

## Appendix VI

# FEDERAL DEPARTMENTS AND AGENCIES WITH DIRECT INVOLVEMENT IN CT SCANNING

Various aspects of CT scanning come under the jurisdiction of different Federal departments and agencies. Many of these agencies are part of the Department of Health, Education, and Welfare, but other agencies and departments also are involved. Federal programs and their involvement with CT scanning are listed in table 22 and described below.

### DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (HEW)

#### Public Health Service (PHS)

##### Office of Health Practice Assessment (OHPA)

As described in chapter 6, the Public Health Service, as part of an interagency agreement, gives advice to the Medicare program on its reimbursement when requested to do so. That function is currently carried out by the Office of Health Practice Assessment in the Office of the Assistant Secretary for Health.

##### Food and Drug Administration (FDA)

*The Bureau of Radiological Health (BRH)* has jurisdiction over the performance of CT scanners under the Radiation Control for Health and Safety Act of 1968. CT scanners must meet the diagnostic X-ray machine standards for safe performance which became effective August 1, 1974. Owners of CT scanners must report to BRH when a new machine is installed or an existing machine modified. BRH develops tests to measure radiation output from CT scanners and patient dose levels. BRH has contracted with George Washington University Medical Center to develop radiation dose data using an EMI head scanner,

*The Bureau of Medical Devices (BMD)* has regulatory control over these medical devices, as described in chapter 3 of this report. Two of its classification panels have Jurisdiction over CT scanners: the Radiology Panel and the Neurology Panel.

*The Bureau of Drugs* has no direct involvement with scanners, but does regulate drugs (contrast materials) used in conjunction with CT scanning. At least one such new drug application has been submitted.

**Table 22.—Federal Departments and Agencies With  
Direct Involvement in CT Scanning**

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<b>Department of Health, Education, and Welfare</b>
<b>Public Health Service</b>
<b>Office of Health Practice Assessment</b>
<b>Food and Drug Administration</b>
<b>Bureau of Radiological Health</b>
<b>Bureau of Medical Devices</b>
<b>Bureau of Drugs</b>
<b>National Institutes of Health</b>
<b>Health Resources Administration</b>
<b>Bureau of Health Planning and Resources Development</b>
<b>National Council on Health Planning and Development</b>
<b>Health Services Administration</b>
<b>The Health Care Financing Administration</b>
<b>Department of Labor</b>
<b>Department of Defense</b>
<b>Veterans Administration</b>
<b>Department of Energy</b>
<b>National Aeronautics and Space Administration</b>
<b>Environmental Protection Agency</b>
<b>Department of Commerce</b>
<b>Domestic and International Business Administration</b>
<b>National Bureau of Standards</b>
<b>The National Council on Radiation Protection and Measurements</b>
<b>The National Science Foundation</b>

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### **National Institutes of Health (NIH)**

As noted in appendix I, NIH has four operational CT scanners. These machines are used both for NIH patients and for clinically oriented research. Extramurally, NIH is supporting about 100 research projects using CT scanning. The largest number of these are funded by the National Cancer Institute (NCI). NCI is itself funding a large collaborative clinical trial of the efficacy of CT scanning. The National Institute of Neurological and Communicative Disorders and Stroke held an International Symposium on Computerized Axial Tomography on October 12-15, 1976.

#### **Health Resources Administration (HRA)**

*The Bureau of Health Planning and Resources Development (BHPRD)* carries out the provisions of P.L. 93-641, the National Health Planning and Resources Devel-

opment Act. Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) are responsible for local and State health planning activities respectively.

The responsibilities of HSAs include: developing the health systems and annual implementation plans (corresponding to short- and long-term plans, respectively); providing technical and financial assistance for developing health resources; reviewing proposed Federal grants for health projects; assisting the State level review of new health services and proposed facilities; reviewing the appropriateness of existing facilities and services; and making their findings available to the State agency. The functions of the SHPDAs include preparing a State health plan, administering the certificate-of-need program and reviews under section 1122 (if the State had entered into an appropriate contract with HEW), reviewing existing institutional health services and facilities, and publishing findings on their appropriateness.

