



Presentation

SEVRRA SOFTWARE

Internacional Atomic Energy Agency



OBJECTIVE

- Explain SEVRRRA app.

FORO SEVRRRA
Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares

Start Practices My Account About SEVRRRA Help Exit

Service=>Cobalt 60

Stage 1: Initial setup of the equipment

- Substage 1: With consequences for patient
 - ✓ RL=> IE-1: Deficiency in the manufacturing process causing an inhomogeneous distribution of 60Co radioactive material in the source
 - ✓ RM=> IE-2: Supply of a wrong source
 - ✓ RM=> IE-3: Error in the manufacturing process
 - ✓ RM=> IE-4: Incorrect source alignment
 - ✓ RM=> IE-5: Significant variations in the manufacturing process
 - + New Initiator Event
- Substage 2: Consequences for radiation protection
- Substage 3: With consequences for the patient

Stage 2: Acceptance and Commissioning

- Stage 3: Equipment maintenance.
- Stage 4: Taking data from each patient for treatment
- Stage 5: Development of treatment plan
- Stage 6: Development of molds. Consequences for patient
- Stage 7: Implementation of treatment

Name: Deficiency in the manufacturing process causing an inhomogeneous distribution of 60Co radioactive material in the source

Description:

Consequences:

Help references:

service ?
Yes No

Risk
FVL PVL CH = **RL**

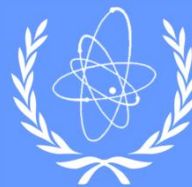
Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

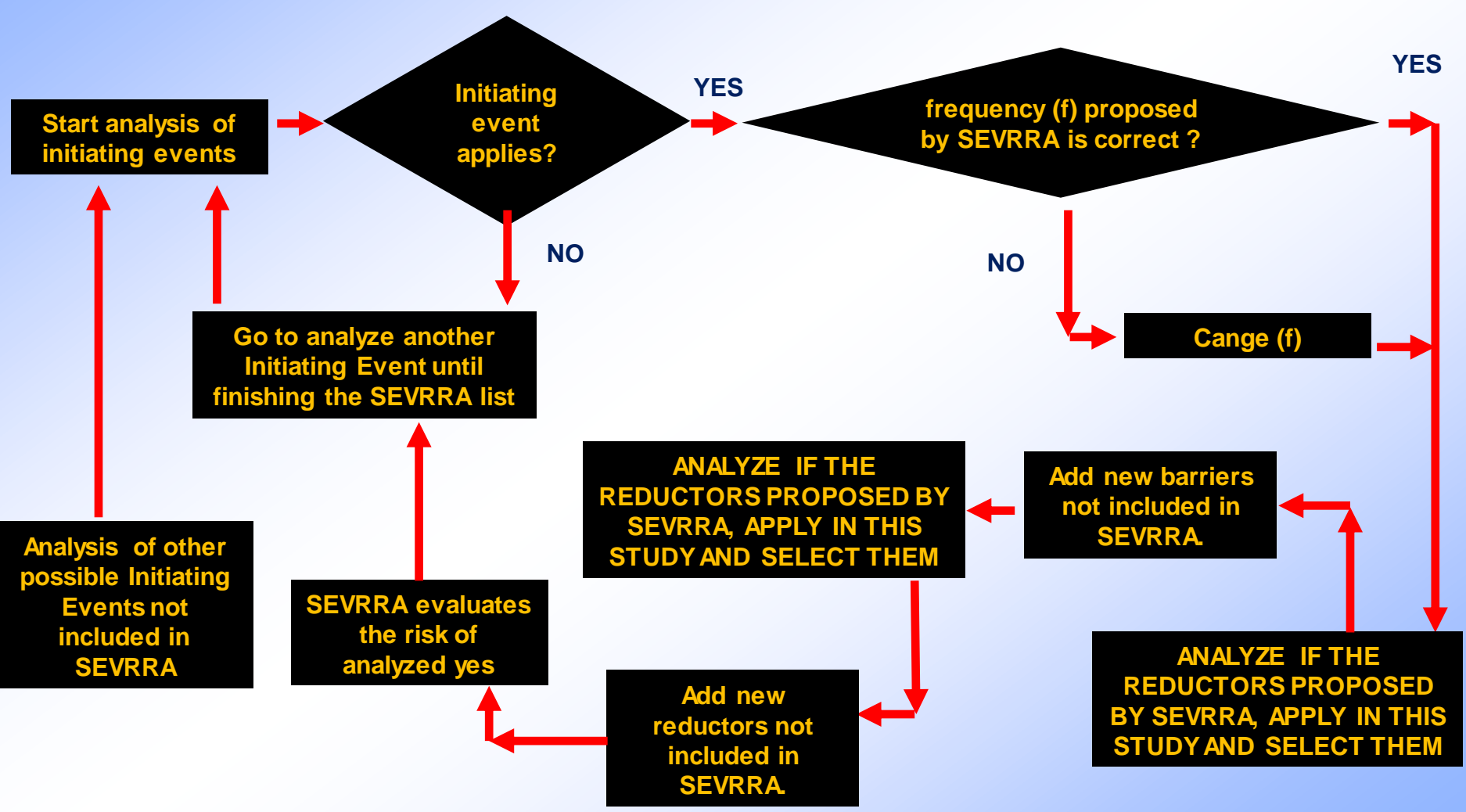
Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Purchase of sources only from recognized manufacturers ?	<input checked="" type="checkbox"/> Treatment planning of test cases on the TPS and comparison with direct measurements, as part of TPS commissioning ?	<input type="checkbox"/> External audit. Physics aspects: auditing procedures for measurement of dose rate and beam flatness control for some randomly selected fields ?
<input checked="" type="checkbox"/> Acceptance test: control test of dose rate, beam symmetry and flatness for specified fields ?	<input checked="" type="checkbox"/> Commissioning tests: control of dose rate and flatness for all fields ?	
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> New Barrier	<input type="checkbox"/> New consequence reducer
<input type="checkbox"/> Reuse frequency reducer	<input type="checkbox"/> Reuse Barrier	<input type="checkbox"/> Reuse consequence reducer

Compute Risk Level





GENERAL CONDITIONS TO APPLY SEVRRRA





Risk Analysis with SEVRRRA.

