A recent newspaper story in the Boston Globe (see http://www.boston.com/business/healthcare/articles/2010/06/23/fda_to_alter_rules_on_devices/) included the following statements:

"Peter Steiger, chief executive of Optasia Medical Inc., a British company with US offices in Sudbury, said medical device makers believe a "wall of silence" has been erected at the FDA. Calls and e-mails to regulators often have not been returned, he said.

"Some of us have experienced unbelievable delay," said Steiger, whose venture-backed company is awaiting approval for software that runs on radiology workstations used to document vertebral fractures in patients with osteoporosis. "A process that is expected to take 90 days has taken 22 months in our case and we still have no decision," ...

In an interview after the session, ... [Dr. Shuren] said the devices center has been working to improve its standards, training, and decision-making ...

Thomas J. Sommer, president of the Massachusetts Medical Device Industry Council, a Boston trade group, said many device makers have complained that communications with FDA regulators have deteriorated over the past 18 months.

In a letter to Shuren last week, members of the Massachusetts congressional delegation urged the agency "to avoid unnecessary regulatory barriers that will needlessly lengthen the review and approval process," especially for small companies trying to bring new technologies to market. The letter didn't specify which barriers the lawmakers were objecting to.

In the June 23, 2010 issue of the Gray Sheet, Dr. Jeffrey Shuren is quoted as stating:

"Shuren acknowledged problems with the review process, including instances of individual reviewers' scientific priorities sometimes holding up a submission more than necessary. He said he is putting increased emphasis on reviewer training within the center and making it clear to managers that they need to take more control of their reviewers when necessary.

What does Dr. Shuren mean that "managers ... need to take more control of their reviewers when necessary?"

Dr. Shuren seems to think that the problem with the regulatory review process at CDRH is "rogue" physicians and scientists (who he collectively refers to as "reviewers"). However, the problem with the regulatory review process at CDRH is that FDA has failed to implement the March 9, 2009 Memorandum to the Heads of Executive Departments and Agencies, see http://www.whitehouse.gov/the_press_office/memorandum-for-the-heads-of-executive-departments-and-agencies-3-9-09/, that states:

"The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological
findings and conclusions. ... The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity. ... When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards. ... Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

There are far too many CDRH “managers” without the requisite scientific and technological knowledge, credentials, experience, and integrity (“managers” meaning those CDRH employees with the legal authority to make regulatory decisions on medical device submissions). While CDRH managers need little if any scientific and technological knowledge, credentials, or experience to “rubber-stamp” recommendations for device clearance and approval, these same managers are incapable of formulating science-based arguments to overturn recommendations against device clearance and approval. Furthermore, the metrics used by FDA to measure manager performance are tied to moving device submissions through the system as fast as possible. Therefore, when CDRH physicians and scientists recommend against clearance or approval, or request additional information from manufacturers, and when coercion and arm-twisting, and threats fail to change the minds of physicians and scientists, managers frequently resort to retaliation.

The Boston Globe story highlights that retaliation at FDA is spilling over into the work that FDA is required to perform on behalf of the Public. Just as the BP oil spill is destroying the environment in the Gulf of Mexico, the manager retaliation spill is destroying the environment at CDRH. In their zeal to retaliate against FDA physicians and scientists, managers at CDRH have grossly mismanaged the regulatory review of medical devices.

The real story behind the Optasia SpineAnalyzer is that CDRH managers who do not have the scientific or technological knowledge, credentials, or experience related to radiological devices, have distorted the scientific review process, have engaged in blatant retaliation, and have tried to blame the science and the scientists.

In the chronology that follows ... [NEED TO WORK ON THIS PART]

DETAILED CHRONOLOGY OF EVENTS


2. Dr. Czerska assembled a Team of 5 scientists to Review the file: Dr. Kristin Mills (Orthopedic Surgeon); Dr. Robert C. Smith (Radiologist); Mr. Joseph Jorgens (Software Engineer); and Dr. Sophie Paquerault (Medical Physicist). The Review Team unanimously
recommended that the manufacturer be sent a Request for Additional Information (i.e., “AI letter”).

