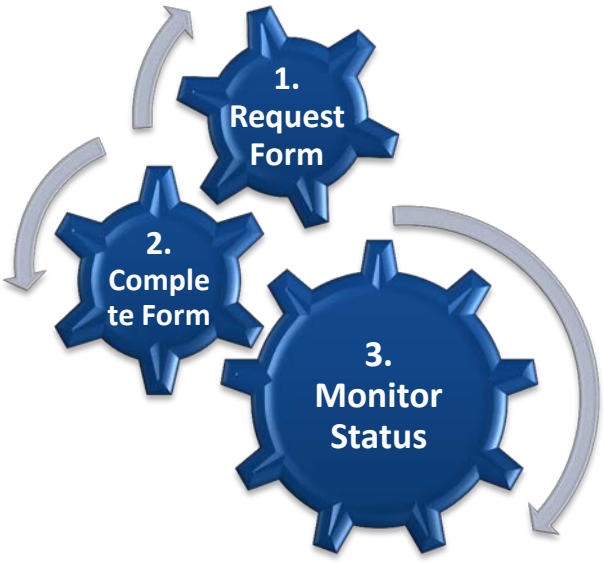
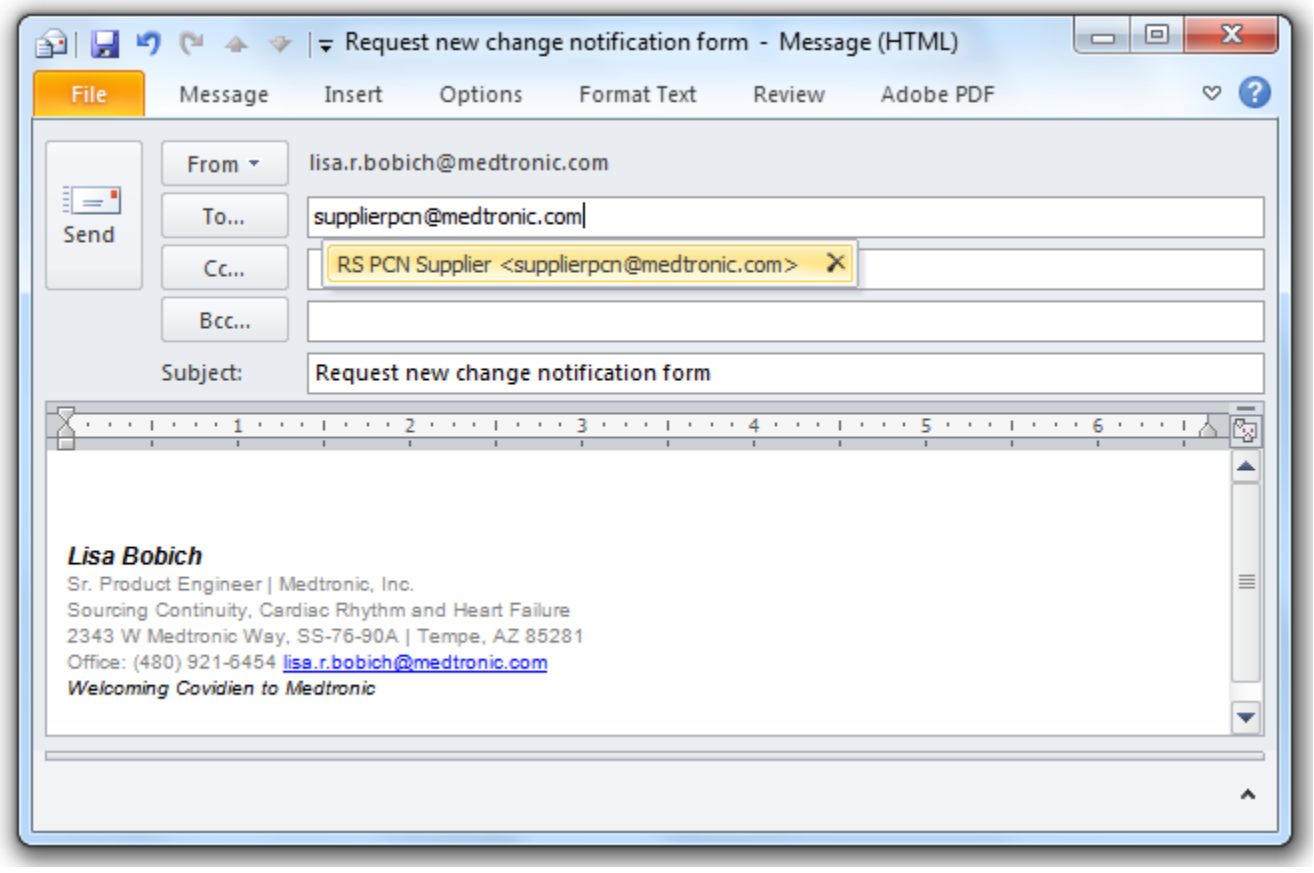
Medtronic CRHF Supplier Change Notification System Instructions:

