



Oklahoma City Campus-Health Sciences Center

OFFICE OF THE PROVOST

September 21, 1989

Linda L. Kasner, Health Physicist Nuclear Materials Inspection Section U.S. Nuclear Regulatory Commission Region 1V 611 Ryan Plaza Drive, Suite 1000 Arlington, TX 76011

Dear Ms. Kasner:

Pursuant to your request, attached is a copy of the audit report completed by Mr. Thomas L. Pitchford.

The NRC audit and enforcement conference, Mr. Pitchford's report, and an internal review of our activities have led to positive changes in the management of our Radiation Safety Program and the Nuclear Pharmacy.

Sincerely, Ihomas K.

Thomas R. Godkins Assistant to the Provost for Administrative Affairs

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Attachment

copy to: Clayton Rich, M.D., Provost Bhagwat Ahluwahlia, Ph.D., Radiation Safety Officer Eugene Patterson, Ph.D., Chair, Radiation Safety Committee

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428 North Cedar Lake Drive Columbia, MO 65203

August 16, 1989

Clayton Rich, M.D. Provost University of Oklahoma 1000 Stanton L. Young Blvd. Oklahoma City, OK 73190

Dear Dr. Rich:

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Thank you for inviting me to your campus to perform an audit of the Radiation Safety Program at the Health Science Center. The exceptionally warm welcome and the courtesies extended by your staff, especially Tom Godkins and Dr. Wally, made the visit both very pleasant and efficient.

The agenda that had been prepared was excellent in that it provided opportunities to discuss the program with each of the key personnel. These frank discussions presented a clear and objective picture of the radiation safety program. A fairly comprehensive review of my findings was presented at the exit briefing, again with your principal staff members present to hear and to discuss the material presented. Individuals present for the exit briefing included Thomas R. Godkins, Assistant to the Provost for Administrative Affairs; Bhagwat Ahluwalia, Ph.D., Radiation Safety Officer; Eugene Patterson, M.D., Chairman Radiation Safety Committee; Victor A. Yanchick, Ph.D., Dean, College of Pharmacy; Stanley Mills, Ph.D., Director of Pharmacy; O. Ray Kling, Assistant Vice Provost for Research Administration; and Joel Hart, FACHE, Administrator, Oklahoma Memorial Hospital.

My audit of your program, conducted during the period of 9 - 11 August 1989 resulted in three principal findings:

- 1. The Radiation Safety Office is clearly understaffed.
- 2. There is poor communications and a lack of cooperation between the Nuclear Pharmacy and the Radiation Safety Office.
- Recent serious errors in the Nuclear Pharmacy Program indicate a need for an internal quality assurance (QA) program.

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I will now provide specific comments about various aspects of the Radiation Safety Program as was presented at the exit interview and will follow the general format outlined in your letter dated July 28, 1989.

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Management of the Radiation Safety Program by the Institution, the Radiation Safety Officer and the Radiation Safety Committee.

The organizational structure is appropriate with the Radiation Safety Officer (RSO) reporting to the Provost. Thomas Godkins provided a clear and accurate overview of the entire program upon my arrival, indicating the awareness and interest of the Provost's office. The RSO has been identified on the U.S. Nuclear Regulatory Commission (NRC) licenses as is required. The RSO's credentials are appropriate, and his experience appears to qualify him fully for the position. The membership of the Radiation Safety Committee meets NRC specifications. I was impressed with the interest and awareness, as well as the knowledge and credentials, of the Committee's members. The Committee members do understand their responsibilities and appear to review thoroughly all information presented. The Committee demands prompt notification of changes that may affect policies or procedures and properly insists on being a part of any NRC license amendment or renewal process.

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Management of the Radiation Safety Office including a review of the present management plan, the role and function of the Radiation Safety Officer, personnel requirements and adequacy of equipment, space and funding.

SCOPE. The program's scope presents many varied responsibilities for the RSO. The Oklahoma University Health Science Center includes an extensive and dynamic Nuclear Pharmacy Program, which includes an extensive commercial enterprise as well as research and teaching workloads. The Oklahoma Medical Center includes both Childrens and Memorial hospitals. Each has an active Nuclear Medicine department, and Memorial has a progressive Radiation Therapy department. Clinical practice and ongoing research are being conducted in each medical facility. The RSO also provides radiation protection services to the Oklahoma Medical Research Foundation. In addition, he is responsible for an unusual and extensive radioactive waste program. The scope of the program is impressive. The role of the RSO is to provide radiation protection services and ensure compliance with all rules and regulations within each of these organizations.

STAFFING. Staffing for the Radiation Safety Office includes an RSO (0.75 FTE), one technician (1 FTE), and two students (each 0.5 FTE) to perform the professional work.

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One secretary provides the administrative support. I was impressed with the efficiency and sense of urgency that each employee expressed. However, the staff is clearly inadequate to cover all the responsibilities assigned. Although the staff members are working to capacity, the records do reveal flaws, such as being incomplete and posting not up-to-date. A few errors were noted, surprisingly few considering the amount of record keeping involved. A copy of a staffing guide prepared by Allen Brodsky, Ph.D., is attached to this report in which he also outlines his experience in medical facilities and at the NRC and other credentials that make him a competent and respected authority in this field, so I will not repeat them. He provides calculations for determining the proper staffing of a radiation safety office within medical and research organizations such as yours.

