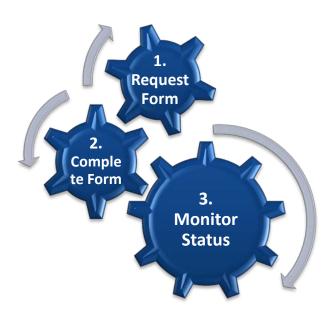
Medtronic CRHF Supplier Change Notification System Instructions:

3 Simple Steps



Step 1: Request Form

- Send request for a new notification form to supplierpen@medtronic.com
 - o Do NOT send attachments with the request email as they will be discarded

😰 🛃 💆	(*	↓ Reque	st new chang	e notification for	m - Messag	je (HTML)	x
File	Message	Insert	Options	Format Text	Review	Adobe PDF	~ ?
	From -	lisa.r.bobi	ch@medtroni	c.com			
Send	То	supplierpo	n@medtronic.c	om			
	Cc	RS PCN	Supplier <supp< td=""><td>plierpcn@medtroni</td><td>c.com> 🗙</td><td></td><td></td></supp<>	plierpcn@medtroni	c.com> 🗙		
	Bcc						
	Subject:	Request	new change n	otification form			
Subject: Request new change notification form Image: Subject in the second s							

- An email reply from RS PCN Supplier will be sent to the requestor
 - The body of the email will contain the unique Tracking ID#
 - Note: Each request is assigned a unique Tracking ID#, therefore a new form must be requested for each change
 - A blank change form will be attached
 - The filename of the form will also include the Tracking ID#

🖂 🚽 🥙 🕐 🗢 🗇 🗢 Medtronic CRHF has received your request for a change - Message (HTML)	- O X
File Message McAfee E-mail Scan Adobe PDF	∞ (?)
From: RS PCN Supplier	Sent: Mon 3/23/2015 12:51 PM
To: Bobich, Lisa	
Subject: Medtronic CRHF has received your request for a change	
Message RequestForm_1349.pdf (116 KB)	
	· 8 · · · I · · · 9 · · · · ·
Medtronic, Cardiac Rhythm and Heart Failure (CRHF) business unit, has received your request for a change. Please complete describe the change and submit it back to this address: supplierpcn@medtronic.com Note: For changes that impact multiple contact each business unit according to the process they have specified.	
All required fields must be completed to submit the form. The required fields are indicated by a red box, when the field is selenot be logged at Medtronic until this form is received. Note : The form fields must remain editable for the system to detect your submission (i.e., scanned forms will result in an error	•
All communication regarding this change should reference your Tracking ID number in the Subject line.	
Tracking ID: REQUEST-001349	
Receipt of this e-mail does not constitute an approval by Medtronic CRHF for this change. Once the form is received and the have been assessed by Medtronic CRHF, you will receive independent notification of the approval or rejection of this change	
Please contact your Medtronic CRHF Sourcing Engineer if you have questions about the form or change approval process.	
Thank you.	
Retention Policy: Medtronic Inbox Retention (6 months) Expires: 9/19/2015	
RS PCN Supplier	2 🗖 🔨

Step 2: Complete Form

- Open the PDF request form
 - o The Tracking ID field is pre-populated and read-only (e.g., REQUEST-XXXXXX)
 - All fields indicated by the red asterisk * are required fields. The form cannot be processed without this information.
- Complete all fields in the PDF request form by providing details of the proposed change.
 - **Note:** The form must be completed using Adobe Reader or Adobe Acrobat so that the editable fields remain intact and can be processed by the automated system.
- Save the PDF request form as a .pdf
- Send the completed .pdf form to supplierpcn@medtronic.com
 - Supporting files may be attached to the email
 - Medtronic contacts may be copied on the email (this is considered an FYI notification only; not a confirmation of assignment)
- The request form template is shown on the following page. Instructions for each field are shown in Appendix A.