Once the performance and the impact of barriers, frequency reducers, and consequences reducers in the risk level of the initiating events in Radiotherapy practices has been understood, it is possible to carry out a risk analysis using preferably a software like SEVRRRA.

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Service=> Cobalt 60

- Stage 1: Initial setup of the equipment
 - Substage 1: With consequences for patient
 - ✓ RL=> IE-1: Deficiency in the manufacturing process causing an inhomogeneous distribution of 60Co radioactive material in the source
 - ✓ RM=> IE-2: Supply of a wrong source
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 - ✓ RM=> IE-4: Incorrect source alignment
 - ✓ RM=> IE-5: Significant variations in the manufacturing process
 - + New Initiator Event
 - Substage 2: Consequences for radiation
 - Substage 3: With consequences for the patient
- Stage 2: Acceptance and Commissioning
- Stage 3: Equipment maintenance.
- Stage 4: Taking data from each patient for treatment
- Stage 5: Development of treatment plan
- Stage 6: Development of molds. Consequences
- Stage 7: Implementation of treatment

Name: Deficiency in the manufacturing process causing an inhomogeneous distribution of 60Co radioactive material in the source

Description:

Consequences:

Help references:

service ?
Yes No

Risk
FVL PVL CH = **RL**

Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

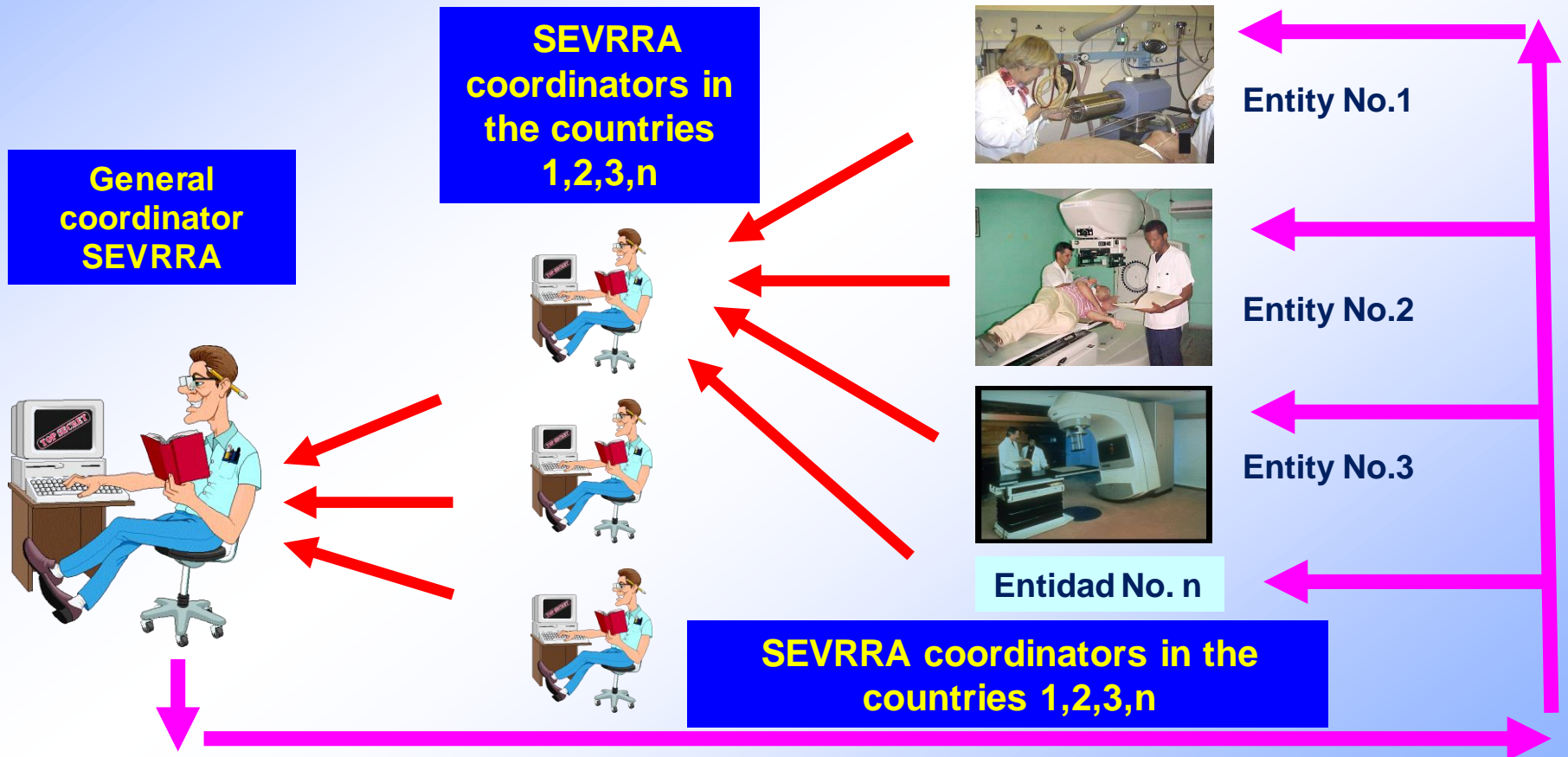
Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Purchase of sources only from recognized manufacturers	<input checked="" type="checkbox"/> Treatment planning of test cases on the TPS and comparison with direct measurements, as part of TPS commissioning	<input type="checkbox"/> External audit. Physics aspects: auditing procedures for measurement of dose rate and beam flatness control for some randomly selected fields
<input type="checkbox"/> New frequency reducer	<input checked="" type="checkbox"/> Acceptance test: control test of dose rate, beam symmetry and flatness for specified fields	<input type="checkbox"/> New consequence reducer
<input type="checkbox"/> Reuse frequency reducer	<input checked="" type="checkbox"/> Commissioning tests: control of dose rate and flatness for all fields	<input type="checkbox"/> Reuse consequence reducer
<input type="checkbox"/> New Barrier	<input type="checkbox"/> Reuse Barrier	