As a minimum, I recommend hiring a well-qualified health physicist with academic training to at least a master's degree and several years' experience. Certification by the American Board of Health Physics would be desirable, but if that criteria cannot be met, then I recommend identifying a person eligible and willing to take the examination. That person would perform much of the work now being done by Dr. Ahluwalia. He could assist in audits of various organizations, prepare correspondence, teach, and assist with other timeconsuming tasks. The opportunity for professional discussions within the office would be invaluable. One full-time, trained, and qualified health physics technician is needed to perform many of the required tasks, such as instrument calibration, laboratory surveys, and some record keeping. A clerk could provide needed additional administrative assistance. (See related discussions below.)

SPACE. The space available for the office is not adequate to meet even present requirements. For example, space limitations require that much of the radioactive material processed by the office be left in the hallway outside the office and that, as specified by the NRC, it be kept under surveillance, in this case by the secretary, while portions of the material are processed in the lab. The lab area is too small to permit significant radioactivity being present at one time, such as determining the activity of incoming ¹⁹²Ir, so it must be taken to another location to be measured. Althc agh a proportional counter is available, there is not sufficient space to set up the equipment. A small portion of the already small lab is declared to be an unrestricted area, free of contamination, to provide the technician with minimal administrative workspace. If the staff is increased, as is strongly recommended, the space will need to be increased to about double the present size.

The space available for radioactive waste is similarly inadequate and is discussed later. The radium safe in the Radiation Therapy department does not provide adequate security Clayton Rich, M.D. Page 4 August 16, 1989

nor is there adequate space to work. The safe is located in a back corner of a small, crowded machine shop in the department. More people than necessary have access to the safe. Newly acquired radium has been placed on the floor near the safe with lead shielding placed around and on top of it. The need for security is clear from reading NRC reports of stolen radiopharmaceuticals, even a "Mo/" Tc generator. As reported, a man stole solid sources and sewed them into a bed where his young son slept when he visited his father. The man apparently attempted to kill his son in order to hurt the divorced mother. The NRC reports of incidents and accidents that have been investigated provide a sense of urgency to ensure adequate security.

RECORDS. Records are surprisingly complete and well maintained considering the staff that is available. However, many of the records are not of the desired quality. Many are handwritten and difficult to read; some are incomplete. Dr. Ahluwalia was able to complete all the details, but records must be complete, legible, and able to stand on their own. The situation could be improved by typing more records or by using the computer to generate more reports. I don't need to comment further about this since the RSO is well aware of the situation and is working in the right direction. His records of incoming material appeared to be complete and were very easy to read since they were computer generated and printed on a good printer. Summaries of the data were easily prepared. Similar efforts, however, must be made with the incineration records to show clearly how much activity has been incinerated, what has been released to the atmosphere, its concentration averaged over a period not greater than one year, and to illustrate ALARA efforts. Time must be taken to review records and correspondence to find and correct errors. The Radiation Safety Office must establish a QA program to ensure completeness and accuracy of records. Increasing the staff should resolve these problems.

CVERALL. Overall the Radiation Safety Program is a good one. The documentation indicating that legal requirements have been met is generally good, and the Radiation Safety Committee seems excellent. Members did complain about not knowing about the recent NRC license renewal. They must be involved at the beginning of and throughout the process. Their interest is an outstanding trait. At least equal concern must be expressed when license violations occur and vigorous efforts made to provide the necessary oversight to correct existing deficiencies and prevent similar situations.

An evaluation of the consulting time used by Dr. Ahluwalia may be appropriate since I was told that he spends excessive time consulting. A cursory review of his records revealed that he used only a small fraction of the allotted time permitted by the University for consulting. Although, this is somewhat outside the purpose of this audit and did not appear to be a problem, it may be an item for management review.

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Management of the Nuclear Pharmacy including a review of the receiving procedures for pharmaceuticals, safety practices and procedures for distribution and waste management.

I spent an hour discussing the Nuclear Pharmacy with Dean Yanchick, Ph.D. and Stanley Mills, Ph.D. Dr. Mills then took about an hour to show me the Nuclear Pharmacy. I was impressed with the dynamic and extensive services they provide. It is unfortunate that several license violations occurred recently and that they were so serious. The cause may be insufficient time to perform the necessary oversight through QA checks. As suggested, the addition of a laboratory manager may solve the problem, but I could not evaluate the workload in the pharmacy. I suggest that consideration be given to justifying the need for such a position, and if it is deemed appropriate, the auditional position could then be There is a need immediately to have a quality control check to ensure no filled. erroneous pharmaceutical preparations or erroneously labelled materials are shipped. The lack of sufficient communication between the Nuclear Pharmacy and the RSO must be overcome to ensure that the RSO is called upon to review all changes to procedures. Such a review may, for example, have discovered that the hoods used for teaching and research did not have charcoal traps before they were put into service with greater iodine activity. Likewise, for capsule production not authorized by the NRC license. There is no guarantee that a second evaluation will find all errors, but a review by an outside party with a regulatory perspective is valuable.

I noted that the manifest form used does not have the certificate required by DOT in 49 CFR 172.204, thus the manifest does not comply with DOT regulations. Any package used to transport radioactive material must be tested to ensure the package will meet the conditions that could be encountered in a transportation accident. A record must be maintained that the tests have been done either by the manufacturer or, if not available, by the user prior to use. Such documentation is not available for the ammo boxes (considered to be DOT 7A containers) used to package the radioactive material.

