/>	EZChrom:Control	Access to control related functions
> <input checked="" type="checkbox"/>	EZChrom:Standard Reports	Access to standard report related functions
> <input checked="" type="checkbox"/>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related
<input checked="" type="checkbox"/>	Open Advanced/Intelligent Report	
<input checked="" type="checkbox"/>	Save Advanced/Intelligent Report	
<input checked="" type="checkbox"/>	Lock/unlock report template items	

OK

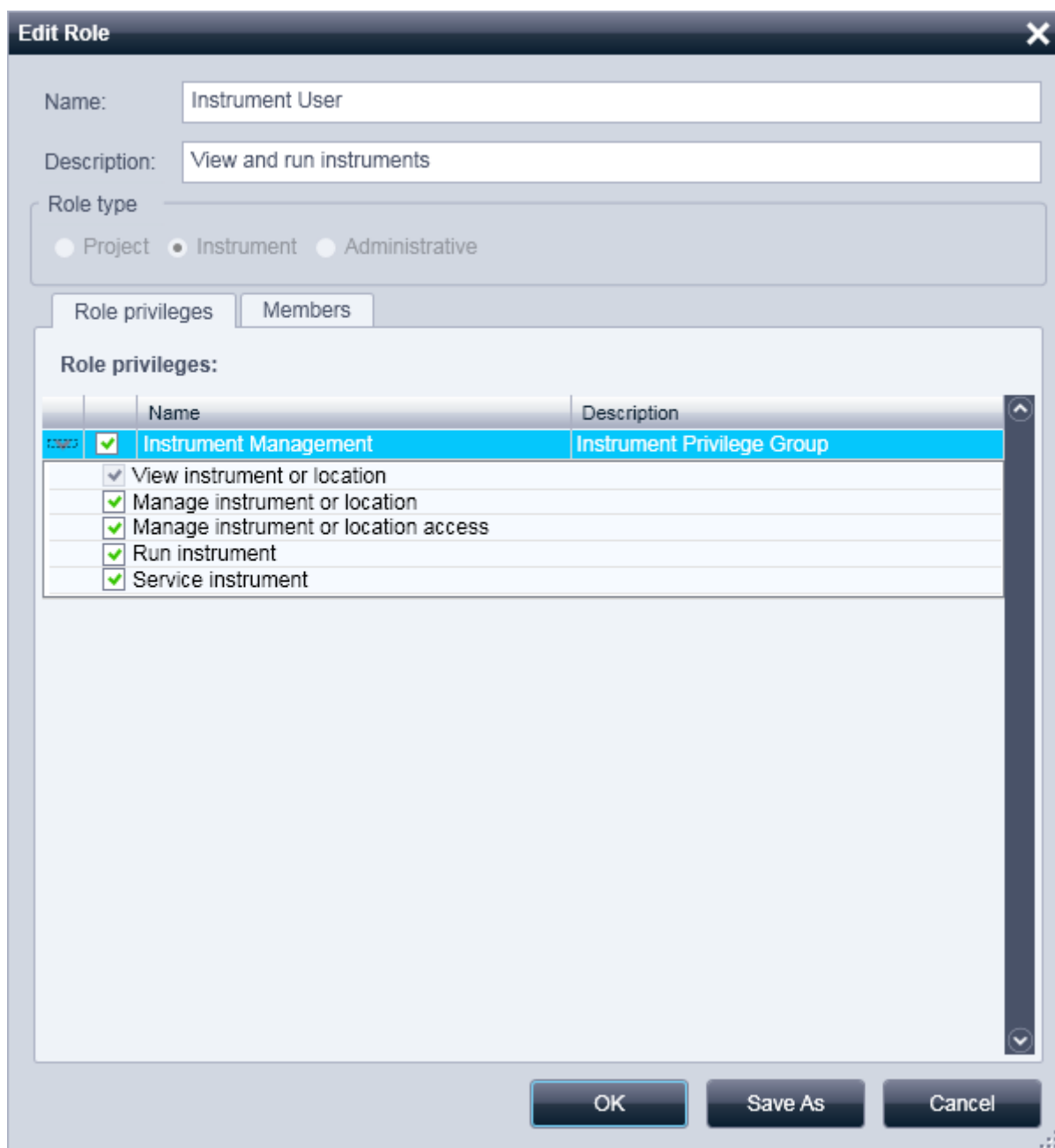
Save As

Cancel

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5.9.5 Instrument User privileges:



Edit Role

Name: Instrument User

Description: View and run instruments

Role type: ☐ Project ☒ Instrument ☐ Administrative


Role privileges | Members

Role privileges:

	Name	Description
<input checked="" type="checkbox"/>	Instrument Management	Instrument Privilege Group
<input checked="" type="checkbox"/>	View instrument or location	
<input checked="" type="checkbox"/>	Manage instrument or location	
<input checked="" type="checkbox"/>	Manage instrument or location access	
<input checked="" type="checkbox"/>	Run instrument	
<input checked="" type="checkbox"/>	Service instrument	


OK Save As Cancel

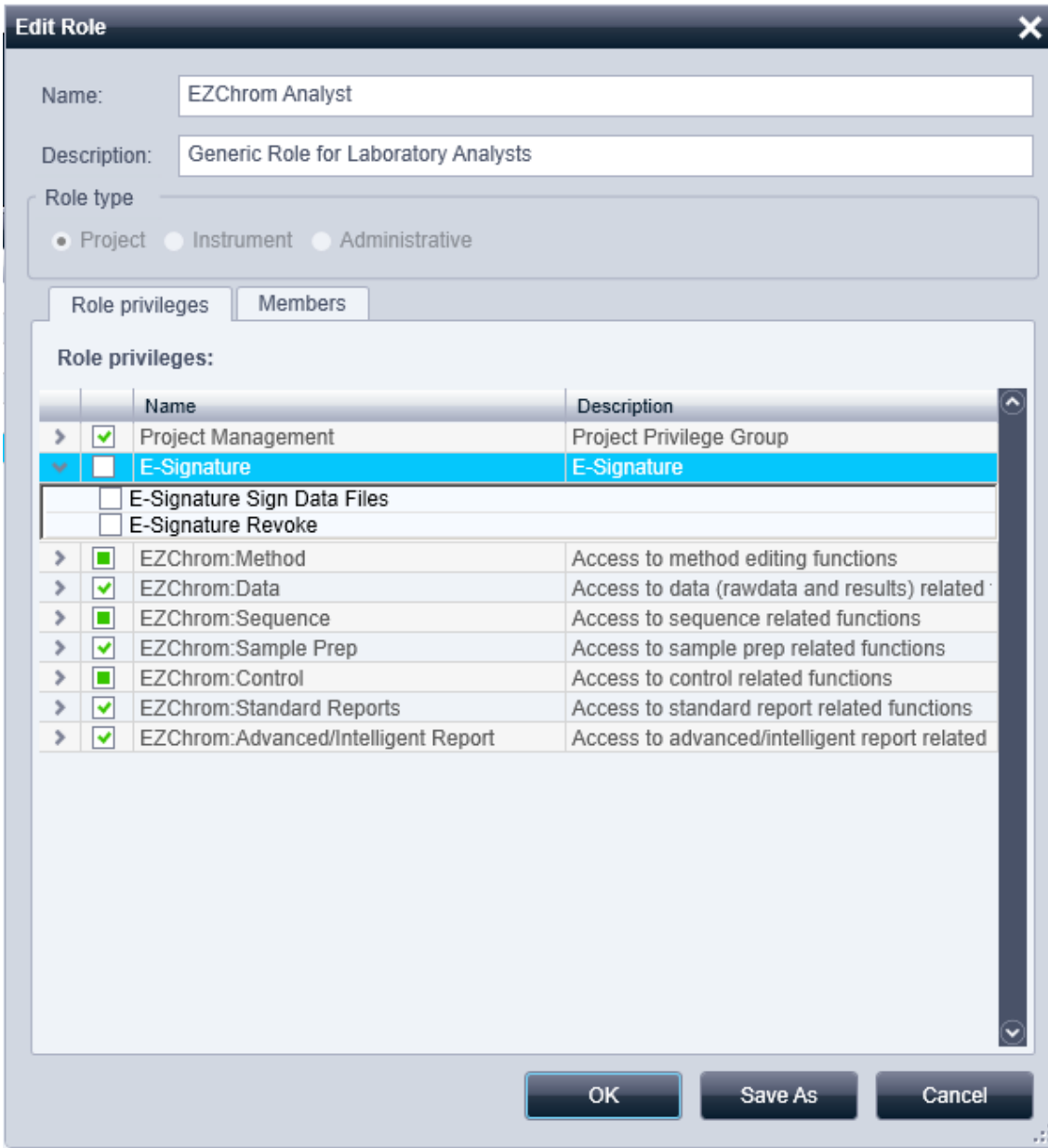
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5.9.6 **EZChrom Analyst**

