Global Q, Inc.

Management Controls - an important area

The learning objective of this TOPIC is discuss the following KEY POINTS:

- Company
- Users, Groups, and Sessions
- Lifecycles
- Integrations
- Manuals
- Records

Product Development

Post Market

Packaging & Labeling

Regulatory Affairs

Process Development

Clinical Affairs

Production

CAPA

Procurement

Management Controls

Training

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⁜ Synopsis Engine - Optiqs₃₆₀™

🏠 Home   📋 Audit Log

Details   System Security   Company Locations

Name	Synopsis Engine - Optiqs<sub>360·
Description	
Logo	

Management Controls ▼   ⊙ Company   👥 Users   ⊷ Lifecycles   🔧 Integrations   📖 Manuals   🧰 Records

⁘ Synopsis Engine - Optiqs₃₆₀™

🏠 Home   📄 Audit Log

Details | System Security | Company Locations

Password Settings

⌃ Quality

Check Quality	○ Disabled ○ Relaxed ○ Strict
Validator	org.apache.directory.server.core.ap
Enable Minimum Length	○ Yes ○ No
Number of characters	
Enable Maximum Length	○ Yes ○ No
Number of characters	

⌃ Expiration

Minimum Age (seconds)		Minimum Age defines the number of seconds that must elapse between modifications to the password.
Maximum Age (seconds)		Maximum Age defines the number of seconds after which a modified password will expire. Default value is 0, does not expire. If not 0, the value must be greater than or equal to the value of the minimum age.
Enable Expire Warning	○ Yes ○ No	Enable Expire Warning to enable and specify the number of seconds before password expiration a warning message will be returned to an authentication user.
Number of seconds		
Enable Grace Authentication Limit	○ Yes ○ No	Enable Grace Authentication Limit to enable and specify the how often an expired password can be used to authenticate.
Number of times		
Enable Grace Expire	○ Yes ○ No	Enable Grace Expire to enable and specify the number of seconds for the grace period.
Interval (seconds)		

⌃ Options

Enable Must Change	○ Yes ○ No	Enable Must Change to enforce that the password must be changed by the user after a password reset.
Enable Allow User Change	○ Yes ○ No	Enable Allow User Change to allow users to change their own password.
Enable Safe Modify	○ Yes ○ No	Enable Safe Modify to enforce that the existing password must be entered when changing the password.

⌃ Lockout

Enable Lockout	○ Yes ○ No	Enable Lockout to enforce authentication failure lockout settings.
Lockout Duration (seconds)		Lockout Duraton defines the number of seconds that the password cannot be used to authenticate due to too many failed bind attempts.
Maximum Consecutive Failures (count)		Maximum Consecutive Failuress defines the number of consecutive failed bind attempts after which the password may not be used to authenticate.

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Management Controls ▼ Company Users Lifecycles Integrations Manuals Records

Users User Groups User Sessions

Angela Mines State: In Work, Status: Checked Out* ≡

🏠 Home History

Details User Groups

User Information

First Name	Angela
Last Name	Mines
Title	Sr. Manager Surge
Email	angie.mines@smith-nephew.com
Phone	901-491-7599
Address	7135 Goodlett Farms Pkwy Cordova TN 38018

Account Information

Account: ae545

eSig. ID: dcb91103-4f2a-460e-9ba6-48e2548965b3

Name

John Doe
Patricia Mays
Trial User
Jacy Hoeppner
Tonika Farmer
Deepthi Koka
John Peyton
Nathan Piland
Devin Mack
Paul Notley
Angela Mines
Aswin Manickam
Wayne Russel
Optiqs Administrator
Hudson Chenault
Tanya Cottrell
Sudip Ghimire
David Johnson
Debra Gilbert
Casey Buckley
Nicholas Cotton
Ullas Bhat
QA Tester
Naveen Kaparaveni
Mitch Hayes
Phan Sopanha
Charles Kendrick
Joe Lee
Optiqs Service
John Peyton OLD
Harish Kumar Manickam
Rob Belau
Eric Gilbert

49 item(s), 1 selected

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Management Controls ▼   ○ Company   👤 Users   •⊟ Lifecycles   ⚙ Integrations   📖 Manuals   ⚖ Records

👤Users   👥 User Groups   ⇄User Sessions

👤 **Angela Mines** State: In Work, Status: Checked Out* ☰

🏠Home   📋 History

Details   **User Groups**

↻   🖨

User Information

First Name	Angela
Last Name	Mines
Title	Sr. Manager Surge
Email	angie.mines@smith-nephew.com
Phone	901-491-7599
Address	7135 Goodlett Farms Pkwy Cordova TN 38018