3. **November 3, 2008**, Dr. Czerska officially recommends that the Agency send an AI letter to the Manufacturer. The Acting Branch Chief of the Radiological Devices Branch, Dr. David Buckles, concurs with the recommendation the same day. The AI letter identified a single deficiency related to the Indication for Use (IFU):

4. **November 17, 2008**, the manufacturer made a Supplemental submission (Supplement 1) responding to the AI letter. All members of the Review Team reviewed the response.

5. **December 8, 2008**, Dr. Czerska held a meeting with the Review Team and documented the outcome of the meeting in CTS:

6. **December 10, 2008**, the Review Team had a teleconference with the manufacturer also as documented in CTS:
7. **December 15, 2008,** Dr. Czerska recommends that the file be placed on hold pending the receipt of the additional information. The Acting Branch Chief of the Radiological Devices Branch, Dr. David Buckles, concurs with the recommendation the same day.

8. **April 10, 2009,** the manufacturer submits a Second Supplement. Dr. Czerska adds Dr. John Dawson (Statistician) to the Review Team. The Team Leader for Dr. Dawson, Dr. Gene Pennello (Statistician), also participates in review of the file. The Review team therefore now consisted of six (6) FDA expert scientists.

9. **April 21, 2009,** the Review Team met to discuss the file and an email was sent to the

10. **April 21, 2009,** Dr. Czerska sends an email to the manufacturer stating, in part:
11. April 22, 2009. Dr. Czerska sends an email to [Redacted] with details regarding the deficiencies. This email stated in part:


13. May 6, 2009. Dr. Czerska sends an email to [Redacted] informing them that there are no outstanding issues with their software documentation.

14. May 13, 2009. [Redacted] sends an email that states: “Please find attached our response to the Agency’s [Redacted]”
15. May 26, 2009, Dr. Czerska sends an email to Dr. Czerska stating: "Consulting Statistician on the organization sends an email to Gene Pennello made substantial contributions to the review."

The review memo stated in part:

16. May 26, 2009, Dr. Czerska sends an email to [redacted] with the outstanding statistical deficiencies stating: "Attached is the stat review. Please let me know if you have any questions."

17. June 5, 2009, [redacted] sends an email to Dr. Czerska stating: "Please find attached our response to the FDA statistician’s review of our prior response to the agency’s statistical queries on our equivalency study."

18. June 15, 2009, Dr. Dawson sends to Dr. Czerska his review of the [redacted] response. This review memo stated in part:
19. June 17, 2009, Dr. (sent an email to Dr. Czerska with additional comments about the many statistical and/or methodological deficiencies. Dr. [mail stated in part:

20. July 7, 2009, Dr. Robert C. Smith sends an email to !s (VP) on behalf of Dr. Czerska. This email stated in part:
21. July 7, 2009, [individual name] responds by email stating: “Thank you for your email. I will review with the team shortly and get back to you with a timeframe for addressing the deficiencies.”

22. July 20, 2009, [individual name] sends an email stating: “Please find attached our response to the agency’s most recent clinical and statistical comments on our equivalency study that we received from Dr. Smith on 7/7/09.”

23. July 22, 2009, [individual name] ends an email after reviewing the latest response:

24. July 27, 2009, Email from Dr. Smith to Dr. Czerska stating: “Let’s set up a meeting with [she can participate by phone if necessary]. Let’s document the consensus of the group and then come to a final decision.”