3 Simple Steps

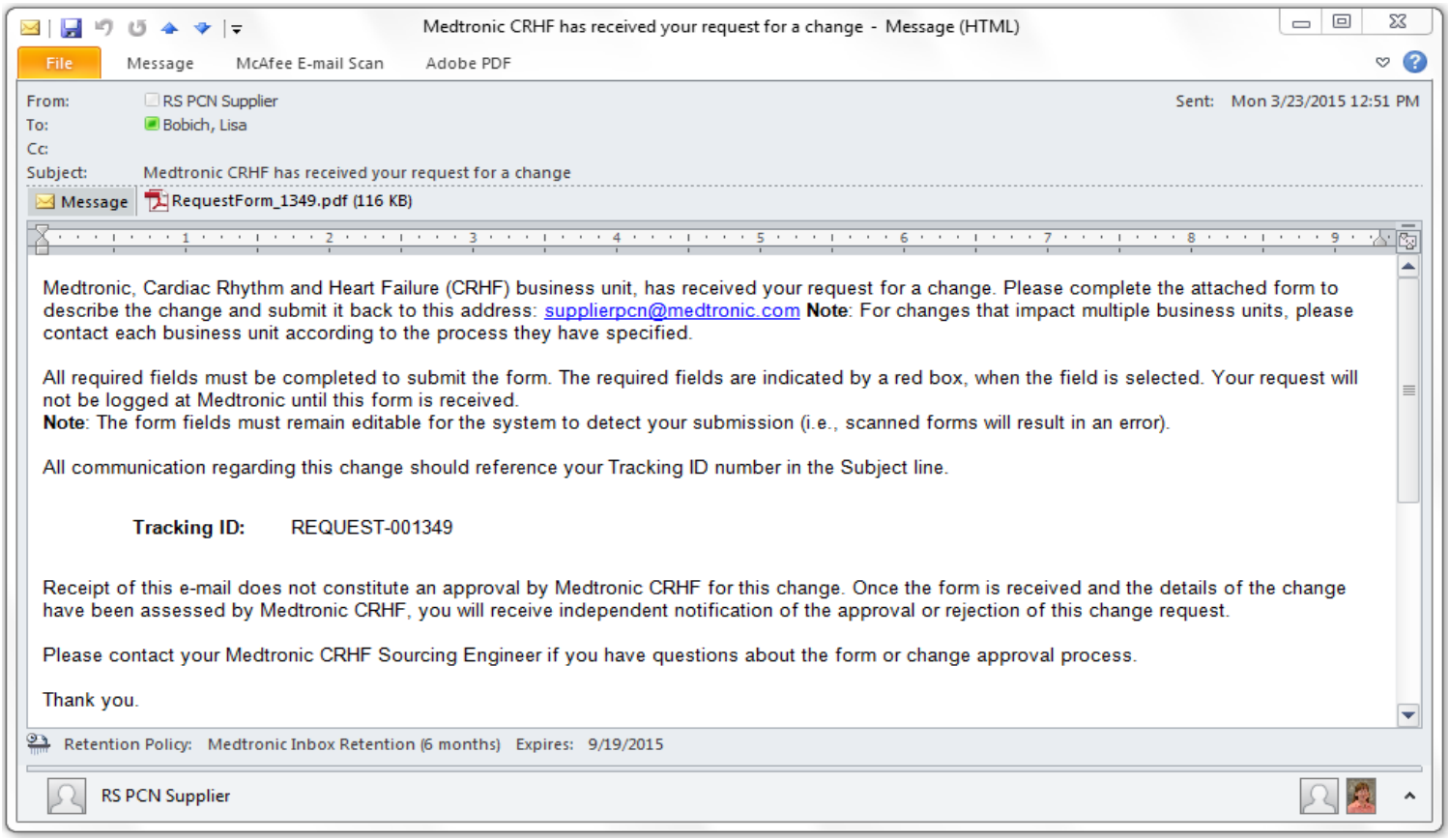


Step 1: Request Form

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



- 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#



Step 2: Complete Form

- Open the PDF request form
    - 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.