019-F171, Version 2.0

Supplier Change Request Form

Change Request Information - To be completed by Supplier

Su	nn	lier	De	tai	Is
. Ju	~~	iiei	-		13

Supplier Tracking I.D.	Enter your unique Tracking / Reference I.D. for this change request. REQUEST-001349
Supplier Name*	Enter the legal name of your company.
	Enter the address of the location this change is being requested for.
Supplier Address*	
Supplier Code	Enter your unique Medtronic Supplier Code (e.g. SAP code), if known.
	Enter the name of the person Medtronic will contact regarding this change request.
Supplier Contact Name*	
	Enter the telephone number of the contact person.
Supplier Contact Phone*	
Complian Contract a mailt	Enter the e-mail address of the contact person.
Supplier Contact e-mail*	

	Change Details					
Change Title*	Provide a brief title for the change (e.g. Change of Supplier for Material XYZ)					
Part Numbers / Rev*	List or attach the Medtronic Pa	List or attach the Medtronic Part Number(s) affected by this change and current Revision.				
Medtronic Facilities*	Identify the Medtronic facilities	Identify the Medtronic facilities you supply this Part Number(s) to.				
	Identify the applicable Change	Type (check all that apply).				
	Capacity	Management/Business Related	Raw Material			
	Control Plan	Manufacturing Process	Response to Audit Finding			
Change Type*	Cost Savings	Measurement Method Change	Response to CAPA			
	Design	Medtronic Initiated Change	Sterilization			
	Equipment/Facility Move	Quality Improvement	Sub-tier Supplier Change			
	Labelling/Packaging	Other:				
Change Description*						
	Material Availability, Compliance	background for the change and WHY it e, Quality Improvement, Cost Savings o c deficiencies the change would addres	etc.) Include reference to any Field			

019-F171, Supplier Change Request Form, Version 2.0

Page 2 of 2

Potential Risks*		Change Evaluation and Timing
on the performance of the part? If the part? Evaluation of Change* If the performance of the part? List and attach any relevant supportive information you currently have available that may assist with processing the change request (e.g. qualification/validation reports, data analysis, risk assessment etc.). If none write 'none'. Supporting Documentation* Provide an estimate and justification for your proposed implementation date for the change. Proposed Implementation Provide an estimate and justification for your proposed implementation date for the change.	Potential Risks*	Describe any currently known potential risks and plans to mitigate.
processing the change request (e.g. qualification/validation reports, data analysis, risk assessment etc.). If none write 'none'. Supporting Documentation* Proposed Implementation Provide an estimate and justification for your proposed implementation date for the change. Proposed Implementation	Evaluation of Change*	Provide a description of how the change will be evaluated. How will you determine the impact of the change on the performance of the part?
Proposed Implementation		processing the change request (e.g. qualification/validation reports, data analysis, risk assessment etc.). If
This document is electronically controlled. Printed copies are considered uncontrolled. Confidential	This docum	

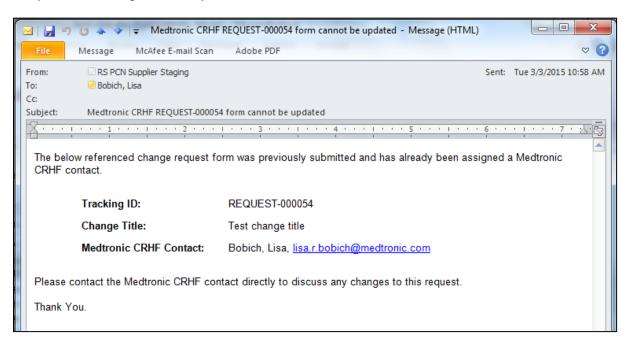
 Supplier/Requestor (person sending the completed form) will be notified when Medtronic CRHF has received your completed change request form.

🖂 🗐 😈 🐟 🗇 🖵 Medtronic CRHF has received REQUEST-001349 - Message (HTML)	J
File Message McAfee E-mail Scan Adobe PDF 🗢 🚱)
From: RS PCN Supplier Sent: Mon 3/23/2015 1:31 PM	1
To: Bobich, Lisa	
Subject: Medtronic CRHF has received REQUEST-001349	
Message 🔁 RequestForm_1349.pdf (144 KB)	
Medtronic CRHF has received your completed request as identified below.	
Tracking ID: REQUEST-001349	
Change Title: Supplier location change	
Medtronic CRHF is in the process of reviewing your change. You will be notified when a Medtronic CRHF contact has been assigned to work with you regarding evaluation and approval of this change. The contact may request additional information regarding this change.	
Receipt of this e-mail does not constitute an approval from Medtronic CRHF for this change. Medtronic CRHF will send you independent notification of the approval or rejection of this change request.	
Thank you.	
Retention Policy: Medtronic Inbox Retention (6 months) Expires: 9/19/2015	
RS PCN Supplier	