25. August 3, 2009, Email from [individual name] stating:

26. September 4, 2009, Email from Dr. [individual name] to Dr. Czerska (copied to the entire Review Team) stating:

27. September 4, 2009, Email from Dr. Czerska to [individual name] at [individual name] stating:
28. **September 6, 2009**, Email from Dr. Smith to Dr. Czerska and the entire Review Team stating the following:

29. **September 7, 2009**, Email from [ ] to Dr. Czerska stating:

   *Thank you for your email. I will need to consult with the relevant staff regarding the agency’s response before I can respond to your questions. I will get back to you shortly.*

30. **September 11, 2009**, Email from [ ] to Dr. Czerska stating in part:
31. **September 16, 2009**, Dr. Smith sends an email to Dr. Czerska stating:

32. **October 1, 2009**, Dr. Czerska sends an email to the entire Review Team stating:

33. **October 1, 2009**, Dr. sends an Email to Dr. Czerska stating:

34. **October 2, 2009**, Dr. Dawson sends an Email to Dr. Czerska stating:
35. **October 2, 2009.** Dr. Smith sends an Email to Dr. Czerska stating:

36. **October 9, 2009.** Email from Dr. [Redacted] to Dr. Czerska stating:

37. **October 30, 2009.** Dr. Czerska completes her final Lead Reviewer review memo, places her


This document:

- Sets forth the general policy of CDRH with respect to internal differences of opinion related to regulatory decisions;
- Explains the Center's procedure for resolving such differences of opinion; and
- Defines the roles and responsibilities of Center staff in this process.

39. **November 10, 2009.** Email from Dr. Czerska to Dr. Michael O'Hara (then Acting Branch Chief, Radiological Devices Branch) reminding Dr. O'Hara that she completed her review of the submission and that the file remains under his review. Dr. Czerska received no response.

40. **November 10, 2009.** Email from Dr. Czerska to Dr. Sharpstein (copied to Ms. Kimberly Holden, Assistant Commissioner; Dr. Shuren; and Dr. Hamburg) stating:

*Although we have been promised that two unadvertised detail positions (those of the RADB branch chief and Mr. Joshua Nippers) will be investigated, we were never informed whether the investigation took place and what were the results of the investigation. Although you have expressed confidence in Ms. Holden to investigate the Details, Ms. Holden has never gotten back to us. Furthermore, you stated that if any of us "have concerns about new specific instances of retaliation," we should let Ms. Holden know. I understand that Dr. Julian Nicholas let Ms. Holden know about a specific instance of retaliation against him that has now resulted in the termination of his appointment. It seems that Ms. Holden is unable to protect any of us from the*
retaliation of Dr. Tillman and Ms. Morris and furthermore, Ms. Holden was unable to assure that CDRH managers clear all personnel actions with her as was her charge from the Commissioners Office.

In the meantime, Dr. Shuren has made a decision to transfer RADB to OIVD. In normal circumstances this might be a welcome change, but it still does not address the fundamental underlying failure to simply hold CDRH managers accountable for misconduct. Furthermore, while this move would get us away from Dr. Tillman and Ms. Morris, we have now learned that the Branch is being transferred with the current detailers in place (i.e., Dr. O’Hara and Mr. Nippers). That does not make sense to still transfer with us some of the very same managers that have caused so many problems. Dr. O’Hara and Mr. Nippers are responsible for unbearable conditions in our everyday work. Both of them were personally appointed by Ms. Morris, and the ties with the division and office we are currently a part of will remain active. Therefore we won’t be able to show the performance we would have under proper management. It is imperative that new leadership (even if a temporary Detail) be appointed immediately upon the transfer of RADB to OIVD.

Since we have been told that this decision is final (i.e., the decision to take the current Acting Branch Chief and Mr. Nippers with us to OIVD), I just wanted to document that this decision is setting us up for failure. We need our own new leadership immediately upon the move to OIVD. The Detail should be advertised immediately. According to Ms. Holden, management can do essentially anything they want with such Details so there is no excuse not to do it right now.

41. November 11, 2009, Email from Dr. Sharfstein to Dr. Czerska stating:

Thanks for the message. I see important changes happening at CDRH -- from administrative changes to policy changes on how to address disputes and a review of the 510(k) process.

A number of issues are still under review by the OIG. In the meantime, I have confidence in the way Dr. Shuren and Kim Holden are approaching a very complex situation.