Compute Risk Level



WHAT IS SEVRRRA?

SEVRRRA, is a software designed as a web platform that allows to use the risk matrix method in radiotherapy using telecobalttherapy, HDR y LDR brachytherapy, and LINAC teletherapy. SEVRRRA can also be used in industrial radiography . It will be improved to be used in nuclear medicine and new radiotherapy techniques (IMRT, Radiosurgery, IORT).





GENERAL CONDITIONS TO APPLY SEVRRRA

In order to apply the risk matrix method used by SEVRRRA It is necessary to create a work team that includes the professionals of the radiotherapy service with vast experience and knowledge of their functions .

The team must include:

- Radiotherapist
- Medical Physicist
- Dosimetrists
- Operator technician of the radiotherapy unit
- Electromedicine specialist
- Mold technician
- TAC and simulator operator
- Radiation protection officer





HOW ARE IE ORGANIZED IN SEVRRRA?

In SEVRRRA, the initiating events found in the risk analysis, developed by FORO, are grouped in the different stages and sub-stages of the practices, and the navigation between them is similar to a Windows file

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Start Practices My Account About SEVRRRA Help Exit

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Service Summary (including Events)

Num.	Stage	Risk Very High (RVH)	Risk High (RH)	Risk Medium (RM)	Risk Low (RL)	Not Apply (NA)	Recorded	Total by Stage	Completed
1	Initial setup of the equipment	0	0	2	0	0	2	2	✓
2	Acceptance and Commissioning	0	5	5	1	0	11	27	✗
3	Equipment maintenance.	0	1	2	0	0	3	3	✓
4	Treatment Clinic Prescription	0	2	1	1	0	4	8	✗
5	Patient anatomical data acquisition	0	1	1	1	0	3	10	✗
6	Volume delineation	0	3	1	2	0	6	6	✓
7	Treatment Planning	0	1	2	0	0	3	16	✗
8	Preparation of molds	0	2	1	1	0	4	4	✓
9	Beginning of treatment	1	1	1	0	0	3	17	✗
10	Positioning for daily treatment	0	2	1	1	0	4	13	✗
11	Implementation of treatment	0	1	0	0	0	1	42	✗
Total User:		1	19	17	7	0	44	148	4
Total Reference:		0	0	8	36	0	44	148	0

Sistema de Evaluación del Riesgo en Radioterapia - SEVRRRA 3.0 (English Versión_DRAFT)



HOW ARE IE ORGANIZED IN SEVRRRA?

In SEVRRRA, the initiating events found in the risk analysis, developed by FORO, are grouped in the different stages and sub-stages of the practices, and the navigation between them is similar to a Windows file. **Example of navigation within the stages and sub-stages**

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Start Practices My Account About SEVRRRA Help Exit

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
 - Substage 1: With implications for radiation
 - Substage 2: With consequences for the Pu
- Stage 2: Acceptance and Commissioning
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Num.	Stage	Risk Very High (RVH)	Risk High (RH)	Risk Medium (RM)	Risk Low (RL)	Not Apply (NA)	Recorded	Total by Stage	Completed
1	Initial setup of the equipment	0	0	2	0	0	2	2	✓
2	Acceptance and Commissioning	0	5	5	1	0	11	27	✗
3	Equipment maintenance.	0	1	2	0	0	3	3	✓
4	Treatment Clinic Prescription	0	2	1	1	0	4	8	✗
5	Patient anatomical data acquisition	0	1	1	1	0	3	10	✗
6	Volume delineation	0	3	1	2	0	6	6	✓
7	Treatment Planning	0	1	2	0	0	3	16	✗
8	Preparation of molds	0	2	1	1	0	4	4	✓
9	Beginning of treatment	1	1	1	0	0	3	17	✗
10	Positioning for daily treatment	0	2	1	1	0	4	13	✗
11	Implementation of treatment	0	1	0	0	0	1	42	✗
Total User:		1	19	17	7	0	44	148	4
Total Reference:		0	0	8	36	0	44	148	0



HOW ARE IE ORGANIZED IN SEVRRRA?

Example of navigation within the stages and sub-stages to analyze the different initiator events grouped in them.

