MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
COMPUTED TOMOGRAPHY (CT) STANDARD ADVISORY COMMITTEE (SAC) MEETING

Wednesday, October 10, 2007

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Shumaker called the meeting to order at 9:05 a.m.

A. Members Present:

Gerrie Baarson, Battle Creek Health System
Sharon Brooks, DDS, Self
Dale M. Downes, Sparrow Hospital
William C. Granger, MD, Blue Care Network of Michigan
Jeffrey Hinman, MD, Spectrum Health
Dean J. Jackson, Marquette General Health System
Calvin C. Johnson, MidMichigan Health
Alice W. Mailhot, Consumer Health Care Coalition
Kathleen A. McManus, Vice-Chairperson, Munson Medical Center
Cassandra R. Saunders, Economic Alliance for Michigan
Daniel B. Shumaker, MD, Chairperson, Michigan Radiological Society
Kristin J. Tesner, Genesys Regional Medical Center
J. Michael Zerin, Detroit Medical Center

B. Members Absent:

Chad M. Grant, Detroit Medical Center

C. Michigan Department of Community Health Staff Present:

Umbrin Ateequi
Larry Horvath
John Hubinger
Irma Lopez
Andrea Moore
Brenda Rogers
Taleitha Pytlowanyj
Matt Weaver

II. Declaration of Conflicts of Interests

None were stated at this time.

III. Review of Agenda

Motion by Dr. Granger, seconded by Dr. Zerin, to accept the agenda as presented. Motion Carried.

IV. Review of Minutes – September 5, 2007

Motion by Dr. Granger, seconded by Mr. Johnson, to accept the minutes as presented. Motion Carried.

V. Review and Discussion of Charge

Dr. Shumaker stated that Dr. Slovis will not arrive to the meeting until shortly before lunch; therefore, the Committee will continue with the agenda until Dr. Slovis arrives to deliver his presentation.

A. Potential Pediatric and Special Needs Criteria and Need for Specific Weighting

The Committee found the incorporated draft language for dedicated pediatric CT into the Standards as generally acceptable. However, Chairperson Shumaker expressed some concern and requested taking a closer review for possible modification of the language inserted in the project delivery requirements, Section 14(1)(c)(x), regarding radiologists, technologists, and nursing staff that work with CT patients having to prove they have continuing education or in-service training on pediatric low-dose CT. Discussion followed.

B. Replace/Upgrade Criteria and Definitions

Ms. Ateequi provided a brief review of the proposed draft language for the Replace and Upgrade definitions. The CON Program Section requested additional language to be added to indicate that a replacement requires a change in the radiation safety certificate. Discussion followed.

Motion by Dr. Hinman, seconded by Mr. Jackson, to accept the new Replace definition language with the elimination of Upgrade. Motion Carried.

<u>Public Comment</u>

Bob Meeker, Spectrum Health

C. Commitment Process

Chairperson Shumaker gave a brief background on what a facility has to do in order to obtain a CT Scanner. He stated that with the proposed language regarding the commitment process, new data would need to be collected about the referring physicians in the annual reporting of CT Scanners. Further, when an application to initiate is made, the referral commitments are obtained; the State would then have a database to look back upon and see if the doctor reached his commitment. Mr. Horvath verified Chairperson Shumaker's information and provided a brief background. Discussion followed.

Mr. Horvath recommended additional language to Section 16 to help clarify the language. He recommended that at the end of Section 16(1) add the following language, "HISTORICAL PHYSICIAN REFERRALS WILL BE VERIFIED WITH THE DATA MAINTAINED BY THE DEPARTMENT THRU ITS ANNUAL SURVEY PROCESS." He also recommended adding the following language at the end of Section 16(4)(b), "COMMITMENTS MUST BE VERIFIED BY THE MOST RECENT DATA SET MAINTAINED BY THE DEPARTMENT THRU ITS ANNUAL SURVEY." Last, he recommended modifying language in Section 13(1)(b)(xi) by deleting the words "DATA COLLECTION NETWORK" and replacing it with "ANNUAL SURVEY PROCESS."

Motion by Dr. Granger, seconded by Dr. Hinman, to approve the proposed language with the modifications. Motion Carried.

Public Comment

Bob Meeker, Spectrum Health
Dennis McCafferty, Economic Alliance for Michigan

D. Criteria and Processes for Addressing Emerging Specialty Use Scanners

Public Comment

Jeff Weingarten, MD, Michigan Otolaryngology Society
Sheila Ray, ENT Otolaryngology Society
Colin Ford, MSMS
Matt Jordan, Xoran Technologies
Jean Aldrich, Eye and ENT Specialists

Chairperson Shumaker stated that one of the main concerns is access. He also stated that he felt portable CT Scanners would be a good place to start in regards to access.

Public Comment

Bob Meeker, Spectrum Health
Matt Jordan, Xoran Technologies
Jeff Weingarten, MD Michigan Otolaryngology Society
Suresh Mukherji, University of Michigan
Dennis McCafferty, Economic Alliance for Michigan

Motion by Dr. Brooks, seconded by Mr. Johnson, that ENT CT Scanners be exempt from CON regulation for a period of three years for the purpose of collecting data on how they are actually being used.

Dr. Zerin stated concern in regards to if they decide to exempt ENT CT Scanners for three years, what will be the process that will be used to acquire the data. Also, he questioned that if they exempt them from the CON process, what would be the process used to get them back into the standards. Lastly, he stated concern on exempting one type of CT Scanner in order to research its purpose, and not exempting others to find out their purposes.

