Case Study 1 - Background

- A catheter manufacturer implemented a design change as an enhancement to increase the amount of barium sulfate to improve on the radiopacity properties of the catheters intended for use on premature newborn infants

- Customer calls for irritation, rash, fevers, other symptoms, injury and death were received after the change

- These types of calls were also received prior to the change

Case Study 1 - Exercise 1

- Should a complaint or complaints be opened?
- What other information would you review? Describe the records and/or data that may provide relevant information to assist in determining the next steps.
- Do any of these events require the submission of a MDR?
- Is a complaint investigation required?
- Since the types of issues described in the calls were similar in nature before and after the design change (enhancement), how would you determine if there is an issue related to the change?

Case Study 1 - Additional Background

- During the monthly data analysis of the complaints for the month after the enhancement was implemented, a trend was noted due to an increase in complaints for irritation, rash, fevers, injury and death
- The change was evaluated using their existing procedures and concluded it was a minor change. A minor change by procedure does not require any testing as long as a justification is completed.
- The justification for classifying as a minor change was based on prior experience and review of the Design FMEA.
- The justification documented for the prior experience was that a similar design change was made to another catheter family and no adverse events have been noted after two years with the change in place.
- Testing was not performed on this change due to a low risk designation on design FMEA. During the development of the risk document, the risk designation was based on the fact that other manufacturers have used barium sulfate on catheters intended for use in the human body with no issues identified.

Case Study 1 - Exercise 2

- Based on the information, should an investigation be initiated? If so, what type of investigation? And, describe the potential root cause(s).
- What other information would you review? Describe the records and/or data that may provide relevant information to assist in determining the next steps.
- Should product be placed on hold?
- Is there a need to recall?

Case Study 2 - Background

- A new device was recently cleared through the Premarket Notification [510(k)] process. One component of the submission to support a determination of substantial equivalence was demonstration of electrical safety through conformance to the IEC 60601 series standards.
- A third party testing facility was utilized to perform this testing. Three months following clearance and product launch, the 3rd party facility informs you that the test report that was supplied to you (and included in the submission) was actually incorrect and that 2 of the 3 units that were tested failed. At this point twenty units have been shipped to Customers.

Case Study 2 - Exercise 1

- Is an investigation required based on what is known?
- What other information would you review? Describe the records and/or data that may provide relevant information to assist in determining the next steps.
- What actions may be needed?

Case Study 2 - Additional Background

- No complaints have yet been received regarding the subject devices.
- The impact of the failures actually may lead to user electrical burns.
- All devices that have been shipped may be affected.
- The test facility was placed on the approved supplier list 13 years ago based on a relationship between the Quality Manager (who has since moved on) and the owner of the test facility.
- The most current revision level of the Supplier Quality SOP was implemented 2 years ago and the previous revision that has been obsolete is not available.
- Testing by a different facility has demonstrated that 3 out of 3 devices fail electrical safety testing.

Case Study 2 - Exercise 2

- Based on the information, should an investigation be opened?
- If so, what type of investigation would you open?
- What other information would you review? Describe the records and/or data that may provide relevant information to assist in determining the next steps.
- Should product be placed on hold?
- Is there a need to recall?