Incoming radioactive material received after duty hours is deposited in a safe on the enclosed and locked loading platform outside the Nuclear Pharmacy. The drivers have keys to get into the platform to deposit the material in the safe. Unfortunately, they also have access to any radioactive material within the safe. No records are available of the time of delivery or wnether a licensee representative visually inspects the packages. Records are apparently not maintained for those packages delivered on weekends to ensure that they have been checked for external radiation levels and contamination within the time limits specified in 10 CFR 20. I recommend that the keys be collected from the

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drivers and that the Campus Security Personnel be involved in the receipt of material delivered after duty hours. They could visually inspect a package and log the time of delivery and condition of the package. Again, involving the security personnel would considerably reduce the likelihood of theft of radioactive material as has occurred in other organizations. Written procedures for such action currently exist for other incoming radionuclides. It was mentioned that SYNCOR has taken much of the radiopharmaceutical business that had been envisioned at the time of the development of the Nuclear Pharmacy. It is unfortunate but a commercial concern is in business to maximize profits and hence will seek the most profitable business and avoid the less profitable. They will not have the teaching and research obligations of the University and so there is no fair competition. The funds needed for teaching and research must be made available from the State to the University.

Policies and procedures of the Radiation Safety Committee.

The Radiation Safety Committee is composed of highly experienced individuals and appears to be an exceptional committee. The Chairman was completely informed of activities involving radioactive material and other sources of radiation. He and others are knowledgeable of the requirements of the Federal, State and University regulations and seemed to express a sincere concern for ensuring that doses are maintained ALARA. The most difficult problem facing the Committee seems to be ensuring rapid, complete and helpful communications between the Nuclear Pharmacy and the RSO. The situation does not appear to be beyond repair since all parties seem to interested in complying with the regulations, but an effort to change will be necessary. If the Chairman does not resolve that issue, then management will need to direct appropriate action. Communications should be in writing to provide a clear and accurate record of activities. That by itself should help to resolve the problem.

 Adherence to licensed conditions and required record keeping for the six licenses under the control of the Radiation Safety Officer.

No deviations from the regulatory requirements are permitted; compliance must be absolute. In fact, ALARA requires us to go beyond the stated requirements related to radiation exposures. It appears that all key personnel have copies of the NRC licenses and regulations that apply to their responsibilities. Each individual should know the license conditions that apply to his area of interest. Periodic review is necessary. The RSO must know all conditions for all licenses. Adherence to all conditions and regulations is enhanced by review by several staff members with different perspectives, e.g., the Clayton Rich, M.D. Page 7 August 16, 1989

pharmacy perspective and the RSO perspective. Since an individual may miss some important item, a redundant check will reduce the possibility of error. This relates directly to the need for another fully qualified health physicist in the Radiation Safety Office to take much of the workload from Dr. Ahluwalia, to be a check on his activities, to assist with communications, to ensure a redundant check on license conditions, and to ensure completeness and accuracy of records that are maintained. Compliance seems to be well documented in most cases. The few areas that need some effort have been noted above.

 Adequacy of space, in terms of quality and quantity, for storage and waste management.

The quality of office space is superb; the quantity is inadequate. It needs to be increased by 50% to meet the current staffing level and by 100% to meet the minimal staffing increase recommended. The space for waste management is inadequate as far as quantity and especially quality are concerned. Although the quantity of space is adequate for current needs, it may not meet the needs of 1991 to 1993 when local storage may be required. If the Host State (Nebraska) for your compact does not have a Low-Level Radioactive Waste Site available by 1993, you may need to store for a longer period of time. Fifty-five gallon drums of waste are hoisted over a balcony and lowered to a basement below ground level. The process is extremely time consuming and presents a safety problem with the possibility of dropping a drum when it is being lowered and placed in storage or being lifted to take it out of storage. Moreover, the basement is damp from rain water seepage. Evidence was observed in the cardboard boxes that had been wet and then crushed by the weight of material above. The drums will rust and will not be suitable for shipping or for continued storage. The possibility of radioactive contamination must be reduced. As a minimum, the barrels and boxes should be put on pallets to keep them off the wet floor. A better solution would identify a more suitable space that would permit rapid and easy unloading from a truck and then storage in a dry location, by category of waste. Removal by category would then also be expedited. It would be desirable to isolate the waste in an area, on the campus, where the population density is low. You presently have appropriate techniques available to reduce the volume of waste by holding it for decay and releasing it as unregulated, incinerating what NRC permits, by disposing what is permitted via the sanitary sewage system, and by compacting what must be shipped. I recommend providing a storage facility that will provide easy access, available room for segregating various categories of waste, and an environment conducive to long-term storage.

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Again, I thank you for the opportunity to review your program. The time available could not have been used more efficient thanks to the frank, succinct conversations with key personnel. Dr. Ahluwalia was available at all times and effectively used his staff to provide written correspondence from the files as requested, to explain computer generatedreports, and to demonstrate for me the procedures they follow in complying with regulations. I was able to see each record requested and visit each site desired without delay. I express my appreciation to all your staff members that provided information to help me quickly see an accurate perspective of your radiation safety program.