Medtronic Global Form

019-F171, Version 2.0

Supplier Change Request Form

Change Request Information - To be completed by Supplier

Supplier Details

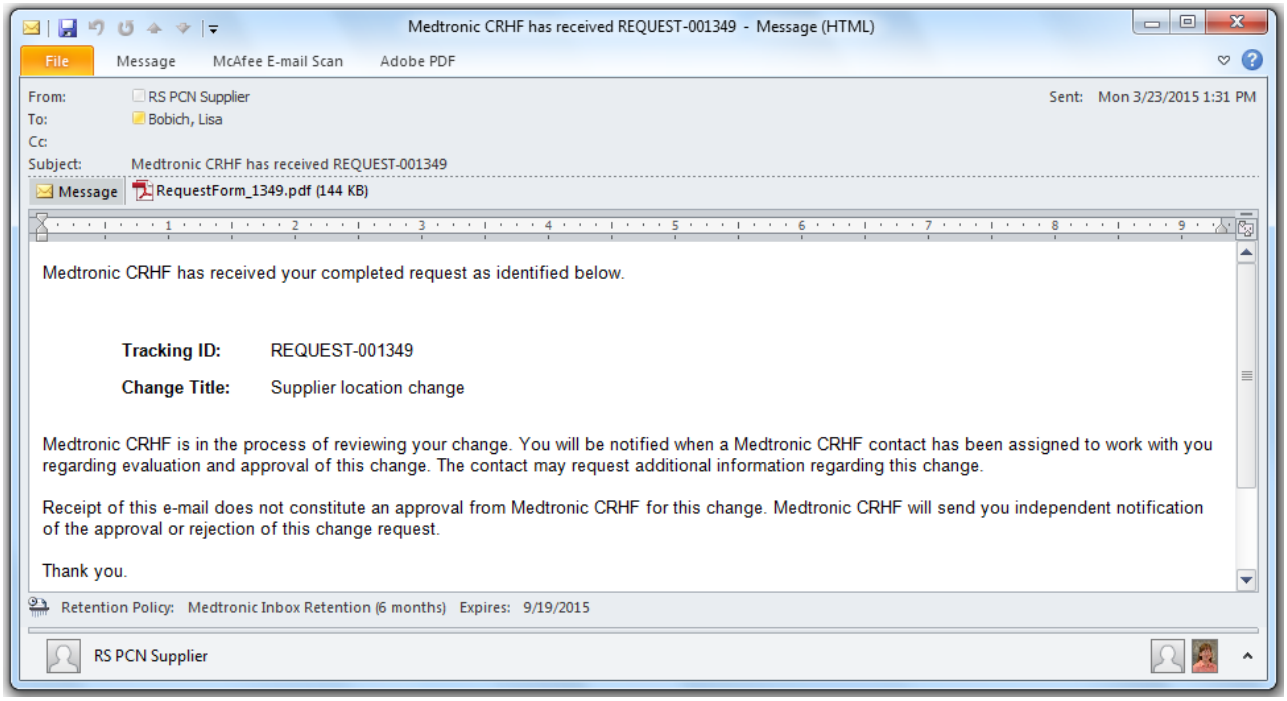
Supplier Tracking I.D.	*Enter your unique Tracking / Reference I.D. for this change request.* REQUEST-001349
Supplier Name*	*Enter the legal name of your company.*
Supplier Address*	*Enter the address of the location this change is being requested for.*
Supplier Code	*Enter your unique Medtronic Supplier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

Change Details

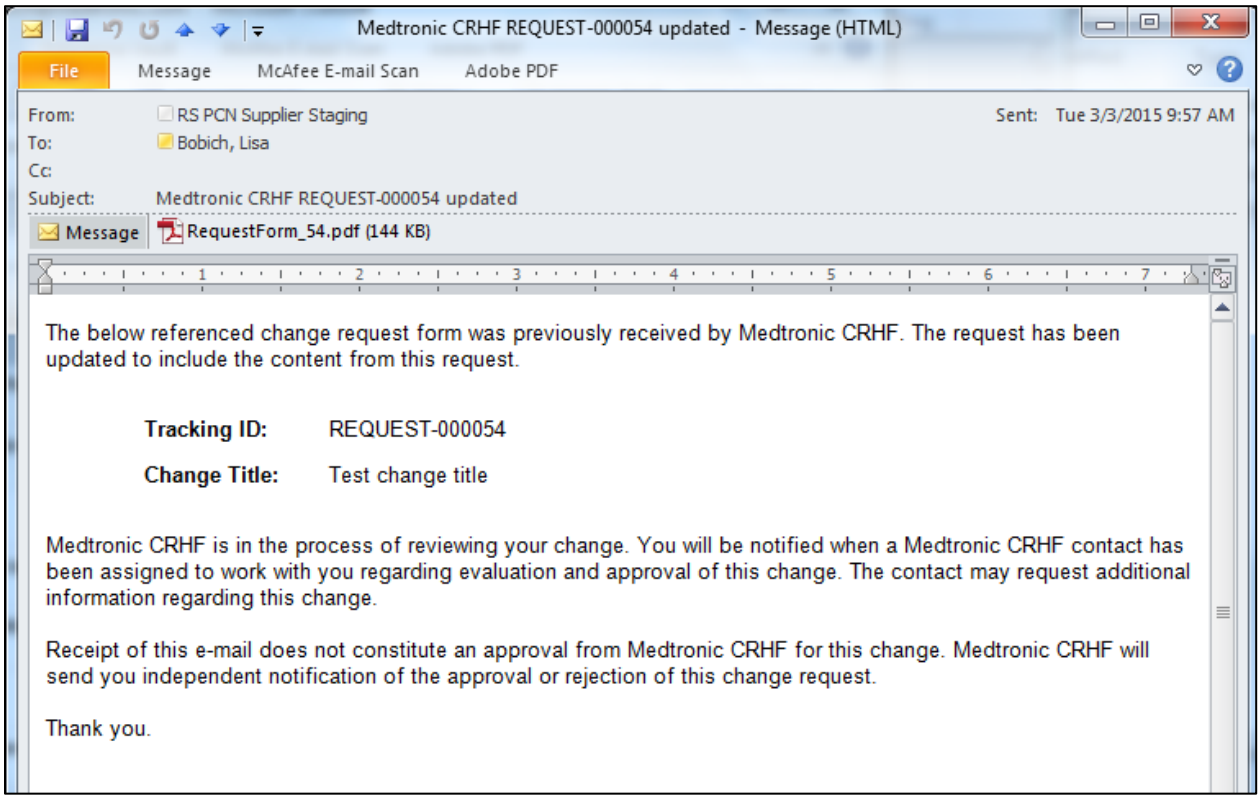
Change Title*	*Provide a brief title for the change (e.g. Change of Supplier for Material XYZ)*		
Part Numbers / Rev*	*List or attach the Medtronic Part Number(s) affected by this change and current Revision.*		
Medtronic Facilities*	*Identify the Medtronic facilities you supply this Part Number(s) to.*		
Change Type*	*Identify the applicable Change Type (check all that apply).*		
	☐ Capacity	☐ Management/Business Related	☐ Raw Material
	☐ Control Plan	☐ Manufacturing Process	☐ Response to Audit Finding
	☐ 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*	*Describe in detail WHAT is changing. Clearly outline the current and future state (From / To). Outline what documentation would be impacted by the change (e.g. specifications, Control Plan, FMEA). Outline if the change is part of a large or multiple phase project plan. If needed, include additional detail in clearly identified 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 etc.) Include reference to any Field Action or CAPA and the specific deficiencies the change would address. Also describe what would happen if the change wasn't made.*		

