

FAX

Frank J. Trembulak

Geisinger

Health System

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Date: 7/18/07
To: Mr. Michael Lesar
Fax: 301-415-5144

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Executive Office
M.C. 22-01
100 North Academy Ave.
Danville, PA 17822-2201
570-271-6467 Tel
570-271-7498 Fax

Frank J. Trembulak
Executive Vice President
Chief Operating Officer

GEISINGER HEALTH SYSTEM

July 18, 2007

Mr. Michael T. Lesar
Chief, Rulemaking, Directives and Editing Branch
Division of Administrative Services
Office of Administration
Washington DC 20555-0001

Subject: Comment submission to Federal Register Vol 72, No. 116, June 18, 2007, and subsequent Federal Register entries on June 25, July 2, and July 9, 2007 entitled:

“Commonwealth of Pennsylvania: Draft NRC Staff Assessment of a Proposed Agreement Between the NRC and Commonwealth of Pennsylvania”

Dear Mr. Lesar:

Geisinger Health System (“Geisinger”)¹ is an integrated health service organization offering a wide range of healthcare services in 42 of Pennsylvania’s 67 counties, with a significant presence in central and northeastern Pennsylvania outside Pittsburgh and Philadelphia. Geisinger is a physician-led organization whose primary mission is managing care and enhancing health of the population served. To this end, there are three complementary components of Geisinger’s integrated health service organization: (1) a multi-specialty physician group practice comprised of 669 employed physicians; (2) managed care/health benefits insurance companies (including one of the largest rural managed care companies in the country) with approximately 205,884 members; and (3) an array of healthcare provider facilities including 55 medical groups locations comprised of 36 primary care sites and 19 specialty care sites, a large tertiary/quaternary care teaching hospital, two secondary acute care hospitals, and a drug and alcohol rehabilitation facility.

Geisinger also conducts a large medical education program, and research endeavors in the clinical, basic science and translational areas. Geisinger is a broad scope Nuclear Regulatory Commission (“NRC”) licensee and has an excellent relationship with the NRC. The attached comments are submitted for your consideration.

¹ Throughout this document the terms “Geisinger Health System” or “Geisinger” shall refer to the entire healthcare system comprised of the Geisinger Health System Foundation (the “Foundation”) as parent of all Geisinger’s related and subsidiary corporate entities.

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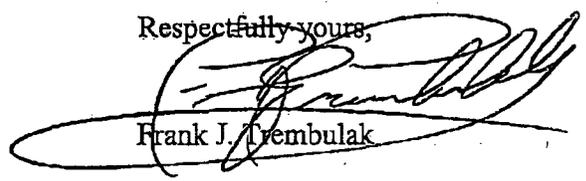
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concerning the Commonwealth of Pennsylvania (the "Commonwealth") assuming the NRC's regulatory authority for radioactive materials as an "Agreement State."

We would be pleased to provide clarification, or further comment on this matter and offer the expertise of Ms. Catherine M Anderko, Geisinger's Director for System Medical Health Physics and Radiation Safety Officer.

We appreciate the opportunity to present these comments and kindly request that they receive due consideration.

Respectfully yours,

A handwritten signature in black ink, appearing to read "Frank J. Trembulak", is written over a horizontal line. The signature is stylized and somewhat cursive.

Frank J. Trembulak

Enclosure

cc: C. Anderko

Geisinger Health System
Comments Concerning the Proposed Agreement Between the
Nuclear Regulatory Commission and the Commonwealth of Pennsylvania

Introduction:

The Commonwealth of Pennsylvania ("Commonwealth") has requested that the Nuclear Regulatory Commission ("NRC") cede and that the Commonwealth assume portions of its regulatory authority. The legal basis for this request is contained in section 274 of the Atomic Energy Act of 1954.

Geisinger is concerned that the Commonwealth does not have the same expertise and track record as the NRC in working as a collaborative partner with licensees to mutually assure radiological health and safety. The Commonwealth is no doubt concerned with the health and safety of its citizens; however, Geisinger's experience with the Commonwealth on similar matters is that the Commonwealth takes a more punitive approach and is inclined to levy substantial sanctions rather than work cooperatively with licensees to take corrective actions to prevent future violations. Geisinger's comments focus on three (3) main themes:

1. Self-identified violations, enforcement actions, and deliberate misconduct.
2. Compatibility with NRC; Commonwealth staff qualifications.
3. Risk-based approach to inspections.

Self-Identified Violations, Enforcement Action, and Deliberate Misconduct:

A licensee, who discovers a violation, corrects it and voluntarily reports it to the NRC, will receive favorable consideration relative to issued penalties and sanctions. The NRC has published documentation (IN 90-01 and others) which addresses the management of self-identified violations, concluding that due credit be effected to the licensee in these cases and speaking to the unproductive nature of issuance of large civil penalties. The NRC has a reputation for working in accord with licensees to assure resolution of problems, developing a working collegial relationship with licensees to foster mutual cooperation in the provision of superior quality radiological services, and approving corrective action plans that are affective and long lasting. We have reviewed published articles that demonstrate this mantra (ORS, Feb 2006, Miller, King et al.), and have had our own personal experiences in this regard. We have also reviewed innumerable published articles which demonstrate the NRC's commitment to the proper administration of 10 CFR 30.10, addressing deliberate misconduct by individuals, and making individuals personally responsible and subject to enforcement action if engaged in intentional acts or omissions in violation of the code.