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Start Practices My Account About SEVRRRA Help Exit

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
 - Substage 1: The LINAC. With consequent
 - Substage 2: Planning System (TPS). With:
 - ✓RH=> IE-1: Erroneous geometric configuration
 - ✓RM=> IE-2: Erroneous configuration
 - ✓RM=> IE-3: Erroneous wedge configuration
 - ✓RM=> IE-4: Erroneous configuration
 - ✗IE-5: Erroneous configuration of conversion coefficient
 - ✗IE-6: Erroneous beam characterization
 - ✗IE-7: Input of conversion coefficient
 - ✗IE-8: Input of erroneous field factors
 - + New Initiator Event
 - Substage 3: Image Acquisition equipment
 - Substage 4: Transfer System TPS-LINAC
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition

Service Summary (Initiating Events)

Num.	Stage	Risk Very High (RVH)	Risk High (RH)	Risk Medium (RM)	Risk Low (RL)	Not Apply (NA)	Recorded	Total by Stage	Completed
1	Initial setup of the equipment	0	0	2	0	0	2	2	✓
2	Acceptance and Commissioning	0	5	5	1	0	11	27	✗
3	Equipment maintenance.	0	1	2	0	0	3	3	✓
4	Treatment Clinic Prescription	0	2	1	1	0	4	8	✗
5	Patient anatomical data acquisition	0	1	1	1	0	3	10	✗
6	Volume delineation	0	3	1	2	0	6	6	✓
7	Treatment Planning	0	1	2	0	0	3	16	✗
8	Preparation of molds	0	2	1	1	0	4	4	✓
9	Beginning of treatment	1	1	1	0	0	3	17	✗
10	Positioning for daily treatment	0	2	1	1	0	4	13	✗
11	Implementation of treatment	0	1	0	0	0	1	42	✗
Total User:		1	19	17	7	0	44	148	4
Total Reference:		0	0	8	36	0	44	148	0

Sistema de Evaluación del Riesgo en Radioterapia - SEVRRRA 3.0 (English Versión_DRAFT)



HOW ARE IE ORGANIZED IN SEVRRRA?

Example of navigation within the stages and sub-stages to analyze a specific initiator event.

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Start Practices My Account About SEVRRRA Help Exit

Service=> Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - ✓ RH=> IE-1: Erroneous geometric configuration of the accelerator
 - ✓ RM=> IE-2: Erroneous configuration of the multileaf collimator on
 - ✓ RM=> IE-3: Erroneous wedge configuration into the TPS
 - ✓ RM=> IE-4: Erroneous configuration of conformal shielding blocks
 - ✗ E-5: Erroneous configuration of compensators or bolus on the TF
 - ✗ E-6: Erroneous beam characterization data and beam output on t
 - ✗ E-7: Input of conversion coefficient to convert Hounsfield units to
 - ✗ E-8: Input of erroneous field factors on the TPS
 - + New Initiator Event
 - Substage 3: Image Acquisition equipment. With consequences for pati
 - Substage 4: Transfer System TPS-LINAC. With consequences for pati
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Location=> Linear Accelerator/Stage 2/Substage 2/Initiating Event 5

Initiating Event	
Code:	AL-PAC2.23
Name:	Erroneous configuration of compensators or bolus on the TPS
Description:	
Consequences:	
Help references:	

Does the initiating event Apply in your service?
Yes No

Risk				
FL	PH	CVH	=	RH

Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

Frequency Reducers	Barriers	Consequence Reducers
<input type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned	<input type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning	<input type="checkbox"/> Annual external audit. Control test of dose rate in reference conditions
	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected
	<input type="checkbox"/> Independent verification of the treatment planning by a different medical physicist than the one who made the planning	<input type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc.
<input checked="" type="checkbox"/> New frequency reducer	<input type="checkbox"/> Redundant verification of the data input on the TPS by a different medical physicist from the one who made the input	<input type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped
<input checked="" type="checkbox"/> Reuse frequency reducer		<input type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages
	<input checked="" type="checkbox"/> New Barrier	<input checked="" type="checkbox"/> New consequence reducer
	<input checked="" type="checkbox"/> Reuse Barrier	<input checked="" type="checkbox"/> Reuse consequence reducer

Compute Risk Level



WHAT DO THE INITIATING EVENTS GROUP?

By analyzing each initiator event, the barriers, frequency reducers and reduction of consequences proposed by SEVRRRA, can be evaluated to select those that are implemented in the radiotherapy service that we are analyzing.

Start
Practices
My Account
About SEVRRRA
Help
Exit

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - ✓RH=> IE-1: Erroneous geometric configuration of the accelerator
 - ✓RM=> IE-2: Erroneous configuration of the multileaf collimator on
 - ✓RM=> IE-3: Erroneous wedge configuration into the TPS
 - ✓RM=> IE-4: Erroneous configuration of conformal shielding blocks
 - ✗E-5: Erroneous configuration of compensators or bolus on the TF
 - ✗E-6: Erroneous configuration of compensators or bolus on the TF
 - ✗E-7: Input of conversion coefficient to convert Hounsfield units to
 - ✗E-8: Input of erroneous field factors on the TPS
 - ➕ New Initiator Event
 - Substage 3: Image Acquisition equipment. With consequences for pat
 - Substage 4: Transfer System TPS-LINAC. With consequences for pati
 - Stage 3: Equipment maintenance.
 - Stage 4: Treatment Clinic Prescription
 - Stage 5: Patient anatomical data acquisition
 - Stage 6: Volume delineation
 - Stage 7: Treatment Planning
 - Stage 8: Preparation of molds
 - Stage 9: Beginning of treatment
 - Stage 10: Positioning for daily treatment
 - Stage 11: Implementation of treatment

Location=> Linear Accelerator/Stage 2/Substage 2/Initiating Event 5

Initiating Event	
Code:	AL-PAC.23
Name:	Erroneous configuration of compensators or bolus on the TPS
Description:	
Consequences:	
Help references:	

Does the initiating event Apply in your service ?	
Yes <input checked="" type="radio"/>	No <input type="radio"/>

Risk				
FL	PH	CVH	=	RH

Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned ➕ New frequency reducer ➕ Reuse frequency reducer	<input checked="" type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning <input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery <input checked="" type="checkbox"/> Independent verification of the treatment planning by a different medical physicist than the one who made the planning <input checked="" type="checkbox"/> Redundant verification of the data input on the TPS by a different medical physicist from the one who made the input	<input checked="" type="checkbox"/> Annual external audit. Control test of dose rate in reference conditions <input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected <input checked="" type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc. <input checked="" type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped <input checked="" type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages
	➕ New Barrier ➕ Reuse Barrier	➕ New consequence reducer ➕ Reuse consequence reducer

Compute Risk Level





HOW IS RISK ANALYSIS PERFORMED?