From my perspective, I would ask that everyone involved do the best job they can under the circumstances.

42. November 30, 2009, Email from Dr. Czerska to Dr. O’Hara again reminding Dr. O’Hara that she completed her review of the submission (on October 30, 2009) and that the file remains under his review. Dr. Czerska received no response.

43. December 10, 2009, Email from Dr. Czerska to Dr. Shuren stating:

We met with you in early September and we have provided to you extensive evidence of managerial wrongdoing and a pervasive hostile work environment at CDRH. Yet
no measures have been taken in any manner to protect us while endless investigations drag on for more than 1.5 years now. Clearly you recognize that there is a serious problem as you have decided to move the entire Radiology Branch out of the Office of Device Evaluation. However, in the meantime, because there is no penalty for doing so (as no manager ever seems to be held accountable), managers continue to lash out and engage in blatant retaliation because we continue to document and report their misconduct to you as well as to Drs. Hamburg and Sharfstein. These managers are allowed to run the FDA like a Mafia organization—rather than protecting whistleblowers, we are specifically and knowingly targeted for termination (e.g., Dr. Nicholas) and/or various forms of retaliation and reprisal.

For the latest act of blatant retaliation against me, yesterday, during OIVD Holiday Party, I was handed a "notice of performance deficiencies and expectations." I worked for FDA for 23 years with fully successful/exceptional performance. Yet, because I have exposed wrongdoing and totally incompetent performance of my Branch chief and other managers, they are now planning to place me on a performance improvement plan. This comes just weeks before the move to OIVD.

I have been advised by Dr. O'Hara that I should seek tutoring sessions from Mr. Joshua Nippers. Dr. O'Hara and Mr. Nippers are the very same people whose serious mismanagement of the 510(k) submission, ..., have brought to your attention. Furthermore, Mr. Nippers has been assigned to tutor me yet he is not even a member of the Radiology Branch and is not an expert in Radiology devices. Somehow, the misconduct of Mr. Nippers and Dr. O'Hara is condoned and my conduct, following the laws, rules, and regulations, is punished. Does it mean that in order to continue my work for FDA I have to be trained in coercion, mismanagement, and dishonesty? Is this the environment you wish to create and promote at CDRH?

I will treat the "notice" as an act of blatant retaliation and although I will respond to the many false and misleading statements, I will not compromise my integrity as a scientist and a physician.

44. December 21, 2009, letter from Dr. Czerska to Dr. Shuren about the above Notice stating in part:

As documented in the email chain above, I worked diligently to remind Dr. O'Hara on a consistent basis of files that awaited his sign-off.

I have consistently offered my assistance to help Dr. O'Hara move files out of the branch. Although he has not accepted my offers, I am always willing to help.

As examples, here are three submissions currently waiting for Dr. O'Hara's final decision:

...
45. **January 4, 2010**, Email from Dr. Czerska to Dr. O’Hara stating:

> At the meeting today, I completely reviewed with you my rebuttal to your December 9, 2009, Notice of Performance Deficiencies and Expectations. I did so on a point-by-point basis responding to every item in the December 9 Notice. I asked you when you will respond to my rebuttal and you told me that you will not respond. I can only interpret this to mean that you cannot (or will not) refute my rebuttal.

> You asked me to brief you on two devices:

- \( \text{I completed my review of this device submission on October 30, 2009 and you have had the submission since that time.} \)
- \( \text{I completed my review of this device submission on July 10, 2009, and you have had the submission since that time.} \)

I offered to answer any specific questions that you may have since you have had these files under review for many months now. In response, you told me that you did not have any specific questions and you told me to provide a very short verbal summary, which I did. I am disappointed that you have not yet taken the time to review these documents, and I urged you to review the Lead Reviewer Memo and the Final expert Consulting reviews as these are complicated submissions. Again, I offered to answer any specific questions that you have after you review the documents.