	Prepared by	Reviewed by	Approved by
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Edit Role

Name:

Description:

Role type

☒ Project ☐ Instrument ☐ Administrative


Role privileges Members

Role privileges:

	Name	Description
>	Project Management	Project Privilege Group
+	E-Signature	E-Signature
	E-Signature Sign Data Files	
	E-Signature Revoke	
>	EZChrom:Method	Access to method editing functions
>	EZChrom:Data	Access to data (rawdata and results) related
>	EZChrom:Sequence	Access to sequence related functions
>	EZChrom:Sample Prep	Access to sample prep related functions
>	EZChrom:Control	Access to control related functions
>	EZChrom:Standard Reports	Access to standard report related functions
>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK Save As Cancel

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Edit Role

Name: EZChrom Analyst

Description: Generic Role for Laboratory Analysts

Role type

☒ Project
☐ Instrument
☐ Administrative


Role privileges
Members

Role privileges:

	Name	Description
> <input checked="" type="checkbox"/>	Project Management	Project Privilege Group
> <input type="checkbox"/>	E-Signature	E-Signature
▼ <input checked="" type="checkbox"/>	EZChrom:Method	Access to method editing functions
<input checked="" type="checkbox"/>	Save method	
<input checked="" type="checkbox"/>	Edit Method Properties	
<input checked="" type="checkbox"/>	Open Method	
<input type="checkbox"/>	Instrument Setup	
<input checked="" type="checkbox"/>	Integration Events	
<input checked="" type="checkbox"/>	Peaks Groups	
<input checked="" type="checkbox"/>	Advanced Parameters	
<input checked="" type="checkbox"/>	Custom Reports	
<input checked="" type="checkbox"/>	System Suitability	
<input checked="" type="checkbox"/>	Review Calibration	
<input checked="" type="checkbox"/>	Calibrate	
<input checked="" type="checkbox"/>	Edit Running Method	
<input checked="" type="checkbox"/>	Update Master Method	
> <input checked="" type="checkbox"/>	EZChrom:Data	Access to data (rawdata and results) related
> <input checked="" type="checkbox"/>	EZChrom:Sequence	Access to sequence related functions
> <input checked="" type="checkbox"/>	EZChrom:Sample Prep	Access to sample prep related functions
> <input checked="" type="checkbox"/>	EZChrom:Control	Access to control related functions
> <input checked="" type="checkbox"/>	EZChrom:Standard Reports	Access to standard report related functions
> <input checked="" type="checkbox"/>	EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK
Save As
Cancel

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	S.Prasad	M. Seshugiri Rao	Ch. Mahendar Reddy
Department	Quality Control	Quality Control	Quality Assurance

 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QC-053-00	Effective Date:	02.06.2017
	Supersedes :	Nil	Next Review Date:	01.06.2020
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Edit Role

Name: EZChrom Analyst

Description: Generic Role for Laboratory Analysts

Role type

☒ Project
☐ Instrument
☐ Administrative

Role privilegesMembers

Role privileges:


	Name	Description
>	<input checked="" type="checkbox"/> Project Management	Project Privilege Group
>	<input type="checkbox"/> E-Signature	E-Signature
>	<input checked="" type="checkbox"/> EZChrom:Method	Access to method editing functions
>	<input checked="" type="checkbox"/> EZChrom:Data	Access to data (rawdata and results) related
>	<input checked="" type="checkbox"/> EZChrom:Sequence	Access to sequence related functions
	<input checked="" type="checkbox"/> Open Sequence	
	<input checked="" type="checkbox"/> Sequence Save	
	<input checked="" type="checkbox"/> Process Sequence	
	<input checked="" type="checkbox"/> Sequence Properties	
	<input type="checkbox"/> Edit Any Running Sequence	
	<input checked="" type="checkbox"/> Edit Own Running Sequence	
>	<input checked="" type="checkbox"/> EZChrom:Sample Prep	Access to sample prep related functions
>	<input checked="" type="checkbox"/> EZChrom:Control	Access to control related functions
>	<input checked="" type="checkbox"/> EZChrom:Standard Reports	Access to standard report related functions
>	<input checked="" type="checkbox"/> EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related

OK


Save As

Cancel

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 Discovery Labs	STANDARD OPERATING PROCEDURE			
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TITLE: MANAGEMENT OF OPEN LAB SOFTWARE				

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TITLE: MANAGEMENT OF OPEN LAB SOFTWARE				

Edit Role

Name: EZChrom Analyst

Description: Generic Role for Laboratory Analysts

Role type

☒ Project
☐ Instrument
☐ Administrative


Role privileges
Members

Role privileges:

	Name	Description
>	<input checked="" type="checkbox"/> Project Management	Project Privilege Group
>	<input type="checkbox"/> E-Signature	E-Signature
>	<input checked="" type="checkbox"/> EZChrom:Method	Access to method editing functions
>	<input checked="" type="checkbox"/> EZChrom:Data	Access to data (rawdata and results) related
>	<input checked="" type="checkbox"/> EZChrom:Sequence	Access to sequence related functions
>	<input checked="" type="checkbox"/> EZChrom:Sample Prep	Access to sample prep related functions
>	<input checked="" type="checkbox"/> EZChrom:Control	Access to control related functions
>	<input checked="" type="checkbox"/> EZChrom:Standard Reports	Access to standard report related functions
▼	<input checked="" type="checkbox"/> EZChrom:Advanced/Intelligent Report	Access to advanced/intelligent report related
	<input checked="" type="checkbox"/> Open Advanced/Intelligent Report	
	<input checked="" type="checkbox"/> Save Advanced/Intelligent Report	
	<input checked="" type="checkbox"/> Lock/unlock report template items.	

OK
Save As
Cancel

	Prepared by	Reviewed by	Approved by
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5.10 Security policy:

- 5.10.1 Minimum password length : 6
- 5.10.2 Password expiration period (days) : 90
- 5.10.3 Maximum unsuccessful login attempts before locking account : 5
- 5.10.4 Account lock time (minutes) : 10
- 5.10.5 In activity time before locking the application (minutes) : 0
- 5.10.6 Password shall preferably be alphanumerical (combination of alphabets and numbers).
- 5.10.7 Each user at first time login shall change their password and should not be disclosed to others.


5.11 User ID creation:

- 5.11.1 User ID must be between 5 characters.
- 5.11.2 User ID must be created with the employee ID Number along with “D” for QC personnel.
e.g.: DXXXX
Here:
“D” refers Discovery and “XXXX” refers Employee ID No.
- 5.11.3 When received the Use ID requisition form QC to QA, the admin of software will create the user ID as per requisition.
- 5.11.4 Allot the role membership as per user level.
- 5.11.5 If existing chemist/Analyst will revise the job responsibilities then his/him allot role membership also will be revise.
- 5.11.6 User ID for Administrator is admin/Admin.
- 5.11.7 Software admin was QA

6.0 FORMATS / ANNEXURE(S):

- 6.1 Instrument User ID requisition form : QC053-FM073

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6.2 List of Users

: QC053-FM074

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	02.06.2017	New SOP Introduced and separately prepared audit trail SOP, SOP No. SOP-QC-039-02	CCF/GEN/17015

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QA001-FM139-01