Users, at this point, must read the situation or event that initiates the accident, question whether it is possible that this event can occur in their practice, and analyze between possible barriers, frequency reducers and consequences reducers which are those that are operative in their facility.

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - RH=> IE-1: Erroneous geometric configuration of the accelerator
 - RM=> IE-2: Erroneous configuration of the multileaf collimator on
 - RM=> IE-3: Erroneous wedge configuration into the TPS
 - RM=> IE-4: Erroneous configuration of conformal shielding blocks
 - IE-5: Erroneous configuration of compensators or bolus on the TF
 - IE-6: Erroneous beam characterization data and beam output on I
 - IE-7: Input of conversion coefficient to convert Hounsfield units to
 - IE-8: Input of erroneous field factors on the TPS
 - Substage 3: Image Acquisition equipment. With consequences for pat
 - Substage 4: Transfer System TPS-LINAC. With consequences for pati
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Location=> Linear Accelerator Stage 2/Substage 2/Initiating Event 5

Initiating Event

Code: AL-PAC2.23

Name: Erroneous configuration of compensators or bolus on the TPS

Description:

Consequences:

Help references:

Does the initiating event Apply in your service?
Yes No

Risk

FL	PH	CVH	=	RH
----	----	-----	---	-----------

Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned	<input checked="" type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning	<input checked="" type="checkbox"/> Annual external audit. Control test of dose rate in reference conditions
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected
<input type="checkbox"/> Reuse frequency reducer	<input checked="" type="checkbox"/> Independent verification of the treatment planning by a different medical physicist than the one who made the planning	<input type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc.
	<input checked="" type="checkbox"/> Redundant verification of the data input on the TPS by a different medical physicist from the one who made the input	<input checked="" type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped
		<input checked="" type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages
	<input type="checkbox"/> New Barrier	<input type="checkbox"/> New consequence reducer
	<input type="checkbox"/> Reuse Barrier	<input type="checkbox"/> Reuse consequence reducer

Compute Risk Level



HOW ARE RISK LEVELS CALCULATED?

When selecting the barriers and reducers, SEVRRRA assigns to each of them the corresponding weights (robustness) according to the criteria established in the methodology of the Risk Matrix. The calculation of Risk is done considering the multiplication of those weights

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Start Practices My Account About SEVRRRA Help Exit

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 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - ✓ RH=> IE-1: Erroneous geometric configuration of the accelerator
 - ✓ RM=> IE-2: Erroneous configuration of the multileaf collimator on the TPS
 - ✓ RM=> IE-3: Erroneous wedge configuration into the TPS
 - ✓ RM=> IE-4: Erroneous configuration of conformal shielding block
 - ✗ IE-5: Erroneous configuration of compensators or bolus on the TPS
 - ✗ IE-6: Erroneous beam characterization data and beam output on the TPS
 - ✗ IE-7: Input of conversion coefficient to convert Hounsfield units to electron density
 - ✗ IE-8: Input of erroneous field factors on the TPS
 - ➕ New Initiator Event
 - Substage 3: Image Acquisition equipment. With consequences for the patient
 - Substage 4: Transfer System TPS-LINAC. With consequences for the patient
- Stage 3: Equipment maintenance.
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Name: Erroneous configuration of compensators or bolus on the TPS

Description:

Consequences:

Help references:

in your service ?
Yes No

Risk
FL PH CVH = RH

Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned ? ●	<input checked="" type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning. Normal=>8	<input checked="" type="checkbox"/> Annual external audit. Control test of dose rate in reference conditions ? ●
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned dose, which allows for error detection in dose delivery ? ●	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected ? ●
<input type="checkbox"/> Reuse frequency reducer	<input checked="" type="checkbox"/> Independent verification of the treatment planning by a different medical physicist than the one who made the planning ? ●	<input checked="" type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc. ? ●
	<input checked="" type="checkbox"/> Redundant verification of the data input on the TPS by a different medical physicist from the one who made the input ? ●	<input checked="" type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped ? ●
		<input checked="" type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages ? ●



HOW ARE RISK LEVELS CALCULATED?

Once the existing barriers and reducers in the radiotherapy service are selected, the system can calculate the risk resulting from the initiating event by pressing the "calculate risk" button of the application.

The screenshot displays the SEVRRRA application interface. The top navigation bar includes 'Start', 'Practices', 'My Account', 'About SEVRRRA', 'Help', and 'Exit'. The main content area is titled 'Location=> Linear Accelerator Stage 2/Substage 2/Initiating Event 5'. It features a table for 'Initiating Event' with fields for Code (AL-PAC2.23), Name (Erroneous configuration of compensators or bolus on the TPS), Description, Consequences, and Help references. A 'Does the initiating event Apply in your service?' dialog box is open, with 'Yes' selected. Below this is a 'Risk' table showing 'RM' (Residual Medium) as the calculated risk level.

Risk				
FL	PVL	CVH	=	RM

Below the risk table, there are three columns for selecting barriers and reducers: 'Frequency Reducers', 'Barriers', and 'Consequence Reducers'. Each column contains a list of items with checkboxes and icons for adding or reusing items. A 'Compute Risk Level' button is highlighted with a hand cursor, and a 'Record' button is also visible.



HOW ARE RISK LEVELS CALCULATED?