 Updates can be made to the form prior to a Medtronic CRHF resource being assigned by updating the PDF request form and re-sending to <u>supplierpcn@medtronic.com</u>:

1	a 🛃 🤊	🗢 🍫 束	Medtronic	CRHF REQUEST-000054 updated - M	essage (HTML)	
	File	Message McAfe	e E-mail Scan	Adobe PDF		∞ 😮
	From:	RS PCN Supplier	Staging		Sent: Tue 3	/3/2015 9:57 AM
	To: Cc:	🖲 Bobich, Lisa				
	Subject:	Medtronic CRHF R	EQUEST-000054	updated		
	🖂 Messag	e 🔁 RequestForm_	54.pdf (144 KB)			
	<u> :</u>	· · · <u>1</u> · · · <u>1</u> ·	· · 2 · · · 1	· · · 3 · · · 1 · · · 4 · · · 1 ·	· · · 5 · · · · 1 · · · · 6 · · · · 1 · ·	· · 7 · 🔬 📴
		w referenced chan to include the con			Itronic CRHF. The request has be	en
		Tracking ID:	REQUEST-0	00054		
		Change Title:	Test change	title		
	been ass		n you regarding		tified when a Medtronic CRHF cor hange. The contact may request a	
				an approval from Medtronic CRH approval or rejection of this chang	F for this change. Medtronic CRH ge request.	F will
	Thank yo	u.				

After a Medtronic CRHF resource has been assigned, updates cannot be made via the form.
 Convey these changes directly to the Medtronic CRHF contact:



Errors/Troubleshooting

- Notification of an incomplete form
 - All fields indicated by the red asterisk * are required fields. The form cannot be processed without this information.
 - If an incomplete form is submitted, the sender will receive an email from the system as follows, identifying any incomplete fields (i.e., Invalid Field(s):).
 - **Note:** The picture in the email is a generic indicator of how errors are shown within the form; it does not reflect the actual field that is incorrect.

🖂 🚽 🧐 👅 🔶 🧇 🗧 🛛 Medtronic CRHF REQUEST-000056 form incomplete - Message (HTML)	
File Message McAfee E-mail Scan Adobe PDF	∞ 🕜
	/3/2015 4:22 PM
To: Bobich, Lisa	
Subject: Medtronic CRHF REQUEST-000056 form incomplete	
Message 🔁 RequestForm_56.pdf (144 KB)	
	· · 7 · · · · ·
The below referenced change request form you submitted contains empty or invalid fields.	
3. 1	
Tracking ID: REQUEST-000056	
Invalid Field(s): Supporting Documentation	
Please complete all required fields and resubmit.	
The required fields will be indicated by a red box when field is selected, as shown below.	
Supplier Name*	
Fier the address of the location this change is being requested for,	
Supplier Address* 123 S Elk St	
The blue highlight ter your unique Medtronic Supplier Code (e.g. SAP code), if known.	
Retention Policy: Medtronic Inbox Retention (6 months) Expires: 8/30/2015	
RS PCN Supplier Staging	∠ 📓 ^

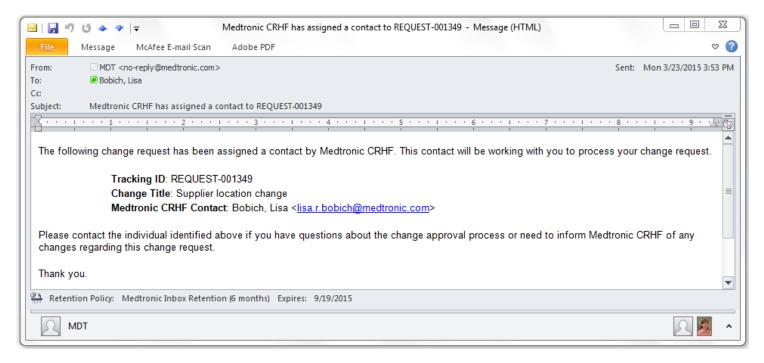
- Notification of an expired form
 - Tracking ID#'s and associated forms will expire after 30 days. A new request form will need to be requested.
 - Sender will be notified of an expired form with the following e-mail response from the system:

🖂 🛃 🖷	🤊 🥶 🐟 🗇 ╤ Medtronic CRHF REQUEST-000057 ID expired - Message					
File	Message McAfee E-mail Scan Adobe PDF	♡ 😮				
From:		/lon 3/9/2015 8:22 AM				
To: Cc:	Bobich, Lisa					
Subject:	Medtronic CRHF REQUEST-000057 ID expired					
🖂 Messi	age 🔁 RequestForm_57.pdf (144 KB)					
8	1 · · · · 1 · · · · 1 · · · · 2 · · · ·	· · 5 · · · · / 🖄				
The be	low referenced Tracking ID you submitted has expired.					
	Tracking ID: REQUEST-000057	=				
new fo	Please resubmit a new request for this change. A new Tracking ID will be assigned and a new form will be sent to you for completion. Please note Tracking IDs expire 30 days after original receipt.					
Thank	You.					
🚔 Reter	ntion Policy: Medtronic Inbox Retention (6 months) Expires: 9/5/2015					
2	RS PCN Supplier Staging	2 🙇 🔺				

- Sender will also receive an expired form error if an older version of the change template is submitted.
- Receipt of additional "Medtronic CRHF has received your request for a change" emails
 - If you received unintended emails with the same Subject line above, the possible reasons include:
 - Corruption of form fields in PDF such that Medtronic automation cannot parse the information from each field in the form (this will also occur if a scanned version of the form is attached)
 - Email sent as 'Reply All' that includes 'supplierpcn@medtronic.com' or 'RS Supplier PCN' as a recipient and does not include the PDF request form

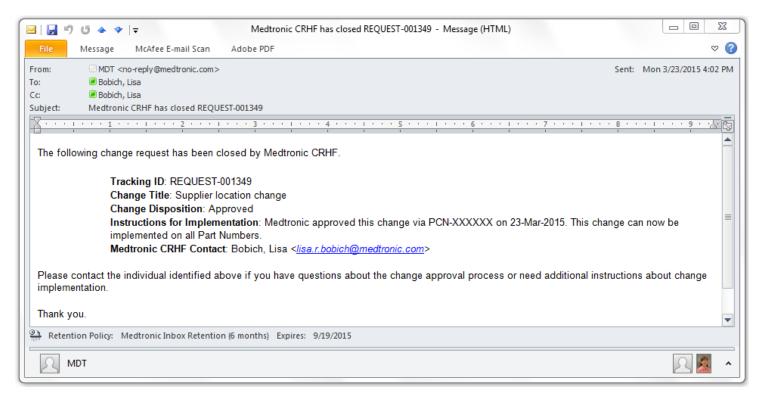
Step 3: Monitor Status

 The Supplier/Requestor will be notified when a Medtronic CRHF resource has been assigned to the change request:



The Supplier/Requestor will be notified of approval or disapproval:

Example of Approval email:

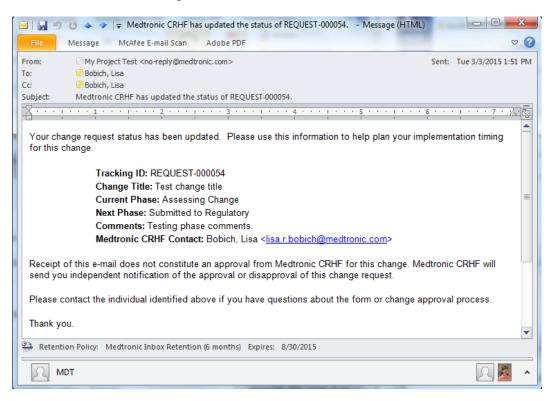


Example of Disapproval email:

🖂 🚽 🥙 👅 🐟 🗇 🗧 🛛 Medtronic CRHF has disapproved REQUEST-000054 - Message (HTML)	x
File Message McAfee E-mail Scan Adobe PDF State	0
From: My Project Test <no-reply@medtronic.com> Sent: Tue 3/3/2015 2:49 To: Bobich, Lisa Cc: Bobich, Lisa</no-reply@medtronic.com>	PM
Subject: Medtronic CRHF has disapproved REQUEST-000054	
Medtronic CRHF has disapproved the change request as identified below.	
Tracking ID: REQUEST-000054 Change Title: Test change title Medtronic CRHF Contact: Bobich, Lisa < <u>lisa.r.bobich@medtronic.com</u> > Reason for Disapproval: Testing disapproval route.	
Medtronic CRHF is unable to approve this change request based on the information currently available. Please contact the individual identified above if you have questions about this request or about the change approval process.	
Thank you.	
Retention Policy: Medtronic Inbox Retention (6 months) Expires: 8/30/2015	
MDT 🛛 🕅	^