Account Information

Account: ae545

eSig. ID: dcb91103-4f2a-460e-9ba6-48e2548965b3

Name (left panel)

- 👤 John Doe
- 👤 Patricia Mays
- 👤 Trial User
- 👤 Jacy Hoeppner
- 👤 Tonika Farmer
- 👤 Deepthi Koka
- 👤 John Peyton
- 👤 Nathan Piland
- 👤 Devin Mack
- 👤 Paul Notley
- 👤 Angela Mines
- 👤 Aswin Manickam
- 👤 Wayne Russel
- 👤 Optiqs Administrator
- 👤 Hudson Chenault
- 👤 Tanya Cottrell
- 👤 Sudip Ghimire
- 👤 David Johnson
- 👤 Debra Gilbert
- 👤 Casey Buckley
- 👤 Nicholas Cotton
- 👤 Ullas Bhat
- 👤 QA Tester
- 👤 Naveen Kaparaveni
- 👤 Mitch Hayes
- 👤 Phan Sopanha
- 👤 Charles Kendrick
- 👤 Joe Lee
- 👤 Optiqs Service
- 👤 John Peyton OLD
- 👤 Harish Kumar Manickam
- 👤 Rob Belau
- 👤 Eric Gilbert

49 item(s), 1 selected

Name (right panel)

- 👥 SNO Project Managers

1 item(s), 0 selected

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Management Controls ▼   ◎ Company   👤 Users   •‖ Lifecycles   ◈ Integrations   ▥ Manuals   ⚒ Records

👤 Users   👥 User Groups   ⇄ User Sessions

👥 **SNO Project Managers** State: In Work, Status: Checked Out* ≡

🏠 Home   🗑 History

Details   Users

Name   SNO Project Managers

Description

Name

Name
🎧 Chris Anderson
🎧 Barry Null
🎧 Angela Mines

Name
- 👤 Administrator Group
- 👤 View Journey
- 👤 Production Group
- 👤 Doc Control Admin Group
- 👤 View Drawing Prints
- 👤 Optiqs Configuration Training Group
- 👤 All Users Group
- 👤 User and Group Admin Group
- 👤 SNO Packaging Project Managers
- 👤 Role and Lifecycle Admin Group
- 👤 Optiqs Administrator Group
- 👤 Maetrics Pilot Group
- 👤 Post Market Group
- 👤 Item Repository Admin Group
- 👤 Optiqs Config Group
- 👤 Set CI Linking Group
- 👤 Element Library Admin Group
- 👤 Management Controls Group
- 👤 Privileged Access Group - Confidential Files
- 👤 Purchasing Group
- 👤 SNO Project Managers

21 item(s), 1 selected

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3 item(s), 0 selected

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Management Controls ▼ | Company | Users | Lifecycles | Integrations | Manuals | Records

Users | User Groups | User Sessions

First Name	Last Name	Email	Phone	Username	Login Timestamp	Logout Timestamp
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/31/2021 19:04	
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 16:35	
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 16:16	10/31/2021 17:05
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 15:51	10/31/2021 16:47
Phan	Sopanha			Panha	10/31/2021 15:34	10/31/2021 15:47
Naveen	Kaparaveni			Naveen	10/31/2021 14:34	10/31/2021 11:10
Phan	Sopanha			Panha	10/31/2021 14:17	10/31/2021 15:47
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 13:16	10/31/2021 10:29
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 12:50	10/31/2021 10:29
David	Johnson			davidj	10/31/2021 11:11	10/31/2021 15:47
Phan	Sopanha			Panha	10/31/2021 10:30	10/31/2021 11:10
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/31/2021 09:55	10/31/2021 11:45
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/31/2021 07:13	10/31/2021 15:19
Naveen	Kaparaveni			Naveen	10/30/2021 22:03	10/30/2021 22:04
Naveen	Kaparaveni			Naveen	10/30/2021 21:47	10/30/2021 21:59
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 21:42	10/30/2021 21:59
Phan	Sopanha			Panha	10/30/2021 19:57	10/30/2021 21:32
Harish Kumar	Manickam			harish	10/30/2021 16:29	10/30/2021 17:04
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 15:56	10/30/2021 21:32
Naveen	Kaparaveni			Naveen	10/30/2021 15:53	10/30/2021 19:26
Naveen	Kaparaveni			Naveen	10/30/2021 15:31	10/30/2021 19:20
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/30/2021 15:30	10/30/2021 21:32
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/30/2021 15:08	10/30/2021 15:26
Naveen	Kaparaveni			Naveen	10/30/2021 14:50	10/30/2021 15:26
Naveen	Kaparaveni			Naveen	10/30/2021 14:46	10/30/2021 15:20
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/30/2021 12:13	10/30/2021 14:42
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 12:04	10/30/2021 14:42
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 11:43	10/30/2021 14:42
Naveen	Kaparaveni			Naveen	10/30/2021 11:40	10/30/2021 14:42
Jacy	Hoeppner GQ	jacy.hoeppner@globalqinc.com	5475516264	Jacy	10/30/2021 10:05	10/30/2021 11:36
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 07:34	10/30/2021 11:36
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 05:36	10/30/2021 11:36
Mitch	Hayes	Mitch.Hayes@globalqinc.com		Mitch	10/30/2021 05:14	10/30/2021 11:36