To register and save the evaluation progress, press the "Record" button of the application.

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Start My Account About SEVRRRA Help Exit

Service=> Linear Accelerator

- Stage 1: Initial setup of the equipment
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 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - RH=> IE-1: Erroneous geometric configuration of the accelerator
 - RM=> IE-2: Erroneous configuration of the multileaf collimator on
 - RM=> IE-3: Erroneous wedge configuration into the TPS
 - RM=> IE-4: Erroneous configuration of conformal shielding blocks
 - E-5: Erroneous configuration of compensators or bolus on the TF
 - E-6: Erroneous beam characterization data and beam output on t
 - E-7: Input of conversion coefficient to convert Hounsfield units to
 - E-8: Input of erroneous field factors on the TPS
 - New Initiator Event
 - Substage 3: Image Acquisition equipment. With consequences for pati
 - Substage 4: Transfer System TPS-LINAC. With consequences for pati
 - Stage 3: Equipment maintenance.
 - Stage 4: Treatment Clinic Prescription
 - Stage 5: Patient anatomical data acquisition
 - Stage 6: Volume delineation
 - Stage 7: Treatment Planning
 - Stage 8: Preparation of molds
 - Stage 9: Beginning of treatment
 - Stage 10: Positioning for daily treatment
 - Stage 11: Implementation of treatment

Location=> Linear Accelerator/Stage 2/Substage 2/Initiating Event 5

Initiating Event	
Code:	AL-PAC2.23
Name:	Erroneous configuration of compensators or bolus on the TPS
Description:	
Consequences:	
Help references:	

Does the initiating event Apply in your service ?
Yes No

Risk				
FL	PVL	CVH	=	RM

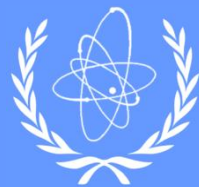
Comment and modification proposals list

Select from the list below, those barriers and reducers that are implemented in your facility:

Frequency Reducers	Barriers	Consequence Reducers
<input checked="" type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned	<input checked="" type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning	<input checked="" type="checkbox"/> Annual external audit. Control test of dose rate in reference conditions
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected
<input type="checkbox"/> Reuse frequency reducer	<input checked="" type="checkbox"/> Independent verification of the treatment planning by a different medical physicist than the one who made the planning	<input checked="" type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc.
	<input checked="" type="checkbox"/> Redundant verification of the data input on the TPS by a different medical physicist from the one who made the input	<input checked="" type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped
	<input type="checkbox"/> New Barrier	<input checked="" type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages
	<input type="checkbox"/> Reuse Barrier	<input type="checkbox"/> New consequence reducer
		<input type="checkbox"/> Reuse consequence reducer

Compute Risk Level

Record



HOW ARE RISK LEVELS CALCULATED?

The analysis is repeated for each initiating event, until the practice is completed.

The screenshot displays the SEVRRRA 3.0 software interface. The top navigation bar includes 'Start', 'Practices', 'My Account', 'About SEVRRRA', 'Help', and 'Exit'. The main content area is titled 'Location=> Linear Accelerator/Stage 2/Substage 4/Initiating Event 1' and 'Initiating Event'. A table shows the event details:

Code:	AL-PAC2.28
Name:	Interconnection problems affecting the electronic data transfer from the TPS to the accelerator
Description:	
Consequences:	
Help references:	

Below the table is a 'Comment and modification proposals list' and a prompt: 'Select from the list below, those barriers and reducers that are implemented in your facility:'. This leads to three columns of options:

Frequency Reducers	Barriers	Consequence Reducers
<input type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned	<input type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery	<input type="checkbox"/> Weekly portal image, with which geometric errors can be detected
<input type="checkbox"/> Reuse frequency reducer	<input type="checkbox"/> Verification of the treatment plan data transferred to the accelerator	<input type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc.
	<input type="checkbox"/> Portal image taken during the initial treatment session for evaluation by the radiation oncologist and the medical physicist, whereby geometric treatment errors can be detected	<input type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped
	<input type="checkbox"/> Commissioning tests for the transfer system. Visual	<input type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages

On the right side, there is a 'Does the initiating event Apply in your service?' section with 'Yes' and 'No' radio buttons, and a 'Risk' calculation table:

FL	PH	CVH	=	RH
----	----	-----	---	----

The bottom of the interface shows the text: 'Sistema de Evaluación del Riesgo en Radioterapia - SEVRRRA 3.0 (English Versión_DRAFT)'. A blue arrow on the left points downwards, indicating the flow of the process.



ADD BARRIERS AND REDUCERS

Users have the option to improve the analysis by adding barriers, reducers and initiating events.

Service=>Linear Accelerator

- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
 - Substage 1: The LINAC. With consequences for the patient
 - Substage 2: Planning System (TPS). With consequences for the patient
 - ✓RH=> IE-1: Erroneous geometric configuration of the
 - ✓RM=> IE-2: Erroneous configuration of the multileaf collimator
 - ✓RM=> IE-3: Erroneous wedge configuration into the TPS
 - ✓RM=> IE-4: Erroneous configuration of conformal shielding
 - ✓RM=> IE-5: Erroneous configuration of compensators
 - ✓RM=> IE-6: Erroneous beam characterization data and
 - ✓RM=> IE-7: Input of conversion coefficient to convert I
 - ✓RM=> IE-8: Input of erroneous field factors on the TPS
 - + New Initiator Event
 - Substage 3: Image Acquisition equipment. With consequences for the patient
 - ✓RM=> IE-1: Incomplete commissioning of the CT equipment
 - + New Initiator Event
 - Substage 4: Transfer of data from the TPS-LINAC. With consequences for the patient
 - ✗E-1: Interconnection problems affecting the electronic data transfer from the TPS to the accelerator
 - + New Initiator Event
- Stage 3: Equipment maintenance
 - Substage 1: With consequences for patients
 - Substage 2: With consequences for radiation workers
- Stage 4: Treatment Clinic Prescription
- Stage 5: Patient anatomical data acquisition
- Stage 6: Volume delineation
- Stage 7: Treatment Planning
- Stage 8: Preparation of molds
- Stage 9: Beginning of treatment
- Stage 10: Positioning for daily treatment
- Stage 11: Implementation of treatment