Sincerely,

Inornas Z. Fitchford

Thomas L. Pitchford, Certified, ABHP

2 Attachments: Paper by Allen Brodsky, Ph.D. Curriculum Vitae of Thomas Lew Pitchford

HOW DO WE DETERMINE STAFFING REQUIREMENTS FOR MEDICAL PHYSICS AND ENGINEERING PROGRAMS?*

by

Allen Brodsky ALLEN B CONSULTANTS, INC. 16412 Kipling Road Derwood, MD 20855

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1. INTRODUCTION AND ABSTRACT

RESEARCH SHE STILLE

There are many standard protocols and literature references to guide the medical physicist or engineer (MPE) in the proper establishment of procedures and quality assurance programs for the use of scientific equipment in patient diagnosis and therapy. However, there are indications that in many medical institutions an acute shortage of appropriate personnel often prevents the careful implementation of these procedures. Moreover, the MPE is often assigned part or all of the responsibilities of a radiation safety officer (RSO), to carry out procedures for the radiation safety of personnel, visitors and patients. Many of these safety procedures are required by regulation. Hospital administration often looks upon the skills of the MPE as appropriate for assuming RSO duties. Thus, guidance provided for staffing RSO duties can often be used to begin an analysis of staffing requirements for the MPE in general.

The NRC's Regulatory Guide 8.18 (1) states that "Management (1) should review the staffing requirements for each of these tasks and provide the necessary personnel to establish and carry out radiation safety program requirements, and (2) should evaluate them on an annual basis." The MPE must often take the initiative in providing management with the staffing analysis needed to perform the annual review of staffing and budgetary requirements for both radiation safety and other medical physics-engineering operations.

The list of tasks referred to is a relatively comprehensive list of radiation safety tasks required for NRC-licensed material uses only, and the same list is presented in both Regulatory Guide 8.16 and in the companion NUREG-0267 (2). In addition, NUREG-0267 presents in Table 1 the "Recommended Minimum Radiation Safety Staffing for Various Categories of Medical Institutions." These staffing estimates are given only for radiation safety duties related to NRClicensed material, but the table indicates that additional technical and professional staff are needed in many institutions for other duties; this is implicated by the suggestion that these other

* Presented at the Fall Meeting of the Mid-Atlantic Chapter of the American Association of Physicists in Medicine, Charlottesville, Virginia, September 24, 1988. Revised October 5, 1988.

personnel may also assume some radiation safety-related duties on a part-time basis. In addition, the NUREG-0267 table mentions in a footnote that additional staff will be needed if the surveys required (3,4) of many low-level clinical and research laboratories are included in the program responsibilities; however, no specific guidance is given on how to determine such additional staffing requirements. A recent survey (5) and additional queries indicate that as many as about 10 additional staff might be required for radiation safety surveys and services for 500 laboratories in a large medical center complex. The influence of radiation safety staffing requirements on the general staffing of MPE will be discussed in the following sections, a comprehensive tabulation of radiation safety tasks in a large medical research institution will be provided, and an estimate of the minimum total full-time equivalent staff of an average ("typical") Medical Physics and Engineering Division will be made for an hypothetical institution combining services for both a 500-bed teaching hospital and a 500laboratory university research program.

2. GUIDANCE ON STAFFING REQUIREMENTS IN NUREG-0267

The author's personal experience with the need for additional staff as a radiological physicist in a large medical center complex and a large hospital provided the original impetus for evaluating staffing requirements for medical physics and engineering. In one position in the early 1970's, this author without any additional help was faced with performing all the tasks of a radiation therapy physicist and a radiation safety officer in a 500-bed hospital. This hospital had a large radiology department, which included a nuclear medicine division and a radiation therapy division with two radiation therapists utilizing a cobalt unit, two X-ray machines, and brachytherapy sources. Although I was promised my own office and a full-time assistant when I accepted the position, these did not materialize in the first budget. With the forthcoming installation of a Clinac-4 linear accelerator, and the assignment to acceptancetest the equipment, perform the final radiation survey, and determine and/or verify all needed depth-dose and tissue-air ratio data within one month for this accelerator alone, I was forced to begin aggressive pleading with the hospital administrator. I was able to hire an outstanding full-time electronic technician just in time to assist with the acceptance testing and other hospital equipment repair and maintenance.

This situation of an acute shortage of medical physics and engineering staff was to continue, however, for each of the five years I was in this position. In order to obtain small increments of staff from year to year, I was forced me to write down all the tasks that I was required to perform, and the tasks that assistant

technicians and secretaries that were needed would perform, and to make job-time estimates for the carrying out of all my duties and responsibilities. Still, from year-to-year only minimal increases in staff were obtainable. I was able to obtain my first assistant physicist only by bringing him in as an apprentice and paying him out of my own pocket to convince hospital administration of my need. By 1975, I had completed all necessary treatment planning and dosimetry for the newly installed therapy machines and sources. By June 1975, I had also added one assistant physicist and four maintenance technicians to the hospital staff, and I returned to the government (NRC) to help write standards and guides for occupational radiation Ed Durkosh, Stu Levin (the State inspector) and I protection. presented a paper on the subject of staffing requirements at the 1985 annual meeting of the Health Physics Society. After I left on June 30, 1975, the next physicist was given his own division and budget, his own secretary and space, additional assistance, and all the equipment that I had listed as needed in the health physics and medical physics inventory.