46. **January 4, 2009**, Email from Dr. Czerska to Ms. Holden (Assistant Commissioner0 and Dr. Shuren, forwarding the above Email sent to Dr. O’Hara, and stating:
When we met on December 23, you assured me that I would not be forced to meet Dr. O'Hara on my own. It was extremely stressful when I showed up to the meeting and neither you or anyone else from the management was there to assist and prevent any further abusive behavior by Dr. O'Hara toward me. Please see my e-mail below. As Dr. O'Hara has told me he will not respond to my rebuttal, I respectfully request that the December 9 Notice of Performance Deficiencies and Expectations be expunged. Please also be advised that I was treated in a discourteous and disrespectful manner and tone by Dr. O'Hara.

I would appreciate your help to quickly resolve this matter and prevent further escalation.

47. January 28, 2010, Email from Dr. Czerska to Dr. O'Hara again reminding Dr. O'Hara that she completed her review of the submission (on October 30, 2009) and that the file remains under his review. Dr. Czerska received no response.

48. February 4, 2010, Email from Dr. Czerska to Dr. O'Hara again reminding Dr. O'Hara that she completed her review of the submission (on October 30, 2009) and that the file remains under his review. Dr. Czerska received no response.

49. February 18, 2010, Email from Dr. Mary Pastel (Associate Director, OIVD) to Dr. Czerska regarding the file stating:

50. March 2, 2010, a meeting was scheduled to discuss the file. Dr. Smith was out sick that day and requested to call in to the meeting from home. For inexplicable reasons, Dr. Pastel refused to allow Dr. Smith to participate by phone (as documented in the Meeting Minutes, see below)

51. March 2, 2010, Meeting is held in the absence of Dr. Smith. Meeting attendees include; Dr. Czerska, Dr. Pastel, Dr. Dawson, and Dr. Mills. On March 2, 2010, Dr. Czerska sent out draft Meeting Minutes. On March 3, 2010, Dr. Pastel sent by Email an edited version of Dr. Czerska's Minutes:

3-3-10 Email from Pastel to Cz...

52. March 10, 2010, Email from Dr. Pastel stating; “Eva, please set up a meeting with the review team plus the following mandatory attendees: myself, Michael O'Hara, Robert Becker, Sahar Dawisha. I expect the meeting to take about half an hour.”
53. March 24, 2010, Email from Dr. Pastel stating: “I am so sorry that my list to you was incomplete. Don St Pierre has to be at the meeting, too. He won’t be back until the week of 10 May. Please reschedule.”

54. March 24, 2010, Email from Dr. Czerska to Mr. Joseph Jorgens, Dr. David Buckles, and Dr. Sophie Paquerault (those members of the Review team that were unable to attend the Meeting held on March 2, 2010) stating:

55. March 23, 2010, at the request of Dr. Pastel, Dr. Czerska organizes a meeting about the Optasia file to occur on May 13, 2010. Dr. Pastel specifically requested that Dr. Czerska invite Dr. Robert Becker (pathologist, OIVD) and Dr. Sahar Dawisha (internal medicine, OIVD) and that Dr. Czerska ask Dr. Becker and Dr. Dawisha.

56. May 12, 2010, at Dr. Dawisha’s request, Dr. Czerska and Dr. Smith meet for 30 minutes with Dr. Dawisha to answer her questions about the file.

57. May 13, 2010, a meeting was held to discuss the file. The meeting is attended by the following individuals: Mr. Donald St. Pierre; Dr. Mary Pastel; Dr. Ewa Czerska; Dr. Dawisha Sahar; Dr. Robert Becker; Dr. Robert C. Smith; Dr. Sophie Paquerault; and Mr.
Joseph Jorgens. Dr. David Buckles and Dr. Kristin Mills were invited to the meeting but were unable to attend.