Location=> Linear Accelerator/Stage 2/Substage 4/Initiating Event 1

Initiating Event

Code: AL-PAC2.28

Name: Interconnection problems affecting the electronic data transfer from the TPS to the accelerator

Description:

Consequences:

Help references:

Comment and modification proposals list

Does the initiating event Apply in your service ?
Yes No

Risk

FL	PH	CVH	=	RH
----	----	-----	---	----

Select from the list below, those barriers and reducers that are implemented in your facility:


Frequency Reducers	Barriers	Consequence Reducers
<input type="checkbox"/> Training of the physicist, that includes the entire TPS commissioning process, the tests to be performed and related lessons learned	<input type="checkbox"/> Comparison of TPS calculations results for tests cases against direct phantom measurement during TPS commissioning	<input type="checkbox"/> Weekly in-vivo dosimetry by which dose delivery errors can be detected
<input type="checkbox"/> New frequency reducer	<input type="checkbox"/> In-vivo dosimetry in initial treatment session, to verify the delivered against the planned doses, which allows for error detection in dose delivery	<input type="checkbox"/> Weekly portal image, with which geometric errors can be detected
<input type="checkbox"/> Reuse Barrier	<input type="checkbox"/> Verification of the treatment plan data transferred to the accelerator	<input type="checkbox"/> At the daily patient setup, the radiotherapy technologists can detect geometric or dose errors by visual signs, such as skin reddening, etc.
	<input type="checkbox"/> Portal image taken during the initial treatment session for evaluation by the radiation oncologist and the medical physicist, whereby geometric treatment errors can be detected	<input type="checkbox"/> QA tests of the TPS (daily, weekly, monthly, quarterly and annually). When a significant inconsistency is detected, treatments are stopped
	<input type="checkbox"/> Commissioning tests for the transfer system. Visual verification of the electronically transferred data	<input type="checkbox"/> Weekly medical evaluation of the patient can detect errors in treatment delivery or from previous stages
		<input type="checkbox"/> New Barrier
		<input type="checkbox"/> Reuse consequence reducer

Compute Risk Level




FACILITY RISK PROFILE

As the analysis is completed, the risk profile of the facility will be outlined:



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Start
Practices
My Account
About SEVRRRA
Help
Exit

Service=> Cobalt 60

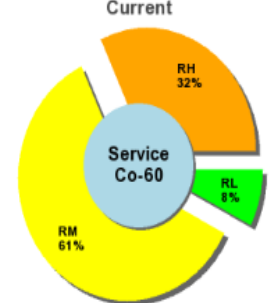
- Stage 1: Initial setup of the equipment
- Stage 2: Acceptance and Commissioning
- Stage 3: Equipment maintenance.
- Stage 4: Taking data from each patient for treatment planning
- Stage 5: Development of treatment plan
- Stage 6: Development of molds. Consequences for Patients with
- Stage 7: Implementation of treatment

Service Summary (Initiating Events) Report

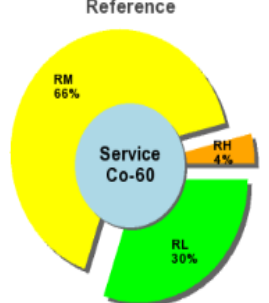
Num.	Stage	Risk Very High (RVH)	Risk High (RH)	Risk Medium (RM)	Risk Low (RL)	Not Apply (NA)	Recorded	Total by Stage	Completed
1	Initial setup of the equipment	0	0	9	1	0	10	10	✓
2	Acceptance and Commissioning	0	4	20	0	0	24	24	✓
3	Equipment maintenance.	0	0	3	0	0	3	3	✓
4	Taking data from each patient for treatment planning	0	8	7	1	0	16	16	✓
5	Development of treatment plan	0	16	4	0	0	20	20	✓
6	Development of molds. Consequences for Patients with	0	0	3	0	0	3	3	✓
7	Implementation of treatment	0	14	34	8	0	56	56	✓
Total User:		0	42	80	10	0	132	132	7
Total Reference:		0	5	87	40	0	132	132	0

RISK COMPARISON:
 Current Service vs. Reference Service

Current






Reference





COMPARISON WITH REFERENCE FACILITY

Once completed, the user can see in a summary report the result of his analysis, comparing it with that of a reference facility

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3. Risk Assessment Results

3.1 Summary

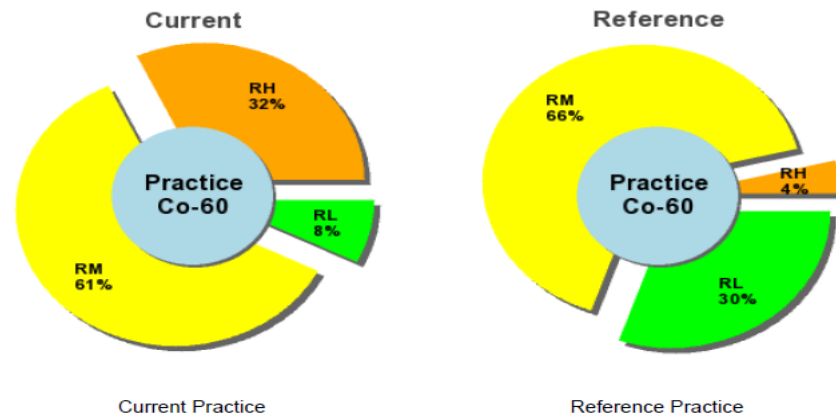
The risk assessment results indicate that taking into account existing safety barriers, frequency and consequences reducers in your Radiotherapy Service, the next risk levels has been reached for initiating events by stage:

Num.	Stage	Risk Very High (RMA)	Risk High (RA)	Risk Medium (RM)	Risk Low (RB)	No Apply (NA)	Analyzed	Total by stage	Complete
1	Initial setup of the equipment	0	0	9	1	0	10	10	✓
2	Acceptance and Commissioning	0	4	20	0	0	24	24	✓
3	Equipment maintenance.	0	0	3	0	0	3	3	✓
4	Taking data from each patient for treatment planning	0	8	7	1	0	16	16	✓
5	Development of treatment plan	0	16	4	0	0	20	20	✓
6	Development of molds. Consequences for Patients with	0	0	3	0	0	3	3	✓
7	Implementation of treatment	0	14	34	8	0	56	56	✓
Total User:		0	42	80	10	0	132	132	7
Total Reference:		0	5	87	40	0	132	132	0

Incorporated Sequences by User:

Núm.	Stage	Risk Very High (RMA)	Risk High (RA)	Risk Medium (RM)	Risk Low (RB)
1	Initial setup of the equipment	0	0	0	0
2	Acceptance and Commissioning	0	0	0	0
3	Equipment maintenance.	0	0	0	0
4	Taking data from each patient for treatment planning	0	0	0	0
5	Development of treatment plan	0	0	0	0
6	Development of molds. Consequences for Patients with	0	0	0	0
7	Implementation of treatment	0	0	0	0
Total		0	0	0	0

3.2 Graphics: Current Practice vs. Reference Practice





FINAL REPORT

3.4 Accident sequences with high and very high risk

Risk Assessment results show that due to the lack of barriers or reducers, the next sequences have High Risk (RH) or Very High Risk (RVH):

IE Code	Initiating Event	Reference Risk	Calculated Risk	Missing Barriers and Reducers
Co60-PAC2.1	Error in the calibration coefficient of the ionization chamber and electrometer (in the standards dosimetry laboratory).	RM	RH	B-222: When performing commissioning tests, the air kerma rate is measured at 1m distance and compared with the value reported by the source manufacturer on the certificate. The measurement can be made in terms of absorbed dose to water and this value can be correlated with the air kerma values reported on the certificate CR-336: Annual external audit. Auditing procedure. Test for dose rate measurement at points around the irradiation head CR-377: At the weekly medical evaluation of the patient, errors in treatment delivery can be detected
Co60-PAC2.16	Error in recording data measured during commissioning, for input to the treatment planning system (TPS)	RM	RH	B-277: Redundant verification of the records by another medical physicist CR-357: Daily patient setup wherein the radiotherapy technologists can detect errors of geometry or dose by observing visual signs on the patient (skin reddening, etc.) CR-377: At the weekly medical evaluation of the patient, errors in treatment delivery can be detected
Co60-PAC2.17	Incorrect generation of data tables for manual treatment planning (for example, depth dose curves)	RH	RH	B-277: Redundant verification of the records by another medical physicist CR-339: Annual external audit. Review of the generated tables based on commissioning tests CR-377: At the weekly medical evaluation of the patient, errors in treatment delivery can be detected
Co60-PAC2.24	Incomplete commissioning of the CT equipment, leading to errors in the density and geometric scales	RL	RH	B-229: Portal image taken during initial treatment session for evaluation by the radiation oncologist and the medical physicist, by which geometric treatment errors can be detected CR-332: Annual external audit CR-350: Weekly portal image wherewith geometric errors can be detected CR-377: At the weekly medical evaluation of the patient, errors in treatment delivery can be detected

The system tells the user in a summary what are the barriers that are missing to the facility in order to reduce their risk level.



AID FOR EVENTS AND BARRIERS

The system is also enabled to include, in a future step, different formats of "aids" for a better understanding of the initiating events, and the ways of reducing the probability of occurrence.

The screenshot displays the SEVRRRA web application interface. The top navigation bar includes 'Start', 'Practices', 'My Account', 'About SEVRRRA', 'Help', and 'Exit'. The left sidebar shows a tree view of stages for 'Cobalt 60', with 'Stage 1: Initial setup of the equipment' selected. The main content area shows the 'Initiating Event' form for 'Cobalt 60 Stage 1/Substage 1/Initiating Event 1'. The form fields include Code (Co60-PAC1.1), Name (Deficiency in the manufacturing process causing an inhomogeneous distribution of 60Co radioactive material in the source), Description, Consequences, and Help references. A red box highlights the 'Help references' field with the text 'Lessons learned from accidents, Safety series, Safety Reports, ...'. To the right of the form is a 'Does the initiating event Apply in your service?' section with 'Yes' and 'No' radio buttons, and a 'Risk' section with a table showing 'FVL', 'PVL', 'CH', and 'RL' (highlighted in green). Below the form is a 'Comment and modification proposals list' and a prompt to 'Select from the list below, those barriers and reducers that are implemented in your facility:'. This leads to a table with three columns: 'Frequency Reducers', 'Barriers', and 'Consequence Reducers'. The 'Barriers' column has three checked items, and a tooltip 'Insert comment or modification proposal' is visible over the second item. At the bottom left is a 'Compute Risk Level' button. A red arrow points from the highlighted text in the 'Help references' field to two book covers at the bottom right: 'safety series' and 'Safety Reports Series No. 7'.