Imagine my delight when one of my first assignments at the U.S. Nuclear Regulatory Commission was to write program guidance for medical institutions (e.g., Regulatory Guides 8.18 and 8.23, NUREG-0267). I of course planned to provide guidance on staffing requirements, since I knew that without proper staffing one cannot meet either regulatory or patient care requirements properly, no matter how well the planning, training, and equipping of the medical physics and associated staff may have been carried out.

Table 1 shows the staffing recommendations in NUREG-0267 for hospital radiation safety alone. The NRC has no authority to recommend staffing for other tasks or programs. However, in this table can be seen some implications of the need for other medical physics staff, and in the footnote mention is made of the need for additional radiation safety staff for institutions having many research laboratories requiring radiation safety surveys. Of course, Table 1 represents only estimates of the minimum staffing for radiation safety, based on four categories of the scope of diagnostic and therapeutic use of radioactive material. Some consideration has been given to the radiation safety requirements of machines that are not licensed by the NRC since the NRC regulation Title 10 CFR Part 20 does provide that combined exposures to licensed and non-licensed sources be controlled. The task of controlling these exposures must fall upon the same personnel in any efficient safety organization. Regulatory Guide 8.18 is essentially a boiled-down version of NUREG-0267, but it represents an accepted staff position of the NRC. Although NUREG-0267, and its included Table 1, had extensive peer review by persons both inside and outside the NRC, and Table 1 is an improvement over that presented in the 1975 paper, the NUREG still represents only the views of its author in any legal sense. However,

the final versions of both Regulatory Guide 8.18 and NUREG-0267 incorporate comments and suggestions from about 25 visits to major medical centers, as well as those from the 75 comments received by letter after publication of the draft versions. An extensive analysis of each of the letters of comment, and how each comment was resolved in consideration of all other related comments, is filed in the NRC public document room. Copies were sent to each of those who commented, since the resolution of comments essentially represents the consensus of the medical and medical physics community on the proper ways of managing radiation protection in medical institutions.

As mentioned above, the limited authority of the Nuclear Regulatory Commission, the staffing indicated pertains only to radiation safety tasks related to the use of NRC-licensed materials in diagnosing or treating patients, or to exposure from non-licensed machines only to the extent that exposures might overlap with those from licensed materials. It must be emphasized that the additional staff that would be needed to administer radiation safety services to research laboratories in a large university-medical center complex was not included, as indicated in the footnote to the table. University research laboratories were to be considered in another guide, but I do not believe that further official guidance has been given for determining such staffing needs.

Table 1 does take into account that additional physics staffing will be needed for other duties and that in some situations some of the radiation safety tasks may be assigned to medical physicists having other primary responsibilities. Preparation of the table recognized that it could only be a general guideline that would have to be adjusted to specific hospital situations. The list of the radiation safety tasks used in making the estimates of staffing requirements is available in both the regulatory guide and NUREG-0267.

3. EVALUATION OF STAFFING REQUIREMENTS FOR RESEARCH LABORATORY RADIATION SAFETY IN MEDICAL INSTITUTIONS.

Recent consulting experience in several medical and research institutions has provided the impetus for the author to evaluate the additional staffing requirements when many research laboratories require monitoring and surveying. Table 2 shows a more detailed list of tasks, built upon the list in NUREG-0267 but tailored to the specific operations and needs of a large medical research center with about 500 laboratory rocms to be surveyed and about 1000 persons receiving personnel monitoring per month. The estimates also include unlicensed sources of radiation inspected by the State. Each task was considered independently and a reasonable estimate was made of professional time, technicial time, and secretarial time associated

with each task. I was astounded to find that when I added up all the hours on my Lotus worksheet that it came to a staff of 13 required to remedy the deficiencies that regulatory agencies had found occurred when a staff equivalent of only one person had been employed. I of course checked my analysis with the thinking of many of my friends around the country who headed radiation safety offices, and also a recent report compiled by John Tolan for the Campus Radiation Safety Officers' Conference (5). It should be noted that in the institution for which Table 2 was prepared, the radiation safety functions in the clinical areas in the hospital were carried out by the equivalent of about one and a half full-time physicists and one technician under a separate hospital license. This analysis does not consider the additonal staffing in radiological physics and medical engineering in the subject institution. Considering that a computerized record keeping system and other management streamlining is to be invoked, it is possible that the research laboratories could be adequately serviced with a staff of about eight to ten full-time equivalents including two health physicists and two secretarial assistants. This does not include industrial hygiene or safety requirements. This estimate is consistent with some of the staffing experience of larger centers listed in Tolan's report (5), which might be of some assistance to persons building medical physics and engineering programs in other institutions.

4. ADDITIONAL GUIDANCE FOR EVALUATING STAFFING REQUIREMENTS

An exhaustive literature review and survey of this topic has not been carried out but I will mention a few additional sources of information that can be checked to be sure that all duties and tasks have been included in a staffing analysis. Regulatory Guide 10.8, Revision 2, is now available giving the criteria and guidance needed for obtaining licenses for medical institutions (4). Sample procedures and methods in this guide have been expanded to include a list of file categories, and a list of equipment and services that might be needed in various medical radiation programs. Some of these services would require staff time for selection and administration if carried out by outside contractors, or might require additional permanent staff if carried out in-house. The NRC's Regulatory Guide 8.23 provides a comprehensive list of the radiation safety surveys to be carried out in medical institutions, and contains a summary list of tasks that can also be used as a checklist (3).