58. **June 7, 2010.** Email from Mr. St. Pierre to Dr. Czerska copied to Dr. Pastel, Dr. Michael O’Hara, Dr. Becker, and Dr. Dawisha, that stated the following:

59. **June 8, 2010.** Email from Dr. Czerska to Mr. St. Pierre stating:

Eva, please set up a meeting with the review team plus the following mandatory attendees: myself, Michael O’Hara, Robert Becker, Sahar Dawisha. At this meeting we will discuss the expect the meeting to take about half an hour.
60. **June 8, 2010**, Dr. Czerska forwarded the above email to Dr. Shuren. Dr. Shuren never responded.

61. **June 10, 2010**, Email from Dr. Czerska to Dr. Shuren stating:

On May 20, 2010 I wrote to you concerning "continuing harassment and retaliation that many members of the Division of Radiological Devices still have to deal with." I told you that "I have tried my best to treat Mr. St. Pierre in a courteous and professional manner, despite the fact that"

"and that "most recently ... I received a nasty, unprofessional, and disrespectful response from Mr. St. Pierre after I expressed my best scientific and professional judgment regarding the regulation of CT devices." I also explained that "I cannot go back to Mr. St. Pierre, or to Dr. Gutierrez, because I am frightened to again approach them under the circumstances."

You wrote back to me on May 21, 2009 and you told me the following:
June 11, 2010, Dr. Czerska wrote to Dr. Shuren regarding mismanagement of a different file stating:

1. In an email to me dated June 10, 2010 (see below), states the following:

This latest episode of retaliation against me, in the form of a letter from Dr. Michael O’Hara entitled Notice of Performance Deficiencies and Expectations, comes shortly after I have continued (over the past 4 months) to disclose wrongdoing (by Dr. O’Hara, Ms. Morris, and Mr. Joshua Nippers) to senior management at FDA and CDRH, including Drs. Hamburg, Sharfstein, and Shuren, as well as Ms. Kimberly Holden. Please see the attached letter that fully documents the long-standing retaliation and discrimination that I have suffered from your CDRH managers. I again ask that you take immediate steps to protect me and other FDA physicians and scientists so that we can do our job to protect the public. I am looking forward to the future, when with proper management I will be able to focus solely on my job as a reviewer without checking constantly on perpetually unfinished documents, constant re-reviews and everyday battle with total lack of understanding of science and regulations [by managers] that
we may do our work our work to assure safety and effectiveness of products we evaluate.
2. [Address redacted]: *further states (in his June 10, 2010 email).*
3. In a June 9 email to , states the following:

4. In a June 9, 2010 email from states the following:
63. **June 12, 2010**, Email from Dr. Shuren to Dr. Czerska stating:

I have forwarded the allegations you made in your June 11, 2010 email below and your June 10, 2010 email sent to me at 4:42 PM to Kelly, Anderson & Associates for further investigation.

64. **June 16, 2010**, Email from Dr. Czerska to Dr. David Buckles (Acting Ombudsman, CDRH) stating:

I would very much appreciate your help with a matter involving the Center for Devices and Radiological Health (CDRH) -- Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision-Making.
my final document has remained under management review for more than 7 months."

- Mr. St. Pierre (who is the Acting Division Director for Radiological Devices in OIVD-- please note that there is no longer a Radiology Branch) met with me (and some members of the Review Team) on May 13, 2010 because Mr. St. Pierre (now my immediate supervisor) did not concur, in part or in whole, on an official document under his review. Mr. St. Pierre discussed the situation with me (and the Review team) in an attempt to resolve the disagreement, but the disagreement was not resolved.

- In accordance with Section 6.4.4, of the Center for Devices And Radiological Health (CDRH) Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision-Making, I believe that the next step was for Mr. St. Pierre is to submit an initiation memorandum and place a copy into the administrative file.

One week ago, I requested that Mr. St. Pierre use the SOP to resolve our difference of opinion, or concur with my recommendation. To date, I have not received a response from Mr. St. Pierre.

Please see below for my June 8, 2010 email to Mr. St. Pierre: ...

Your help would be greatly appreciated. Thanks.