It is Geisinger's experience that the Commonwealth does not practice the same regulatory philosophy. The Commonwealth approach is to penalize and prosecute a licensee rather work in unison with a licensee to find constructive solutions to issues that are discovered by the licensee and self-identified to the Commonwealth. Regulators who prefer to sanction first and not consider good faith self-reporting and exhaustive corrective efforts of licensees, are not concerned with the public good and ensuring superior quality radiological services, and certainly are not promoting positive working relationships with licensees. Geisinger attests to these statements as evidenced by a 2005-2006 case of self-identified and self-reported deliberate misconduct by a rogue employee at one of Geisinger's facilities, which resulted in the Commonwealth issuing a proposed four million dollar civil penalty. This proposed penalty was issued despite the immediate and exhaustive corrective action plan that Geisinger instituted before the Commonwealth even became involved in the case. It is important to note that Commonwealth inspectors had regularly inspected the subject quality control records and associated equipment, and did not uncover the purposeful misconduct of this employee. It was a Geisinger Health Physicist who found the irregularities in the quality control records and initiated the appropriate corrective actions. In the spirit of full disclosure and compliance, Geisinger voluntarily reported

the problem to the Commonwealth and to the FDA within 24 hours of discovery. The Commonwealth did not interact with Geisinger's Radiation Safety Officer ("RSO"), did not inspect the radiation safety program, and never considered 10 CFR 30.10 before judging on their own that the licensee was responsible for the situation, and proposed the enormous unprecedented fine. The basis for the Commonwealth-issued violations and fines were based on FDA regulations and not their own. The FDA, following a thorough investigation of the situation, issued NO violations against Geisinger, and in fact applauded the immediate and comprehensive action plan taken by us. The FDA initiated criminal charges against the rogue employee who was responsible for the deliberate misconduct. We would also note that the Commonwealth's performance in this case was called out to the highest levels of the respective Commonwealth agency and received no conciliation. The Commonwealth was not interested in the facts and mitigating circumstances of the case, but rather the opportunity to levy a significant fine.

Before the Agreement between the NRC and the Commonwealth is approved and finalized, we believe it is imperative that language be added to the Legal Agreement to assure that the Commonwealth exercises the same approach to self-identified violations that is displayed by the NRC. We urge the NRC to require the Commonwealth to have structured written guidance on how to respond to cases of deliberate misconduct. The underlying philosophy must be prescriptive against civil penalty and 100% related to achieving common goals, that is, protection of the public health and safety. The Federal Register publication of June 18, 2007 Vol 72 No. 116 states that "the law will provide the Commonwealth the authority to.....issue orders, enforce compliance, use sanctions, impose civil penalty, and suspend or revoke licenses". We strongly recommend that the Legal Agreement address control mechanisms and limitations to the deployment of the Commonwealth's power over licensees. FR Vol 72, No. 116 also states that "the Commonwealth has adopted procedures to assure fair and impartial treatment of licensees using ethical conduct". As we have not routinely observed this behavior with the Commonwealth, we are requesting that detailed language describing this assurance be incorporated into the Legal Agreement to protect licensees against excessive enforcement action.

Compatibility with NRC: Commonwealth Staff Qualifications

We are concerned that the Commonwealth and the NRC staff do not have equivalent qualifications, training, and experience. The NRC inspectors are typically educated in Health Physics and experienced radiation safety professionals, the same has not been observed with Commonwealth field inspectors. While there may be some Commonwealth management staff that are Certified Health Physicists ("CHP") and experienced in operational radiation safety programs, they do not typically interact directly with licensees. Field inspectors usually have no formal Health Physics education, have not worked professionally as Health Physicists, and therefore have limited understanding of radiation safety operations. They are however, allowed to self interpret code and make decisions in the field about what they perceive as violations. Having medical facilities that cross two Commonwealth regions, we have seen Commonwealth inspectors from different regional offices interpret and enforce regulatory code in different ways.

We recommend that there needs to be a consistent centralized State-wide approach to interpretation and enforcement of Commonwealth regulations regardless of region. We further recommend that the qualifications for Commonwealth field inspectors should be equivalent to that of the NRC inspectors.

Risk-Based Approach to Inspections

The NRC has a well documented risk-based approach to inspections, focusing on critical higher risk program elements rather than lower risk areas which pose no significant risk to public health and safety. There is an assessment of the whole program with consideration given to novel approaches to problem solving, not simply a focus on finding any and all violations. By using a risk-based approach an inspector is focused on seeking to address violations that directly impact on the provision of quality radiological services.

The Commonwealth's inspection approach is not risk and performance based, but is geared towards finding as many violations as possible regardless of their significance. As part of the agreement between the NRC and the Commonwealth, it is imperative that there be a provision which requires the Commonwealth to conduct risk informed-performance based inspections. Additionally, the NRC should establish a monitoring system overseeing the Commonwealth's performance in all respects of this delegated authority.

July 18, 2007