Change Evaluation and Timing	
Potential Risks*	*Describe any currently known potential risks and plans to mitigate.*
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?*
Supporting Documentation*	*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'.*
Proposed Implementation Date*	*Provide an estimate and justification for your proposed implementation date for the change.* MM/DD/YYYY

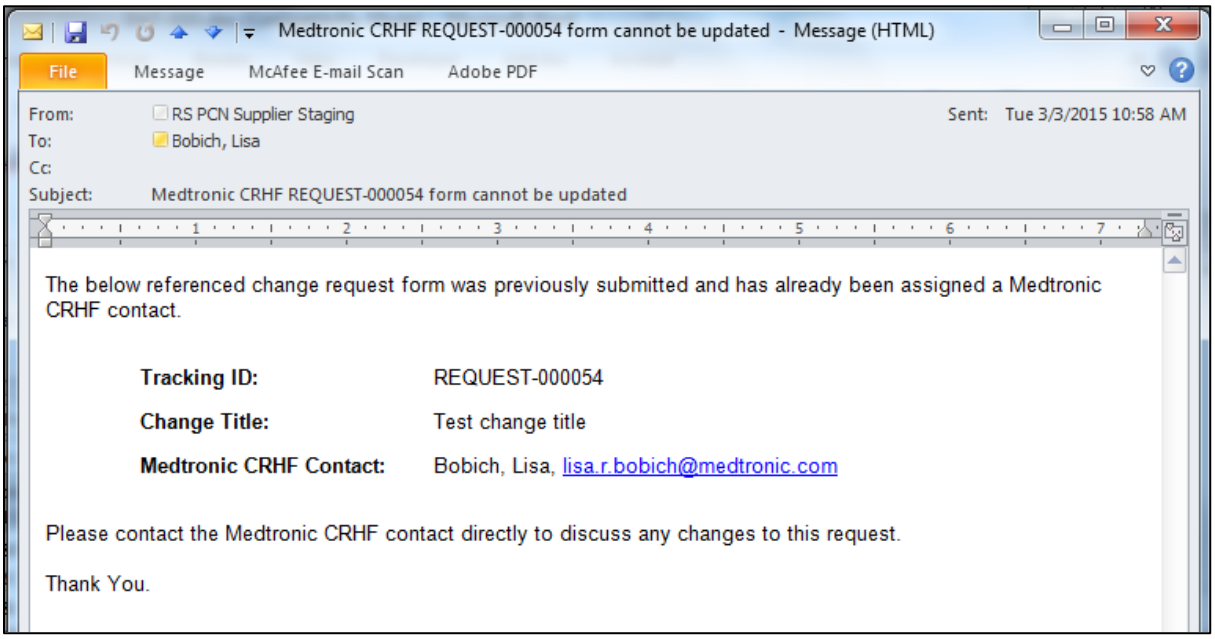
- Supplier/Requestor (person sending the completed form) will be notified when Medtronic CRHF has received your completed change request form.



