Public Welfare—Design of Medical Equipment

Case No. 08-10

Facts:

Engineer A, an experienced professional engineer, is employed by MedTech, a company that manufacturers medical equipment. A key company product is respirators that are used in hospitals. Engineer B, a company colleague of Engineer A, asks Engineer A to evaluate a respirator designed by MedTech for infant use. Following his review, although not an expert on respirators, Engineer A determines that a relief valve intended to protect against overpressure being applied to the infant's lungs may have been incorrectly placed so that under certain circumstances, an infant could potentially experience dangerously high pressure levels—although no incidents have been reported. Correcting the error would involve stopping the manufacturing process for part of a week to correct problem. Engineer A brings the issue and his proposed solution to the attention of the appropriate manager, who is not an engineer, and Engineer A assumes that the matter will be taken care of immediately. However, a month later Engineer A learns from Engineer B that nothing has been done to correct the issue. Hundreds of new respirators are now on the market, and Engineer A is concerned about the increasing likelihood of a tragic event. Engineer A again urges the manager to take immediate action. When the manager indicates that the matter is still being looked into by a design team, Engineer A indicates that if prompt measures are not taken to correct the problem, he will be compelled to report the matter to an appropriate federal regulatory agency.

Question:

Was it ethical for Engineer A to indicate that if prompt measures are not taken to correct the problem, he will be compelled to report the matter to an appropriate federal regulatory agency?

References:

Section I.1.	-	*NSPE Code of Ethics:*	*Engineers, in the fulfillment of their professional duties, shall hold paramount the safety, health, and welfare of the public*
Section I.6.	-	*NSPE Code of Ethics:*	*Engineers, in the fulfillment of their professional duties, shall conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession.*
Section II.1.a.	-	*NSPE Code of Ethics:*	*If engineers' judgment is overruled under circumstances that endanger life or property, they shall notify their employer or client and such other authority as may be appropriate.*
Section II.4.	-	*NSPE Code of Ethics:*	*Engineers shall act for each employer or client as faithful agents or trustees.*

Discussion:

This case presents one of the classical ethical dilemmas faced by engineers, which is the fundamental conflict between the obligation to hold paramount the public health and safety and some another key provision of the NSPE Code of Ethics—here the obligation to act for each employer or client as "faithful agent or trustee." As is often the case with these types of situations, sometimes mitigating factors and circumstances impact upon one's understanding of this conflict (e.g., the knowledge held by the engineer, the risks involved, level of personal involvement, actions taken and not taken by individual the engineer/employer, and other factors).

The NSPE Board of Ethical Review has considered a variety of cases involving similar considerations. Among one of the earlier cases of this type was BER Case No. 76-4. In that case, the XYZ Corporation was advised by a State Pollution Control Authority that it had 60 days to apply for a permit to discharge manufacturing wastes into a receiving body of water. XYZ Corporation was also advised of the minimum standard that must be met. In an effort to convince the authority that the receiving body of water, after receiving the manufacturing wastes, would still meet established environmental standards, the corporation employed Engineer Doe to perform consulting engineering services and submit a detailed report. After completion of his studies but before completion of any written report, Engineer Doe concluded that the discharge from the plant would lower the quality of the receiving body of water below established standards. He further concluded that corrective action would be very costly. Engineer Doe verbally advised the XYZ Corporation of his findings. Subsequently, the corporation terminated the contract with Engineer Doe with full payment for services performed and instructed Engineer Doe not to render a written report to the corporation. Thereafter, Engineer Doe learned that the authority had called a public hearing and that the XYZ Corporation had presented data to support its view that the present discharge met minimum standards. In concluding that Engineer Doe had an ethical obligation to report his findings to the authority upon learning of the hearing, the Board concluded that upon learning of the hearing, Engineer Doe was squarely confronted with his obligations to the public concerning its safety, health, and welfare. Said the Board, "The NSPE Code requires that his duty to the public to be paramount. In this case, it is presumed that a failure to meet the minimum standards established by law is detrimental to the public health and safety."

In the present case, unlike the facts in BER Case No. 76-4, Engineer A is not faced with a scheduled public hearing at which he believed he had an obligation to correctly report information that was within his personal knowledge and for which the failure to report could result in a direct and demonstrable harm to the public. In contrast, Engineer A is faced with a situation where, in his personal opinion, a serious risk may exist and the failure to adequately address the risk could result in tragic consequences. But unlike the facts and circumstances involved in BER Case No. 76-4, Engineer A was not personally involved in the engineering decision-making process and did not have any particular expertise in the technical area involved. Although an experienced professional engineer and by all indications a well-intended individual acting in good faith, as is sometimes the case in matters of this type, Engineer A may not be in possession of all of the necessary information to make an informed judgment. Engineer A's statement—which essentially amounted to a threat to the manager—was not a reasonable or ethical response to the circumstances in question. The Board believes that there were more reasonable and appropriate internal mechanisms within MedTech that could and should have been explored by Engineer A before threatening to report the matter to governmental authorities. While Engineer A may have had legitimate concerns, those concerns should be balanced with other legitimate factors, including the objective consideration of the concerns, the level of potential risk involved, and a review of appropriate "next steps" to address the issue.

This conclusion does not diminish, in any way, Engineer A's concern regarding his obligation to hold paramount public safety. As the facts indicate, Engineer A has properly raised the public safety issue, and it appears that MedTech was in the process of investigating the matter and determining whether a basis exists for those concerned. That investigation was presumably being conducted by individuals competent in the design and manufacturing of the respirator device in question.

If after making additional inquiries, Engineer A determines that no meaningful actions are being taken to address the issue, Engineer A should explore internal mechanisms within MedTech to seek further recourse regarding this issue. Only if such efforts do not produce satisfactory results should Engineer A consider exploring external avenue for action.

Conclusion:

It was not ethical for Engineer A to indicate that if prompt measures are not taken to correct the problem, he will be compelled to report the matter to an appropriate federal regulatory agency. Instead, Engineer A should have sought to determine what internal steps are being taken to address the concerns. However, if after making additional inquiries, Engineer A determined that no meaningful action was being taken to address the issue, Engineer A should have explored internal mechanisms within MedTech to seek further recourse regarding this issue. Only if such efforts did not produce satisfactory results should Engineer A consider exploring external avenues for action.

NOTE: The NSPE Board of Ethical Review considers ethical cases involving either real or hypothetical matters submitted to it from NSPE members, other engineers, public officials, and members of the public. The BER reviews each case in the context of the NSPE Code and earlier BER opinions. The facts contained in each case do not necessarily represent all of the pertinent facts submitted to or reviewed by the BER.

Each opinion is intended as guidance to individual practicing engineers, students, and the public. In regard to the question of application of the NSPE Code to engineering organizations (e.g., corporations, partnerships, sole proprietorships, government agencies, and university engineering departments), the specific business form or type should not negate nor detract from the conformance of individuals to the NSPE Code. The NSPE Code deals with professional services, which must be performed by real persons. Real persons in turn establish and implement policies within business structures.

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