The Bureau of Health Planning and Resources Development (BHPRD) is responsible for providing technical assistance and policy guidance (through the issuance of regulations) to these agencies. Technical assistance takes two forms: one is general guidance on the implementation of P.L. 93-641; the other is the development of recommended criteria and standards for reviewing and ruling on applications for capital expenditures or services. P.L. 93-641 established 10 Centers for Health Planning to provide technical assistance in the form of training of HSA and SHPDA board members and staff, and direct consultations with HSAs and SHPDAs for specific projects.

*National Council on Health Planning and Development.* Under the National Health Planning and Resources Development Act of 1974, HEW is required to establish a National Council on Health Planning and Development composed of 15 members. Six of the 12 are at-large members, and 6 are representatives of HSAs and SHPDAs. The Council met for the first time on December 10, 1976. The functions of the Council are to advise, consult with and make recommendations to the Secretary of HEW with respect to the development of national guidelines, the implementation and administration of P.L. 93-641, and the evaluation of new medical technology for the organization, delivery, and equitable distribution of medical services.

### **Health Services Administration (HSA)**

HSA provides CT scanning when necessary through its direct service programs, including Public Health Service Hospitals and the Indian Health Service.

### **The Health Care Financing Administration (HCFA)**

HCFA administers the Medicare program, which funds medical services mainly for the elderly. Medicare presently reimburses for CT head scanning and has been requested to reimburse for CT body scanning; that request is still under consideration. HCFA does not make decisions regarding direct coverage of CT scanning by the Medicaid program, but does provide matching funds to the State programs that might include reimbursement for CT scanning. X-ray services are mandated under the Medicaid program, and the required State plan might or might not include CT scanning. In addition, Medicaid reimbursement is on a "cost-related" basis: if purchase

of a CT scanner increases a hospital's costs; inpatient charges may be increased for all patients, and Medicaid payments increase.

HCFA also administers the Professional Standards Review Organizations (PSRO) program, a peer review program concerned with quality of care and with utilization of services and facilities. HCFA is developing guidelines for the relationship between PSROs and State planning agencies and Health Systems Agencies. HCFA encourages PSROs to provide technical assistance to such programs about the distribution and use of CT scanners, and such assistance already has been given in a few local areas. HCFA is not presently developing any materials relating to appropriate use of CT scanners for PSRO programs.

HCFA also staffs the National PSRO Council, which has the following functions:

- (1) to advise the Secretary of HEW on the administration of the law;
- (2) to provide for the development and distribution, among Statewide Professional Standards Review Councils and PSROs, of information and data which will assist such councils and organizations in carrying out their duties and functions; such information includes regional norms of medical care;
- (3) to review the operations of statewide councils and PSROs to determine their effective and comparable performance; and
- (4) to make or arrange for studies and investigations designed to lead to recommendations to the Secretary of HEW and to the Congress on how to improve the program.

The PSRO Council also must approve local norms and standards of care. Thus, the PSRO Council may disapprove such norms and standards if they are not adequate.

## **DEPARTMENT OF LABOR**

The Occupational Safety and Health Administration (OSHA) has responsibility for ensuring the safety of the workplace. Thus, it has jurisdiction over medical settings where employees may be exposed to X-rays. General guidelines, dating back several years, set standards for allowable radiation exposure, and employers must ensure that this dose is not exceeded.

## **THE DEPARTMENT OF DEFENSE (DOD)**

The Department of Defense operates hospitals and clinics to provide medical care for active duty and retired members of the Army, Navy, Air Force, and Marines. Acquisition of an expensive technology such as a CT scanner must be approved by the Department of Defense Health Council, which includes the Surgeons General of the Army, Navy, and Air Force, and the Assistant Secretary of Defense for Health

Affairs. Because local levels are expected to coordinate their requests with civilian facilities, local HSAs are also usually consulted.

Military hospitals and clinics have been using the CT scanning facilities of civilian institutions for some time and paying fees out of operating budgets. A decision has been made to purchase six scanners, two for each of the uniformed services. One of these was operational as of July 1, 1977. DOD also funds health research but is not supporting research related to CT scanning.

