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RECORD #327

TITLE: HEALTH PHYSICS POSITION: CLARIFICATION OF REPORTING REQUIREMENTS OF
10 CFR PART 21 CONCERNING VENDOR SUPPLIED HEALTH PHYSICS TECHNICIANS

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SUBJECT: HEALTH PHYSICS POSITION-CLARIFICATION OF REPORTING
REQUIREMENTS OF 10 CFR PART 21 CONCERNING VENDOR
SUPPLIED HEALTH PHYSICS TECHNICIANS

The enclosed subject position is issued in response to several licensee and regional questions identified during a counterpart meeting concerning the handling of contractor health physics technicians under 10 CFR Part 21. The Vendor Inspection Branch and the Office of the General Counsel concur.

If you have any questions on this position, please contact Dan Carter at (301) 504-1848 or Jim Wigginton at (301) 504-1059.

Original signed by LeMoine J. Cunningham

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Enclosure: As stated

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Health Physics Position
Clarification of Reporting Requirements of
10 CFR Part 21 Concerning Vendor Supplied
Health Physics Technicians

10 CFR 21.3 includes the following definitions of "basic component," "defect," "substantial safety hazard," and "deviation:"

Basic component, ... means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. Also, in all cases, "basic component" includes... consulting services (emphasis added)...whether these services are performed by the component supplier or others.

Defect means a deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard.

Deviation means a departure from the technical requirements included in a procurement document

Substantial Safety Hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, ...

Further, NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) For Reporting of Defects and Noncompliance," Rev. 1, defines criteria to be used for determining a "major reduction in the degree of protection provided to public health and safety." (Note that the term "public health and safety" includes both members of the public and licensee workers/employees.) These criteria, clarified and updated to be consistent with the new Part 20 (§§20.1001-20.2401), are as follows:

- * Exposure to an individual in a restricted area in excess of 0.25 Sv (25 rem), (five times the annual total effective dose equivalent limit)
- * Exposure to an individual in an unrestricted area to more than 5 mSv (0.5 rem) in a year (five times the annual total effective dose equivalent limit)

According to these definitions, under 10 CFR Part 21 a report to the Commission is required if a worker could receive an occupational dose of 0.25 Sv (25 rem) or more and/or a member of the public could receive 5 mSv (0.5 rem) or more due to a defective basic component.

On the basis of the definitions in the regulations and clarification given in NUREG-0302, contractor-supplied health physics technicians (HPTs) are included under the definition of "basic components" under Part 21 if, due to a defect (deficiency), they could create a substantial safety hazard. An HPT could be considered deficient if the technician is unqualified (possesses insufficient knowledge, training or experience) for an assigned task, or if the technician is impaired (e.g. under the influence of alcohol or drugs).

Examples of possible situations when a deficient contract HPT providing inadequate job coverage (e.g., in actual or potential very high radiation areas) could create a substantial safety hazard to plant personnel would include:

- * Spent fuel transfer operations
- * Removal of shielding (shield plugs)
- * Transversing incore probe (TIP) operations
- * Work activities on systems potentially containing irradiated components or equipment (e.g., the spent fuel pool)

The following is an example scenario in which a licensee would be expected to make a report of "defect" under Part 21:

A contract HPT is responsible for covering work in the upper drywell region of a boiling water reactor while the shuffling of fuel is in progress. In discussions with the technician, the licensee questions what actions should be taken by the HPT in the event that a spent fuel (SF) bundle is dropped across the reactor pressure vessel above an unshielded portion of the drywell. On the basis of the contract HPT's response, the licensee determines that the HPT is unaware of both the special hazards (intense high radiation fields) associated with such an incident and any special actions that must be taken to mitigate the consequence of a dropped SF assembly (e.g., protect workers in the drywell).

The technician's lack of knowledge (i.e., not being fully qualified to provide adequate job coverage and to effect timely evacuation of the affected area) to protect worker safety in the event of dropping a SF bundle is an example of when a "defect" could cause a "substantial safety hazard."

The responsibility for reporting this type of deficiency under 10 CFR Part 21 would be held by either the contract HPT supplier or the licensee, depending on who invoked Part 21. If a licensee invoked Part 21 in the procurement document by requesting technicians be ANSI/ANS senior technicians capable of performing safety-related services (i.e., services that if not performed properly, could create a substantial safety hazard), then the supplier would be required to make the report of a "defect" to the NRC. If, on the other hand, the technician services were obtained on a commercial grade basis and the licensee subsequently certified, "dedicated," the technician (i.e., tested and certified the technician's qualifications to perform safety-related services), then the licensee would be required to make the report of "defect" to the Commission as required by 10 CFR Part 21.

However, when the supplier is required to report the "defect" and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists (e.g., does not have the resources or access to information required to make the determination), the supplier must inform the purchaser or affected licensee within five working days of this determination so that the licensee may evaluate the deviation or failure to comply, pursuant to §21.21(a). In this scenario, the licensee would be responsible for reporting the defect.

The following is an example of a situation when a supplier would have to notify a licensee that one of its technicians is defective and make a Part 21 report to the NRC:

A licensee purchased the services of several HP technicians from a supplier. The contract technicians are to be used to provide job coverage for maintenance work in high and very high radiation areas. The procurement document stated that the technicians be fully ANSI qualified senior technicians experienced with working in and around high/very high radiation areas.

Subsequent to the commencement of the contract technicians' work coverage, the supplier determines that one of the technicians falsified her/his resume. The technician was found to have no experience working in high/very high radiation areas and, further, was not a fully qualified senior technician.

In this case, the supplier would then be required to notify the licensee of this defect and the supplier would have to make a Part 21 report to the NRC. The Part 21 report would be required based on the nature of the work potentially causing a substantial safety hazard (i.e., work in a very high radiation area where, if a technician did not properly monitor work activities, personnel could have received an exposure of greater than 0.25 Sv (25 rem.)

If, in the above example, the licensee had not stated in the procurement document that the technicians be fully ANSI qualified senior technicians then they would have been purchased as "commercial grade" versus "basic components." If the licensee performed a dedication of the technicians by interviewing and testing, and permitted them to perform work in high/very high radiation areas, and subsequently determined a technician is deficient then the licensee would be required to make the Part 21 report to the NRC of a "defect" to a "basic component."

A licensee could fulfill its reporting requirements of a "defect" as required in 10 CFR Part 21 under 10 CFR 50.73 by issuing a license event report (LER) or by submitting a report under 10 CFR 50.72, as long as all the information required under 10 CFR Part 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," is included. From discussions with representatives of the Office of the General Counsel the names of the contracting entity should be used in lieu of an individual's name in any Part 21 report.