2289 item(s), 0 selected

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Management Controls ▼   Company   Users   Lifecycles   Integrations   Manuals   Records

Name

- Admin 101
- EU MDR Readiness Project
  - Plan
  - + Manage
  - − Retrieve
    - + Clinical
    - − Design
      - Retrieve Drawing Prints
      - Retrieve Reusable Instrument Evaluations
      - Retrieve Product List
      - Retrieve Product Specs / Standards Evaluati...
      - Retrieve Biocompatibility Reports
      - Retrieve Product HFEs
      - Retrieve Lifetime Evaluations
      - Retrieve Hazardous Substance Evaluations
      - Retrieve Design V&V Reports
      - Retrieve Sterilization Validations
      - Retrieve Sterilization Validation Adoptions
    - + Labeling
    - + Packaging
    - + Production
    - + Quality
    - + Risk Management
    - + Software
  - + Understand
  - + Compare
  - + Control
- + Admin 101
- + Intro to Interfacing 101
- + PROTO Acquisition Remediation Project jch
- + Pack Config Documentation Project
- + Screen Dev 102
- + Process Only Lifecycle

326 item(s), 1 selected

Retrieve Drawing Prints State: Not Started ☰

🏠 Home   📋 History

Details | Description | Predecessors/Successors | **Performer Roles** | Action Items | Preview | Parameters

Name: Retrieve Drawing Prints

Policy: [_____] ▼

Procedure: [_____] ▼

Work Instruction: [_____] ▼

Planned Duration: [_____]

Planned Hours: [_____]

Screen View: Retrieve Records

Icon: [_____] ▼

Visibility Rule:
- ○ Always show this item
- ● Show if user is in performer role(s)
- ○ Show if assigned to user
- ○ Hide this item

Name

- 👤 Development Engineer
- 👤 Project Manager
- 👤 Optiqs Admin

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3 item(s), 0 selected

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Management Controls ▼ | Company | Users | Lifecycles | Integrations | Manuals | Records

Requests and Transactions | Systems and Interfaces | Services and Routers | Scheduled Tasks

⚙ **10/08/2021** interfaceName: changed_Defects, systemName: Cockpit,

🏠 Home | 📋 History

General | Data | XML In | XML Out

System Name: Cockpit

Interface Name: changed_Defects

Requests/Transac...	System.Interface	State
− ⬇ 08/10/2021	Jira.changed_Issues	Complete
⚙ 08/10/2021	Cockpit.send_Defects	Complete
⚙ 08/10/2021	Cockpit.systemChanged_Defects	Complete
⚙ 08/10/2021	Jira.send_Defects	Complete
⚙ 08/10/2021	Jira.systemChanged_Defects	Complete
⚙ 08/10/2021	System.systemChanged_Defects	Complete
⚙ 08/10/2021	Jira.updateSystem_Defects	Complete
⚙ 08/10/2021	Jira.changed_Issues	Complete
− ⬇ 08/10/2021	Cockpit.changed_Defects	Complete
⚙ 08/10/2021	Cockpit.send_Defects	Complete
⚙ 08/10/2021	Cockpit.systemChanged_Defects	Complete
⚙ 08/10/2021	Jira.send_Defects	Complete
⚙ 08/10/2021	Jira.systemChanged_Defects	Complete
⚙ 08/10/2021	System.systemChanged_Defects	Complete
⚙ 08/10/2021	Cockpit.updateSystem_Defects	Complete
⚙ 08/10/2021	Cockpit.changed_Defects	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Jira.changed_Issues	Complete
+ ⬇ 08/10/2021	Cockpit.changed_Defects	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Cockpit.changed_Defects	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Jira.changed_Issues	Complete
+ ⬇ 08/09/2021	Cockpit.changed_Defects	Complete