In regard to non-safety tasks of the medical physicist and engineer, the experience of the director(s) of the medical physics and engineering program(s) in a specific institution is probably the best source for listing these tasks and estimating staffing requirements. However, the many functions that the physicist and engineer is directed to perform can also be outlined in further detail by reference to the many textbooks, handbooks, and AAPM manuals available.

5. OVERALL ESTIMATE OF STAFFING REQUIREMENTS

Table 3 presents the author's summary estimate of the staffing requirements for a large 500-bed hospital under the same license as a university research program with 500 separate laboratory rooms and about 1000 badged personnel. I have added some estimates of my own for medical physics and engineering functions other than radiation safety. However, I would like to receive the opinions of others on these estimates, and information on any other sources for estimating staffing requirements for hospitals and university-medical research complexes of various sizes and scopes. Exhibit A is a sample questionnaire. I will turn over any information received to the American Association of Physicists in Medicine for consideration in developing a consensus on this subject of guidance on estimating staffing requirements.

REFERENCES

1. U. S. Nuclear Regulatory Commission, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low 's Reasonably Achievable," Regulatory Guide 8.18, Revision 1, USNRC, Washington, DC 20555, Oct. 1982.

2. A. Brodsky, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," NUREG-0267, Revision 1, USNRC, Washington, DC 20555, 1982.

3. U. S. Nuclear Regulatory Commission, "Radiation Safety Surveys at Medical Institutions," Regulatory Guide 8.23, Revision 1, USNRC, Washington, DC 20555, January 1981.

4. U. S. Nuclear Regulatory Commission, "Guide for the Preparation of Applications for Medical Use Programs," Regulatory Guide 10.8, Revision 2, USNRC, Washington, DC 20555, August 1987.

5. John Tolan, Compiler, "Staffing and Salary-Range Survey," Campus Radiation Safety Officers (available from CRSO Conference, 518 Clark Hall, University of Missouri, Columb a, Missouri 65211 (\$5.00)), May 1987.

Table 1 ****

RECOMMENDED MINIMUM RADIATION SAFETY STAFFING FOR VARIOUS CATEGORIES OF MEDICAL INSTITUTIONS*

Category	Radiation Sources	Technician Time	Professional (Health Physics) Time
I	Low-level clinical and research laboratories** handling microcurie quantities of I-131, I-125, Cr-51, C-14, and H-3, plus radiographic units and fluoroscopes	6 man-hours per month	4 man-days/yr (plus daily supervision by full-time qualified staff radio- logist or other health professional)
II	Category I plus nuclear medicine	1 full-time radiation safety technician (possibly doing some minor part-time electronics maintenance)	1/2 time of health physicist (possibly including calibration of diagnostic x-ray units)
ш	Category II plus teletherapy, radionuclide therapy, or brachytherapy	l full-time radiation safety technician***	<pre>1 full-time health or radiological physicist (possibly performing some diagnostic calibrations)</pre>
IN	Category III plus multi-megavolt therapy	2 full-time technicians - radiation safety and electronics***	<pre>1 full-time health physicist and 1 or more full-time radiological physicists with some radiation safety responsibilities</pre>

All personnel are in addition to clinical radiological physics requirements. Also, for categories II-IV, the person serving as Radiation Safety Officer (RSO) should be a full-time member of the hospital staff.

Major medical centers having larger research complexes may require larger radiation safety staffs just to meet survey requirements for the research laboratory areas. In some cases, medical research laboratories are serviced by university radiation safety offices when they are located in university medical complexes. Since situations vary, experience with the programs and organization of each institution is often needed to judge staffing requirements for surveying medical research uses of licensed radioactive materials (see Regulatory Guides 8.23 and 10.8).

Plus proportionate secretarial-clerical assistance for correspondence and recordkeeping requirements.

**** - This Table 1 is the Table 1 from NUREG-0267 (Reference 2).

Table 2

STAFFING ESTIMATES FOR A RADIATION SAFETY OFFICE SERVING 500

RESEARCH LABORATORIES

SIMPPING ESTIMATES FOR ENDIATION SAFELY OFFICE

1. Administration and Consultation by Rediation Safety Officer Staff	Prof. HP Time	Admin.Sac. Time	Technician
(Podessional time estimates plus apporting paramal time.)	(hours)	(hours)	(hours)
Approval of users and asquisitions (2 hours/day x 250 days)	500	250	250
Approval of equipment, operations & procedures (1 visit/day x 250 days)	250	250	100
Preparation of liverse applications and ameriments (4nours/month)	100	50	0
Reparation of safety evaluation peperts for licensing (4 hours/month)	200	10	ø
Programming of mutine saveys by RE Office (1 hour Assk with tech.)	52	26	52
Programing of well-through surveys by RS Office (0.5 hour/week + arc.st	13	125	125
Walk-through saveys smi-smally by RS Officer (1 h/lab.x 400)	400	0	0
Walk-through surveys annually by RS Officer and VP/P (16 hours/year)	16	2	16
Spervision of mutine radiation rafety operations (1 hour /day)	250	a	a
Revisions to rediation safety procedures and menual (8 hours/month)	96	40	ä
Periodic rediation safety instruction for staff & admin. (8 h/mp.)	96	œ.	24
Conferences, presentations and lectures with faculty & atmin. (3 bak.)	156	26	
Inspections and discussions with pepulatory agencies (2 insp./yr.)	100	100	100
Seniners, courses, professional & tech. meetings, keeping up-to-date	80	40	40
Selecting and ordering equipment and applies, and services	20	10	10
Bacility, equipment & procedure design, meetings with antilitects	80	ā	8
Record maintenance, related computer programming and input	80	1848	500
Bongency plans, instructions and drills for university staff	32	16	64
Bangercy instructions and arrangements with fine, police, madical	16	Ø	32
Refliation Safety Coumittee meetings, minutes, follow-up actions	400	100	100
Reputation of neports to negulatory agencies, former encloses	200	100	200
Reperation of arrual budget percomendations, staffing, hiring	40	40	20
Inventory of equipment, supplies, radiation staroes, machines	1640	100	100
Reficentive waste interbories, preparations for shippert	50	50	50
Inventories of environmental maleases to air, severe, incineration	50	50	50
Resperation of Arnual Rediation Safety Office Reports	16	16	16
SUBDINS	3293	2537	1857
2. Surveys of Redicectivity (Isotope) Users Apens (400 labs.)			
Complete radiation safety audit, monitoring and mear survey (2/vr.)	50	120	3200
While-through surveys, rapid monitoring, snear four surfaces (6Ar.)	200	360	2400
Hood and ventilation checks, filter replacements	200	20	600
Checking stack monitons and incinazator ashas	12	0	24
Save,s of waste disposal area	6	ø	12
SHOWE	468	500	6236