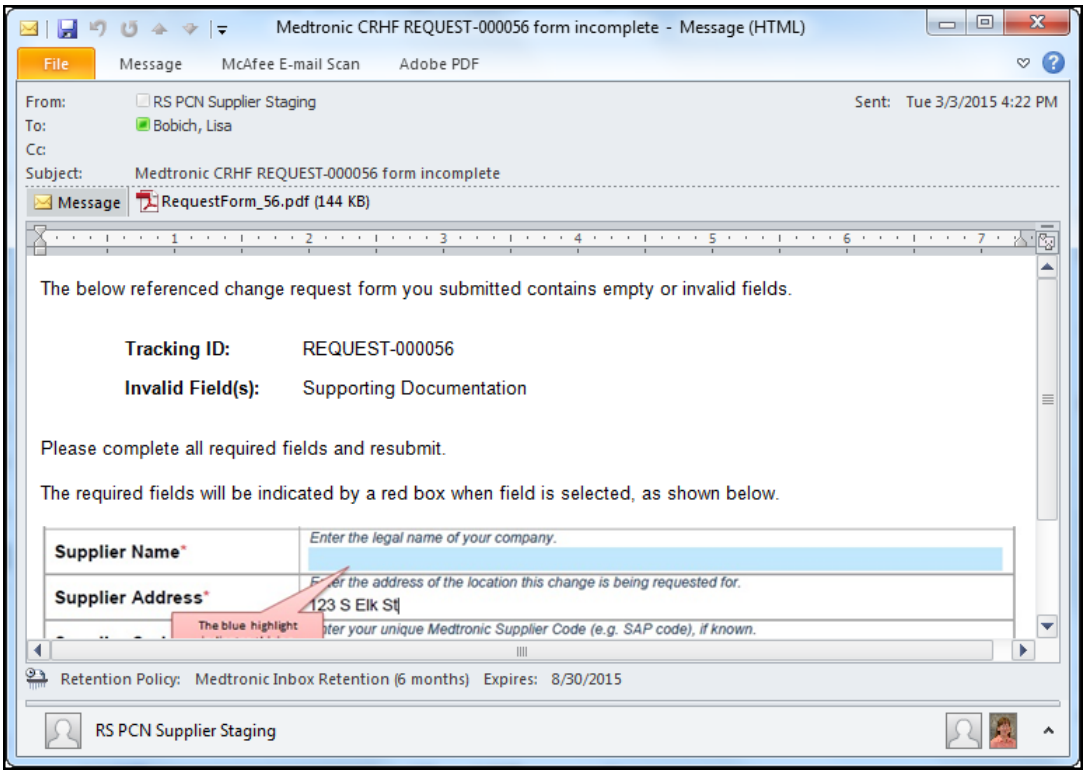
- Updates can be made to the form prior to a Medtronic CRHF resource being assigned by updating the PDF request form and re-sending to supplierpcn@medtronic.com:



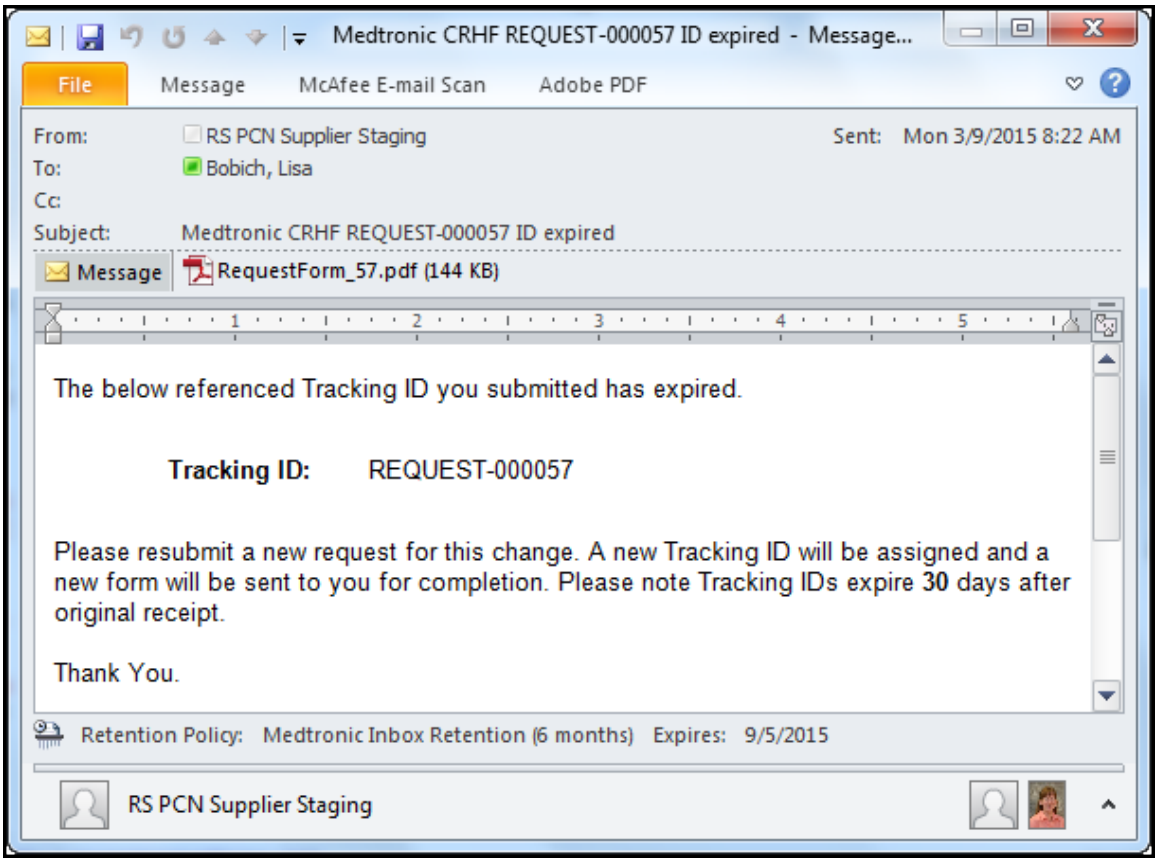
- After a Medtronic CRHF resource has been assigned, updates cannot be made via the form. Convey these changes directly to the Medtronic CRHF contact:



- **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.



- 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:

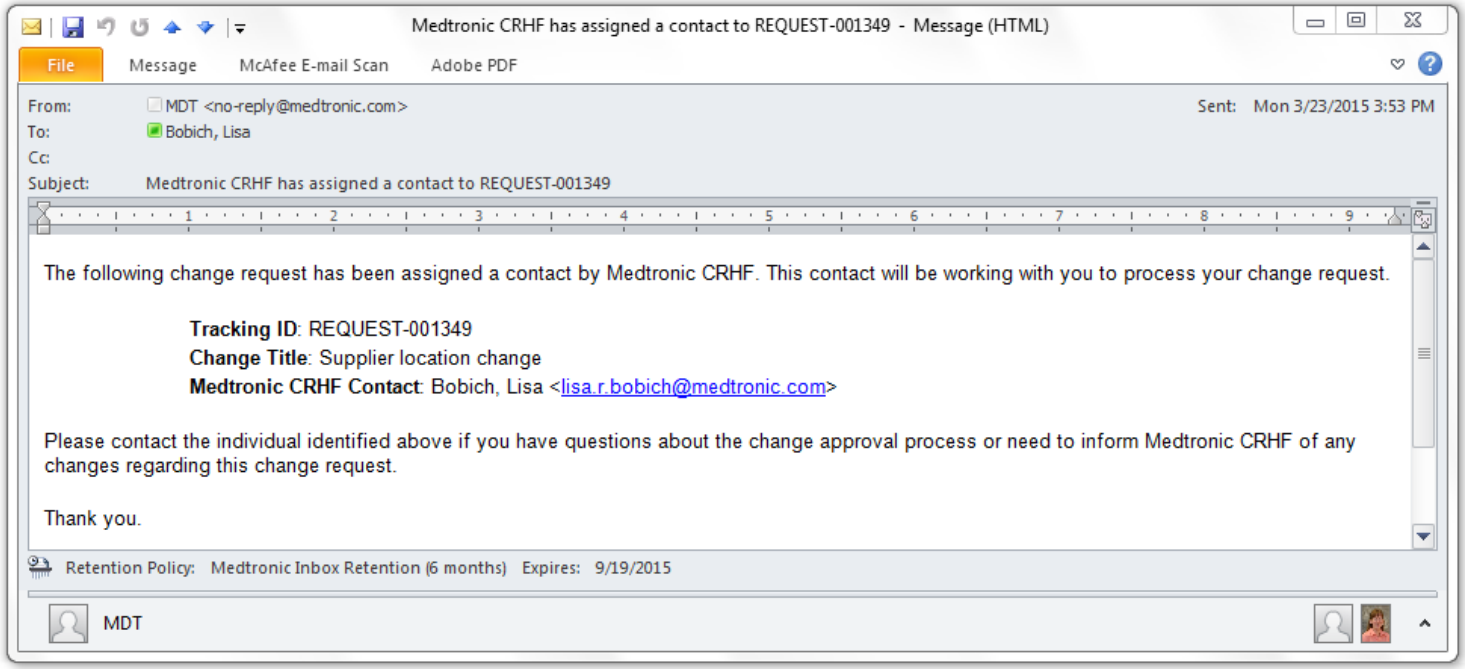


  - Sender will also receive an expired form error if an older version of the change template is submitted.