2217 item(s), 1 selected

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Management Control ▼ | Users | User Groups | Lifecycles | Quality Manuals | Company Setup

Quality Policy

Home | Audit Log

Effective Version | Details | Version History | Reference Documents

Name	Number
ABC Medical, Inc.	
IVDR Documentation - BSI	
510K Submissions	GS1207
Quality Policy	GS1432
Adverse Events	GS2007
Health Hazard Evaluation	GS8238
Process Specifications	GS4439
Supplier Corrective Action	GS2984
Post Market	GS2390
Corrections and Removals	GS8097
Process Monitoring	GS2298
Clinical Studies	GS3119
Customer Complaints	GS5045
Design Control Policy	GS7049
Risk Management	GS6598
Master Validation Plan	GS8340
Management Review	GS2308
Clinical Evaluation Reports	GS7012
Process Validation	GS4391
Document Control	GS1782
Preventive Maintenance	GS7391
Supplier Audit	GS3398
Organization	GS6723
Corrective and Preventive A...	GS4097
Control of Measurement Eq...	GS3092
Internal Audit	GS3994
Process Design	GS3397
Nonconforming Product	GS2945
Supplier Qualification	GS3364
Process Deviations	GS6574
MSquared Quality Manual	
A New Quality Manual Item	

Name	State
A New Quality Manual It...	Draft
Quality Policy.pdf	Effective

Quality Policy.pdf (QMIF9258)

Quality Manual File | Change Control Record

⬇ Download File

76% ⊖ ⊕ ‹ 1/2 ›

abc Abc Medical, Inc

ABC123 Rev. 1

Policy
Level 1 Document
Subsystem: Management Controls   Effective

Quality Policy

Effective Date: dd mmm yyyy

1 **PURPOSE:**
The purpose of this policy is to establish requirements for the Quality Policy at Abc Medical, Inc.

2 **SCOPE:**
The scope of this procedure is all Abc Medical, Inc. sites.

3 **DEFINITIONS AND ABBREVIATIONS**
3.1 Refer to **add reference to definitions procedure here.**

4 **REFERENCES:**
4.1 External References, Standards and/or Regulations
4.1.1 Add references to external standards and regulations
4.2 Procedures:
4.2.1 Add references to external standards and regulations
4.3 Work Instructions:
4.3.1 Add references to external standards and regulations
4.4 Forms:
4.4.1 Add references to external standards and regulations

5 **RESPONSIBILITIES**
5.1 Define responsibilities for Top Management.
5.2 Define responsibilities for specific organizational roles.

6 **REQUIREMENTS:**
6.1 Define the general, high level requirements for the policy.

7 **PROCEDURE:**
7.1 Refer to **Define a process flow diagram of the process**
7.2 Define each process step and its requirements in general terms, leave specifics to procedures that implement the requirements.

8 **RECORD KEEPING:**
8.1 Refer to **define the record keeping procedure.**

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Management Controls ▼   Company   Users   Lifecycles   Integrations   Manuals   Records

Record Types   PDF Record Templates

Record Type

- 00250 - PKG Design Verification Testing Protocol
- 00251 - PKG Design Verification Testing Report
- 00361 - PKG Attributes and Considerations
- 01381 - PKG FAI Report
- 01617 - Production Readiness Checklist
- 1169 - Packaging Development Plan
- 1170 - Labeling Requirements
- 1175 - Process Characterization Protocol
- 1176 - Process Characterization Report
- 150 - PKG Product/Process FMEA
- 150 - Product/Process FMEA
- 160 - Control Plan
- 160 - PKG Control Plan
- 166 - Project Initiation
- 167 - User Needs Strategy
- 168 - Design and Development Plan
- 169 - Project Brief
- 170 - Product Specification
- 171 - Risk Management Plan
- 172 - SERB Device Risk Assessment
- 173 - Design Transfer Plan
- 174 - Research Study Plan
- 175 - User Needs Review
- 176 - Concept Selection Review
- 177 - Design Review 1
- 178 - Design Review 2
- 179 - Product Evaluation
- 180 - Project Launch and Logistics
- 181 - Design Review 3
- 182 - Overall Risk Acceptance
- 183 - Pre-Release Audit
- 184 - Limited Release Review
- 185 - Post Launch Review