Table 2 (continued)

3. Surveys, Redistion-Producing Machines and Generators (90)			۰.
Van de Graaffs	4	0	8
Electron microscopes	8	Ø	8
Dantal machines	160	1	160
x-vay diffraction units	20	1	20
Other redistion-producing equipment	20	0	20
SLATOINS	212	2	216
4. Personal Monitoring for External Radiation			
Distributing, collecting, shipping, receiving, 1.000 badgestrings/mo.	24	24	480
Determining requirements for personal monitoring	8	8	16
Revieu of expanse mentes from personnel monitoring, reports	96	12	96
Special insetigations of ecosure and notifications	12	6	12
Retrieval of empare histories for the hims and terminations	4	4	50
Estatin personal consumes into compter monds, filing	Ø	240	480
Cality anarance - blarks, expains calibrations, spiles	24	Ø	24
SUBIOTALS	168	294	1158
5. Biomesy and Bralustion of Intakas and Internal Doess			
Determining who requires bicessay, bicessay frequencies, methods	70	10	Ø
Ordering and distributing containers, collection of samples	ø	2	600
Shipping himsey samples to radioanalytical laboratories	2	24	100
In-huse measurement of samples by liquid scintillation countiny	12	Ø	100
In vivo thyroid or organ counting i house at RS office	24	Ø	48
Set up of in-house o ntiny and analytical procedures	48	Ø	48
Retrieval of previous exposures for new-hines and terminations	4	4	50
Interpreting bioassay peralts in terms of internal doess	96	10	10
Entering internal exposure information into computer moonds, files	12	96	Ø
Quality assurance - preparation of blanks, standards, spikes, evaluation	96	0	96
Energency biosessy, planning, implementation, does evaluation	120	40	-120
SETOTALS	484	186	1172

Table 2 (continued)

* * * * *

6. Redistion safety applies, instrument maintenance and calibration			
Ordering signs, susses, supplies, instruments	12	48	12
Calibration of radiation measuring and air monitoring equipment	12	Ø	48
Rochest chamber and TLD callibrations	6	ø	12
Shimin institutos instruments for calibratics at unive	á	a	200
Check source preparation and calibration	24	ě	24
CHATTAN C			202
		**	000
7. Leak testing sealed sources			
Snear testing large irradiators, counting, calculations, reports	6	1	6
Checking leak test peoults of investigators, entering into files	12	6	12
SUBIDINS	18	7	18
8. Decontamination and waste disposal			
Decontamination and anveying of spills and excess contamination	12	ø	120
Collection of radioactive wastes from laboratories, instructions	12	12	3500
Packaging, surveying, placending, recording contents	24	12	200
Arranying for shippents, assisting in loading, completing manifests	12	6	72
Accerging and monitoring incineration of westes	12	Ø	12
Picking up and storing sealed sources not in use	0	ø	4
Reports required to EPA and State	8	2	32
SUBTOTINES	92	38	3952
9. Special surveys and consultation to assist investigators			
Pre-constitutel arveve and discussions to establish safety requirements	340	24	120
Background surveys of baseline contamination for raw lab. users	0	0	200
SECONS	240	24	323
GRAND TOTALS	5031	3636	15237
FILL OTHE FULLANENTS (a) lowing for mak loads, vacations, abarrow)	3	2	8

Table 1

ESTIMATED STAFFING REQ	UTREMENTS FOR P	EDICAL	PHYSICS AND E	NGINEEKING
IN A	LARGE INSTITUTI	ON		
Task Type	Prof.time (man-hr) Health P.P.	or E.	Tech.timeSe (man-hr) (c.time Support* man-hr)H=hospl. U=univers
DIRECT RADIATION SAFETY RELATED TASKS:				C=U+H
Tasks required by rad. safety regs. (500 lab.spaces	2.00		7.00	1.00 U
Tasks for nuclear medicine and other diagnostic source	0.50		1.00	0.50 H
Rad. safety for diagnostic machines	0.50		1.00	0.50 H
CHEMICAL AND FIRE SAFETY, LOSS PREVENTION:		2.00	1.00	1.00 C
EQUIPMENT ACCEPTANCE, OPERATION, MAINTENANCE, GAR				
Radiation therapy dosimetry treatment planning, QA		2.00	2.00	0.50 H
CAT and other tomog.		1.00	0.10	0.10 H
Nuclear medicine equipment, acceptance, maint., GA	•	1.00	0.10	0.10 H
Diagnostic x-ray equipment, acceptance, maint., QA	•	0.50	1.00	0.10 H
Other hospital electronic and scientific equipment,				
repair, testing		1.00	3.00	1.00 C