- 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

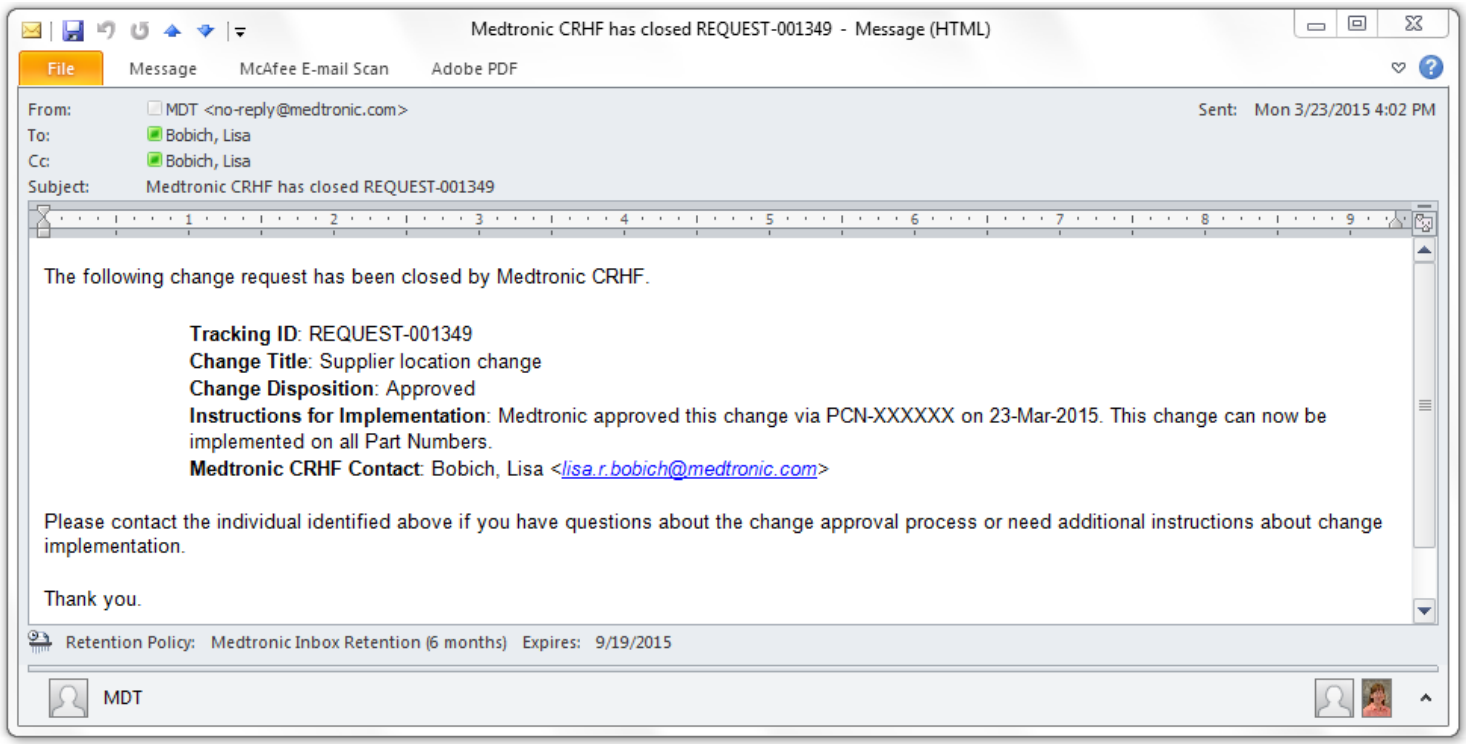
Step 3: Monitor Status

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

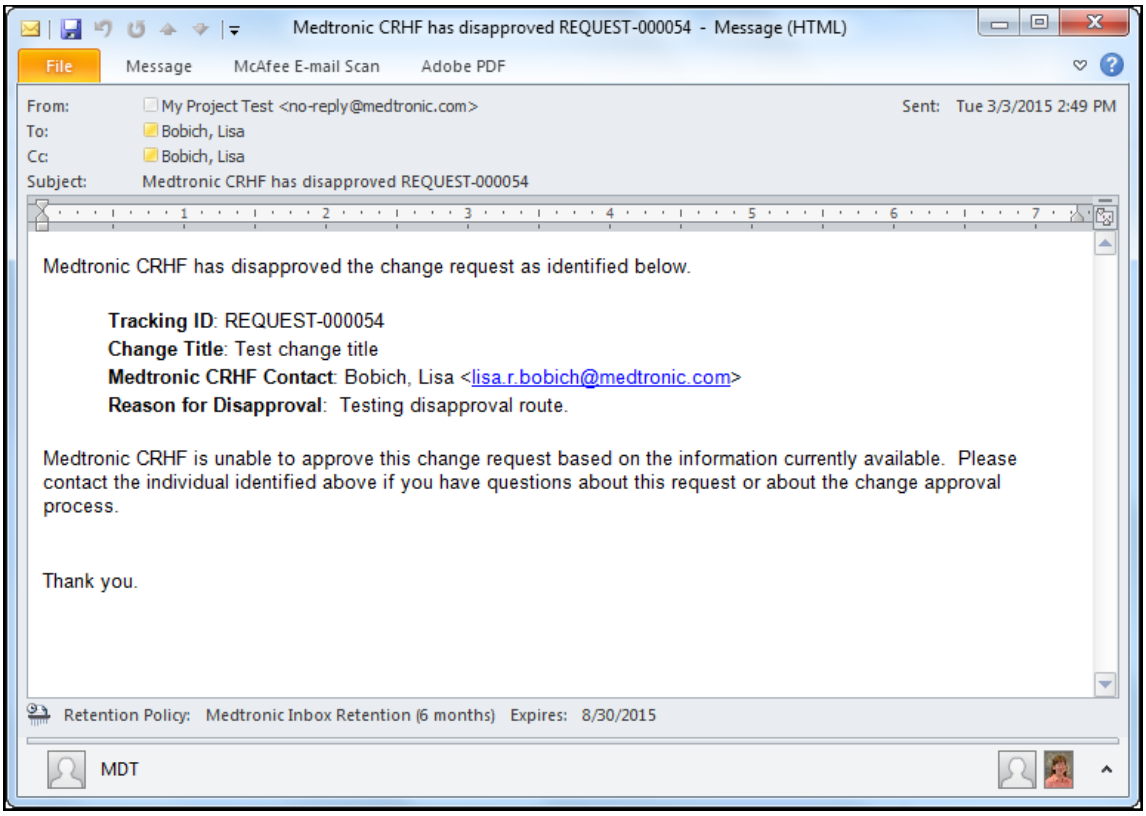


- The Supplier/Requestor will be notified of approval or disapproval:

Example of Approval email:

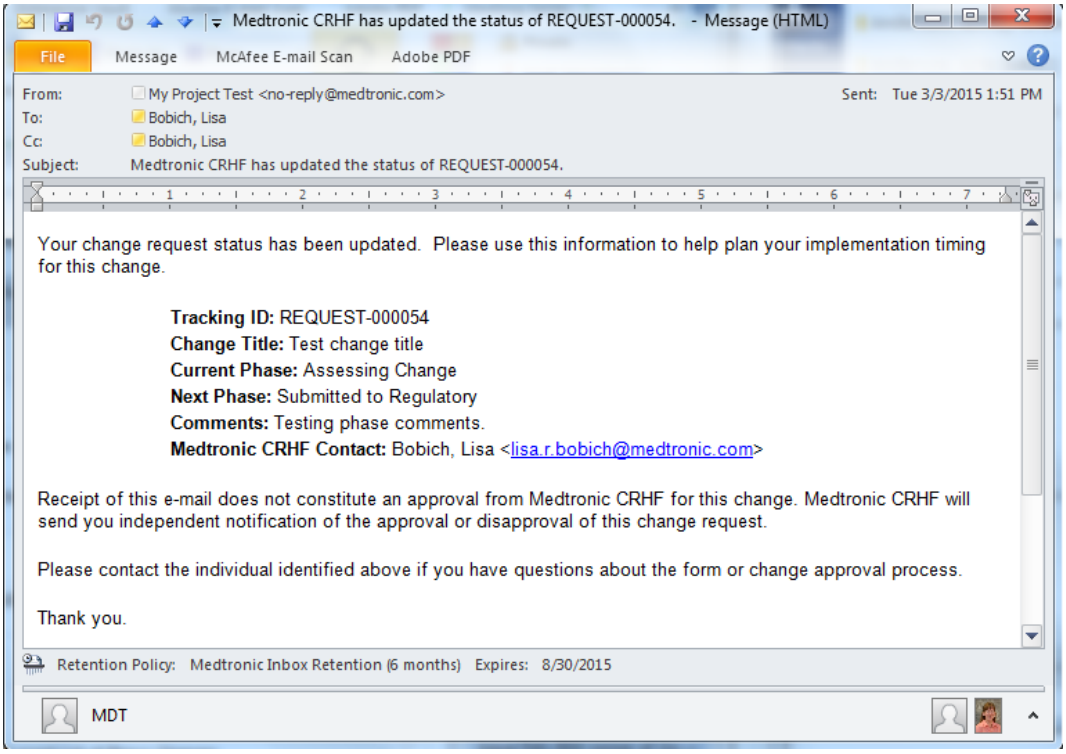


Example of Disapproval email:



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 Address	• Enter the complete manufacturing address (e.g., street, city, state/province, zip code, country) where the change is being made. • If sub-tier supplier change, enter your manufacturing address.	Y
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) / Rev	• List the Medtronic part number(s) affected by this change. • A list may be submitted as an attachment.	Y
Medtronic Facilities	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) • **MTC** (Tempe, AZ) • **MPROC** (Villalba or Juncos, Puerto Rico) • **Rice Creek** (Fridley, MN) • **SMO** (Tolochenaz, Switzerland) • **MSO** (Singapore) • Various OEMs (Original Equipment Manufacturers)	Y
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. • 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.	Y
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). • Include reference to any Field Action or CAPA. • What will happen if the change is NOT made? • What is the benefit for Medtronic?	Y
Change Evaluation and Timing		
Potential Risks	• Describe any currently known potential risks associated with the proposed change. • Describe any plans to mitigate the risk. • Provide justification for implementation date (implementation date requested in later field).	Y
Evaluation of Change	• Provide a description of HOW the change and its impact to the performance of the part will be evaluated. • If no evaluation is planned, provide a rationale for no evaluation.	Y
Supporting Documentation	• Identify any supporting documentation that will be provided relevant to this change **OR** write '**None**'. • To send attachments, reply to original e-mail and attach the change notification form and supporting document(s). o Examples: qualification and/or validation plans and reports, data analysis, risk assessments.	N
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. • Pick a date from the calendar pop-up by clicking on the down arrow that appears at the right of the cell.	Y