180 item(s), 1 selected

171 - Risk Management Plan State: Released, Status: Checked In ≡

🏠 Home   📋 History

Details

Name: 171 - Risk Management Plan

Description: SNO-Matrix
PRIORITY TECHNICAL FILE CHECKLIST ITEM

Actual Record Type: 171 - Risk Management Plan

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Management Controls ▼ | Company | Users | Lifecycles | Integrations | Manuals | Records

Record Types | PDF Record Templates

Risk Assessment State: New, Status: Checked Out*

🏠 Home | 📋 History

General | Template | Record(s) To Append | Preview

Update Template From File

Record Template Information

Record Template

- Risk Assessment
- MDR Technical File - BSI
- DFMEA
- User Needs Document
- IVDR Scientific Validity Report
- Risk Management Plan Record
- MDR Clinical Evaluation Plan
- PMI
- IVDR Performance Evaluation Plan
- Declaration of Conformity
- Design and Development Plan
- Use Specification
- MDR Clinical Evaluation Report
- Preliminary Hazard Analysis
- Product Initiation
- IVDR Performance Evaluation Initiation Checklist
- Optiqs 360 Training Certificate
- IVDR Analytical Performance Report
- IVDR Clinical Performance Report
- IVDR Technical File - BSI
- IVDR Performance Evaluation Report
- NSAI Technical File
- Function Analysis

Name: Risk Assessment

Description:

Record Collector:

☐ Generate Appendix Separately

Record Section Information

No items to show.

23 item(s), 1 selected

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```xml
1  <?xml version="1.0" encoding="UTF-8"?>
2  <!--Designed and generated by Altova StyleVision Enterprise Edition 2020 r
3  <xsl:stylesheet version="2.0" xmlns:xsl="http://www.w3.org/1999/XSL/Transf
4      <xsl:output version="1.0" method="xml" encoding="UTF-8" indent="no"/>
5      <xsl:param name="altova:bGeneratingFromPxf" select="false()"/>
6      <xsl:param name="SV_OutputFormat" select="'PDF'"/>
7      <xsl:param name="SV_BaseOutputFileName" as="xs:string?">
8          <xsl:sequence select="for $i in altovaext:get-base-output-uri(), $
9      </xsl:param>
10     <xsl:param name="SV_GeneratedFileNamePrefix" select="if ( $SV_BaseOutp
11     <xsl:variable name="XML" select="/"/>
12     <xsl:import-schema schema-location="file:///C:/Aswin%20GlobalQ/GlobalQ
13     <xsl:variable name="fo:layout-master-set">
14         <fo:layout-master-set>
15             <fo:simple-page-master master-name="page-master-0-even" margin
16                 <fo:region-body margin-top="1.20in" margin-bottom="0.70in"
17                 <fo:region-before region-name="even-page-header" overflow=
18             </fo:simple-page-master>
19             <fo:simple-page-master master-name="page-master-0-odd" margin-
20                 <fo:region-body margin-top="1.20in" margin-bottom="0.70in"
21                 <fo:region-before region-name="odd-page-header" overflow=
22             </fo:simple-page-master>
23             <fo:simple-page-master master-name="page-master-0-even-first">
24                 <fo:region-body margin-top="1.20in" margin-bottom="0.70in"
25                 <fo:region-before region-name="even-page-header" overflow=
26                 <fo:region-after region-name="even-page-footer-first" over
27             </fo:simple-page-master>
28             <fo:simple-page-master master-name="page-master-0-odd-first" m
29                 <fo:region-body margin-top="1.20in" margin-bottom="0.70in"
30                 <fo:region-before region-name="odd-page-header" overflow=
31                 <fo:region-after region-name="odd-page-footer-first" overf
32             </fo:simple-page-master>
33             <fo:page-sequence-master master-name="page-master-0">
34                 <fo:repeatable-page-master-alternatives>
35                     <fo:conditional-page-master-reference master-reference
36                     <fo:conditional-page-master-reference master-reference
37                     <fo:conditional-page-master-reference master-reference
38                     <fo:conditional-page-master-reference master-reference
39                 </fo:repeatable-page-master-alternatives>
40             </fo:page-sequence-master>
41         </fo:layout-master-set>
42     </xsl:variable>
```