## **THE VETERANS ADMINISTRATION (VA)**

The Veterans Administration operates a system of medical care facilities, including 171 hospitals. Care is planned centrally, but such planning responds to local level requests. The Radiology Service of the VA makes all decisions concerning CT scanning, with the assistance of an advisory committee including the directors of Medicine, Surgery, Neurosurgery, and Neurology, VA's policy is to purchase a CT scanner only after the local Health Systems Agency (HSA) has certified it as needed, although such HSA review is not required by law.

Six VA hospitals had operational CT scanners by July 1977; five were being installed, and three more scanners were on order. In addition, local VA hospitals pay for scanning by civilian institutions out of operating budgets. VA also funds health research. A research project in Boston will link four satellite hospitals to the area VA hospital's CT equipment to evaluate sharing of such equipment, permitting a radiologist in the central hospital to read the scans.

## **DEPARTMENT OF ENERGY (DOE)**

As the primary agency in energy research, development, and demonstration, DOE encourages peaceful uses of atomic energy, including radioisotopes and radiation. For this reason, ERDA (now DOE) funded a project at the University of California at Los Angeles to conduct research on the CT scanner—focused both on instrument development and imaging techniques.

## **NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)**

NASA has a medical science program which supports research in medical applications. The program is presently supporting two projects related to CT imaging of the heart. Other projects to improve the technology of radiology are also being supported, especially to achieve higher sensitivity of X-rays with lower radiation doses,

## **THE ENVIRONMENTAL PROTECTION AGENCY (EPA)**

EPA has broad responsibilities for protecting public health from radiation hazards. These responsibilities include the development of national guidelines in radiation protection. EPA also carries out research on environmental hazards.

Under Federal Radiation Council authority, which was transferred to this agency in 1970, EPA has been studying the hazards of exposure to ionizing radiation, including radiation from medical and dental X-rays. EPA presently has an Interagency Working Group on Medical Radiation, which is developing broad guidelines on diagnostic radiology for Federal medical care facilities. The Working Group is developing recommendations on the qualifications of medical personnel who prescribe and operate X-ray equipment, the description of adequate X-ray equipment, and the principles which minimize patient exposure without sacrificing diagnostic quality. The guidelines being developed are expected to cover routine radiographic procedures, but have not yet considered the CT scanner. The Public Health Service of HEW, although furnishing technical assistance, has declined a request from EPA to participate in the Interagency Working Group.

## **DEPARTMENT OF COMMERCE**

### **Domestic and International Business Administration**

Nonprofit institutions, including nonprofit hospitals, are permitted to import scientific instruments duty-free. The Department determines whether a piece of equipment qualifies as a scientific instrument, and it has classified scanners made by EMI, Ltd. as scientific instruments.

### **National Bureau of Standards (NBS)**

In order to set standards for a variety of technologies, NBS develops measuring instruments of many types. To evaluate structural materials with nondestructive methods, NBS has developed ultrasonic imaging devices. NBS and NIH will cooperate on comparing ultrasonic devices with CT scanners. NBS may attempt to develop CT scanning devices that use ultrasound instead of X-ray.

## **THE NATIONAL COUNCIL OF RADIATION PROTECTION AND MEASUREMENTS**

This Council is a nonprofit corporation chartered by Congress and made up of nationally recognized scientists. The Council collects, analyzes, and disseminates information and recommendations about radiation protection and measurement. Council recommendations provide the scientific basis for radiation control, and they

are used by Federal Government organizations such as the Nuclear Regulatory Commission, the Public Health Service, and the Environmental Protection Agency. The Council has not produced any reports specifically related to CT scanning, but does have general reports concerning equipment design and use, protection of patients, and similar topics that bear upon CT scanners.

### **THE NATIONAL SCIENCE FOUNDATION (NSF)**

NSF supports medical research under several different programs. Presently, it is supporting three projects related to CT scanning, two to improve imaging by CT scanners, and one to attempt imaging by ultrasound.