65. June 21, 2010, Email from Dr. Buckles to Dr. Czerska stating:

Thanks for your note about your interactions with respect to the 510(k) review. If you wish, I'd be happy to discuss the matter with you further. Please feel free to stop by or to schedule a meeting with me at your convenience.

66. June 21, 2010, Email from Dr. Czerska to Dr. Buckles stating:

I would love to stop by, but unfortunately I am not well and I don't know when I will be back in person. In the meantime I am trying to work a little from home. I would therefore appreciate if you could give me your response by e-mail.
SOP and Mr. St. Pierre must submit an initiation memorandum and place a copy into the administrative file?

67. June 23, 2010, Email from Dr. Buckles to Dr. Czerska stating:

I've been doing a little research and thinking about your question, and I think the answer might have to do with how Radiology is currently structured. I don't know how things are set up since Radiology moved to OIVD. Are you a branch or a division? Do you have a designated branch chief and division director? The reason I ask is that the SOP seems to be set up around the concepts of "first-level" and "second-level" supervisors and I'm trying to figure out how things fit together so I can give you a good answer.

68. June 23, 2010, Email from Dr. Czerska to Dr. Buckles stating:

Hi Dave,
It is not that I am an expert on SOP procedure, but I already went through one in our current office, so:

- Radiology is a Division, the Division of Radiological Devices (DRAD). There is no longer any Branch Chief or Branch.
- Mr. St. Pierre is the Acting Division Director and is my immediate supervisor
- Dr. Gutierrez is Mr. St. Pierre's immediate supervisor.
- With regard to Sections 6.4.4 to 6.4.6 of the SOP (see below), Mr. St. Pierre is the "first-level" manager and Dr. Gutierrez is the "second-level" manager.

According to Section 4.7 (Definitions):

Manager. For the purposes of this SOP, the term manager will refer to any individual who has supervisory authority over another staff member. This term does not apply to line employees, such as lead reviewers, who have requested and received a consult on a particular scientific matter. The term immediate supervisor is used in this document to refer to the manager immediately above the initiator. The supervisory chain is the chain of managerial oversight beginning at the level of a given staff member and ending at the level of the Center Director. The terms next-level manager and higher-level manager are used in this document to refer to managers at progressively higher levels of the supervisory chain.

According to Sections 6.4.4 to 6.4.6:

6.4.4 If the manager and author are not able to resolve the difference of opinion through discussion, then the manager should prepare an initiation memorandum, following the guidelines described in Section 6.2.3, above. As described above, the manager should submit the initiation memorandum to his or her immediate supervisor (i.e., the second-level manager), with a copy to the CDRH.
Ombudsman. The initiation memorandum must be added to the administrative file.

6.4.5. The CDRH Ombudsman should evaluate the initiation memorandum for completeness and eligibility as described in Section 6.2.4, above, and should notify the initiator (i.e., the first-level manager) and the second-level manager of whether or not the initiation memorandum is complete and eligible no later than 10 calendar days after receipt.

6.4.6. The second-level manager may, at his or her discretion, turn to relevant resources in order to develop a thorough understanding of the issue at hand and aid in addressing it, as described in Section 6.2.5, above.

With regard to section 6.4.4, Mr. St. Pierre is the "manager" referenced and Dr. Gutierrez would be the immediate supervisor of Mr. St. Pierre. With regard to paragraph 6.4.5, Mr. St. Pierre would be the "first-level" manager and Dr. Gutierrez would be the "second-level" manager.

I hope this is helpful. I look forward to your answer to my question. Thanks

69. June 23, 2010, Email from Dr. Buckles to Dr. Czerska stating:

Thanks very much for the information, this is helpful. Given this organizational structure, since Don St. Pierre is the first-level supervisor, in the situation you describe it would be incumbent upon him to file an initiation memo per section 6.4.4 of the SOP. Please let me know if you would like for me to communicate that to Mr. St. Pierre or if you would prefer to keep our communication confidential.