Additional notifications the system can send:

- Notification of a status update for the PCN:
- Note: The status update notifications are optional and are at the discretion of the assigned Medtronic CRHF resource. In the example below, the Supplier/Requestor is in the 'To:' field and the Medtronic CRHF assigned resource is in the 'Cc:' field.



	Appendix A: Change Request Form Field Details	
Form Field	Field Instructions	Required?
	Supplier Details	
Supplier Tracking ID	Assigned and populated by the system. REQUEST-XXXXXX.	Y
Supplier Name	Enter the Legal name of your company.	Y
Supplier	• Enter the complete manufacturing address (e.g., street, city, state/province, zip code, country) where the change is being made.	Y
Address	If sub-tier supplier change, enter <u>your</u> manufacturing address.	
Supplier Code	Enter your unique Medtronic supplier ID (e.g. SAP or JDE), if known.	N
Supplier Contact Name	Enter the name of the person Medtronic will contact regarding this change.	Y
Supplier Contact Phone	Enter the phone number of the contact person.	Y
Supplier Contact E-mail	Enter the e-mail address of the contact person.	Y
	Change Details	
Change Title	Provide a brief title to describe the change (e.g., Change of Supplier for material X).	Y
Part Number(s) /	List the Medtronic part number(s) affected by this change.	Y
Rev	A list may be submitted as an attachment.	
	Identify the Medtronic facilities to which you supply the Part Number(s). This is a free-form field and any entry is acceptable.	
	For reference, CRHF facilities include:	
	MECC (Brooklyn Center, MN)	
	• MV (Mounds View, MN)	
Medtronic	• MTC (Tempe, AZ)	Y
Facilities	MPROC (Villalba or Juncos, Puerto Rico)	
	Rice Creek (Fridley, MN)	
	• SMO (Tolochenaz, Switzerland)	
	• MSO (Singapore)	
	 Various OEMs (Original Equipment Manufacturers) 	
Change Type	Identify the applicable Change Type (check all that apply). Reserve the use of Other for when no other type applies.	Y

Appendix A: Change Request Form Field Details		
Form Field	Field Instructions	Required?
Change Description	 Provide a detailed description of WHAT is changing. Outline current (FROM) and future (TO) state for the change. 	Y
	 Outline what documentation may be impacted by the change (e.g., specification, drawing, control plan, FMEA). 	
	 Identify clearly if this is a sub-tier supplier change, and identify the sub-tier supplier. 	
	Additional details can be provided in attachments.	
Reason for Change	• In non-expert terms, provide a background for the change and WHY it is necessary (e.g., capacity, raw material availability, compliance, quality improvement, cost savings, Medtronic initiated).	Y
	 Include reference to any Field Action or CAPA. 	
	 What will happen if the change is NOT made? 	
	What is the benefit for Medtronic?	
Change Evaluation and Timing		
Potential Risks	 Describe any currently known potential risks associated with the proposed change. 	Y
	 Describe any plans to mitigate the risk. 	
	 Provide justification for implementation date (implementation date requested in later field). 	
Evaluation of Change	 Provide a description of HOW the change and its impact to the performance of the part will be evaluated. 	Y
	If no evaluation is planned, provide a rationale for no evaluation.	
Supporting Documentation	• Identify any supporting documentation that will be provided relevant to this change OR write ' None '.	N
	 To send attachments, reply to original e-mail and attach the change notification form and supporting document(s). 	
	 Examples: qualification and/or validation plans and reports, data analysis, risk assessments. 	
Proposed Implementation Date	• Provide an estimate for your proposed implementation date (format: DD-MMM-YYYY) for the change(s). The proposed implementation date can be no sooner than the completion of all evaluation activities.	Y
	• Pick a date from the calendar pop-up by clicking on the down arrow that appears at the right of the cell.	