TOTALS: 3.00 7.50 16.20 4.80 (Medical Physics and Engineering Division, Full-Time Equivalents (FTE's

CONCLUSION: Minimum Medical Physics and Engineering Division = 32 FTE's, for institution of 500-bed teaching hospital combined with 500 lab. space research program.

*Footnote: Author's estimate for average large institution, not counting staff research time, and assuming combined safety and operating staff for both hospital and university programs, with all types of science and engineering personnel (e.g., health physicists, industrial hygienists, safety engineers, medical physicists and medical engineers, and associated technical staff, reporting to a single director. Much of the hospital funding (H) may be obtained by adding a small percentage to appropriate patient billings and much of the university support may be charged to projects and grants.

EXHIBIT A

QUESTIONNAIRE ON MEDICAL PHYSICS-ENGINEERING AND HEALTH PHYSICS STAFFING IN MEDICAL INSTITUTIONS

त्रक्षा द संसर्घ

1. Type of facility (hospital or medical-hospital complex, etc.)

2. Number of patient beds_____

3. Number of research laboratory room spaces_____

4. Radiation therapy equipment_____

5. Nuclear medicine equipment

6. Separate licenses or same for hospital and research labs, specify

7. Radiation safety duties (areas included)

8. Staffing: No. prof. physicists No. technicians Secretaries or engineers

Currently

-

100

Needed for adaquate care

Desired for complete program (except research)

9. Additional comments or sources of information (include on back):

Signature, position, affiliation, address and telephone no., if possible:

PLEASE RETURN OR MAIL TO: Dr. Allen Brodsky (301)840-5443 16412 Kipling Road Derwood, MD 20855

CURRICULUM VITAE

THOMAS LEW PITCHFORD

OFFICE:

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HOME:

	University of Missouri Office of Research Safety 18 Clark Hall Columbia, MO 65211 314) 882-3721	428 N. Cedar Lake Drive Columbia, MO 65203 (314) 442-0208
CERTIFICATION	1976 - Present	American Board of Health Physics
APPOINTMENTS	<u>1984</u> - 1993	Missouri Low-Level Radioactive Waste Advisory Committee (Present Chair)
	1988 - 1991	Editor, Health Physics Society Newsletter
	1988 - 1993	American Board of Health Physics
	1981 - 1986	Associate Editor, Health Physics
	1983 - 1984	Membership Committee, Health Physics Soc.
	1979 - 1981	Technical Electronic Product Radiation Safety Standards Committee, Bureau of Radiological Health, FDA
	1974 - 1976	Adjunct Professor College of the Pacific San Francisco, CA
	1974 - 1976	Adjunct Professor Skyline College San Francisco, CA
	1972 - 1988	Established and Taught (two-week course) Principles of Radiation Safety Letterman Army Medical Center
EXPERIENCE:	1988 - Present	Director, Research Safety Office Radiation Safety Officer University of Missouri
	1981 - 1988	Biosafety Officer and Associate RSO University of Missouri
	1976 - 1981	Radiological Hygiene Consultant. US Army Health Services Command San Antonio, TX
	1972 - 1976	Chief, Health Physics Service Letterman Army Medical Center San Francisco, CA

Fichior Page 2		
Experience (cont.):	1969 - 1972	Executive Officer, US Army Nuclear Medical Research Detachment Landstuhl, Germany
	1965 - 1969	Principal Investigator, Armed Forces Radiobiology Research Inst. Bethesda, MD
EDUCATION:	1969 - 1971	University of Utah MBA Degree, Management
	1964 - 1965	New York University MS Degree, Radiological Health
	1950 - 1954	Washington & Jefferson College BA Degree, Pre-Medical
PROFESSIONAL	1966 - Present	Health Physics Society (National)
ATTIATIONS:	1981 - Present	Mid-America Chapter, Health Physics Soc. (President 1986-1987, Vice President 1985-1986, Secretary/Treasurer 1983-85)
	1933 - Present	Greater St Louis Chapter, HPS (Founding member)
	1981 - Present	Missouri River Valley Chap, AAPM
SELECTED PUBLICATIONS:		A Gamma Radiation Survey of Orange County, NY(Thesis, NYU)
		Monkey (Macaca mulatta) Survival Times After Pulsed Gamma-Neutron Radiations, AFRR1 Scientific Report 68-5
		The Acute Mortality Response of Beagles to Pulsed Mixed Gamma-Neutron Irradiation, AFRRI, Scientific Report 68-15
		Beagle Incapacitation and Survival Times After Pulsed Mixed Gamma-Neutron Irradiation, AFRRI Scientific Report 68-24
IVIC FUNCTIONS:		Optimists International, Southside Optimists Club, Founding President (1983-84)
		Cedar Lake Homeowners Assoc.

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President 1985-1986 .