Mr. Horvath stated that there is no such thing as an exemption; they are either covered by CON regulation, or not. They may also be covered under CON with very limited criteria. Discussion followed.

Motion by Dr. Brooks, seconded by Chairperson Shumaker, to Table the Brooks/Johnson Motion. Motion Failed.

Brooks/Johnson Motion. Motion Failed.

VI. Presentation – CT and Radiation Dose by Tom Slovis, MD, Detroit Medical Center

Dr. Slovis provided a brief presentation and written report (Attachment A). He stated his purpose is to discuss the health of children and adults in regards to biological effects from radiation.

Lunch break from 12:06 p.m. to 1:23 p.m.

VII. Review and Discussion of Charge – Continued

D. Criteria and Processes for Addressing Emerging Specialty Use Scanners – Continued

Public Comment

Conrad Nagle, William Beaumont
Matt Jordan, Xoran Technology

Motion by Chairperson Shumaker, seconded by Dr. Hinman, to permit level one and two trauma centers to obtain a specialty use scanner of their choice and not have to meet the current volume thresholds for a body scanner.

Mr. Horvath stated that the centers that have a CT Scanner would be subject to the three year review and would have to fill-out the annual survey so the Department can see how the scanners are being used. Dr. Granger stated that there needs to be clarification on whether or not the scans for the specialty use scanners could be used to meet CT CON volume requirements in the total or would you just take the fixed base units. He also stated there needs to be clarification on if there is a provider with a level one or two trauma center and may have off-site operating rooms, do the exemptions apply to those operating rooms. Discussion followed.

Shumaker/Hinman Motion. Motion Carried.

Chairperson Shumaker stated that the Committee needs to look at the language for Dental CT Scanners and make sure it is uniform with the rest of the standards.

Motion by Dr. Brooks, seconded by Ms. Tesner, that the language regarding Dental CT Scanners be made to conform to the language in the rest of the Standards in terms of acquisition, replacement, upgrade, relocation, with a minimum volume requirement of 200 scans per year, and that the threshold number for expansion be 300 scans per year. Motion Carried.

Public Comment

Caroline Ruddell, Michigan Dental Association
Melissa Cupp, Wiener & Associates
Dennis McCafferty, Economic Alliance for Michigan

Motion by Dr. Brooks, seconded by Ms. Tesner, to adopt the language (Attachment B) regarding exemption of Dental CT Scanners from CON regulations based on a modification to the definition of a CT Scanner as presented (Attachment B). Motion Failed.

Motion by Dr. Brooks, seconded by Dr. Zerin, to modify the definition of dental procedures (Attachment C) in the Standards.

Dr. Zerin asked Dr. Brooks to give examples of procedures that are being done in other states that Michigan cannot do presently.

Brooks/Zerin Motion. Motion Carried.

VIII. MDCH – Review of Draft Language

Ms. Ateequi provided a brief overview of the draft language and proposed recommendations.

IX. Next Steps

Ms. Ateequi provided a brief summary of the actions taken by the Committee. Dr. Granger requested the language regarding radiation safety and what constitutes a change in the radiation safety certificate.

X. Future Meeting Date(s)

November 14

XI. Adjournment

Motion by Dr. Granger, seconded by Dr. Zerin, to adjourn the meeting at 2:53 p.m. Motion Carried.

Biological Effects of Radiation

Thomas L. Slovis, M.D.
Children's Hospital of Michigan
October 10, 2007

1. Think of radiation as a medicine:
   a.) When INDICATED, it can cure or diagnosis illness
   b.) Too much → complications (deterministic effects)
   c.) Any → can cause a severe reaction – allergic (medicine) cancer (radiation)
   d.) Effects → lifelong and cumulative (stochastic)
   e.) Particularly severe effect on children when given adult dosages; age dependent (Fig. 1)
   f.) No dose of radiation can be considered safe (linear-nonthreshold)

2. Highest man-made radiation dose given by diagnostic imaging. Largest contributor is CT.

3. "Low dose" radiation causes mutations (Fig. 2).

4. Overlap of CT doses and atomic bomb blast (Fig. 3).

5. Life is risky – Table (Fig. 4)

   For children receiving head or abdominal CT, the actual risk of radiation-induced cancer is 1:2000 to 1:10,000.

   Considering we are doing over 3 million CTs/year on children, this is a large public health problem.

6. Operative word is the discussion is **Indicated Examination** – appropriate examination. When used appropriately, CT is, perhaps, our most valued diagnostic examination.

7. The diagnostic imager has a choice of modalities and, therefore, can use the most appropriate one – US and MR have no radiation; angiography has more radiation (risk/benefit decision).

   "If your only tool is a hammer, you use it for inserting nails, screws, or fixing things."

   This is one of the problems with non-imaging subspecialists having CT.

8. Even when examination is indicated, the imager can modify the CT parameters (mA, kVp, phases of examination, etc.) to give the patient the least exposure but still getting diagnostic images. Those not trained in CT physics, image quality and operation of sophisticated imaging equipment will not be able to do this.

9. ALARA concept

   As **L**ow **A**s **R**easonably **A**chievable dosage is our goal:

   a.) Communication with referring physician

   b.) Indicated exam

   c.) Proper parameter

      1) Age group

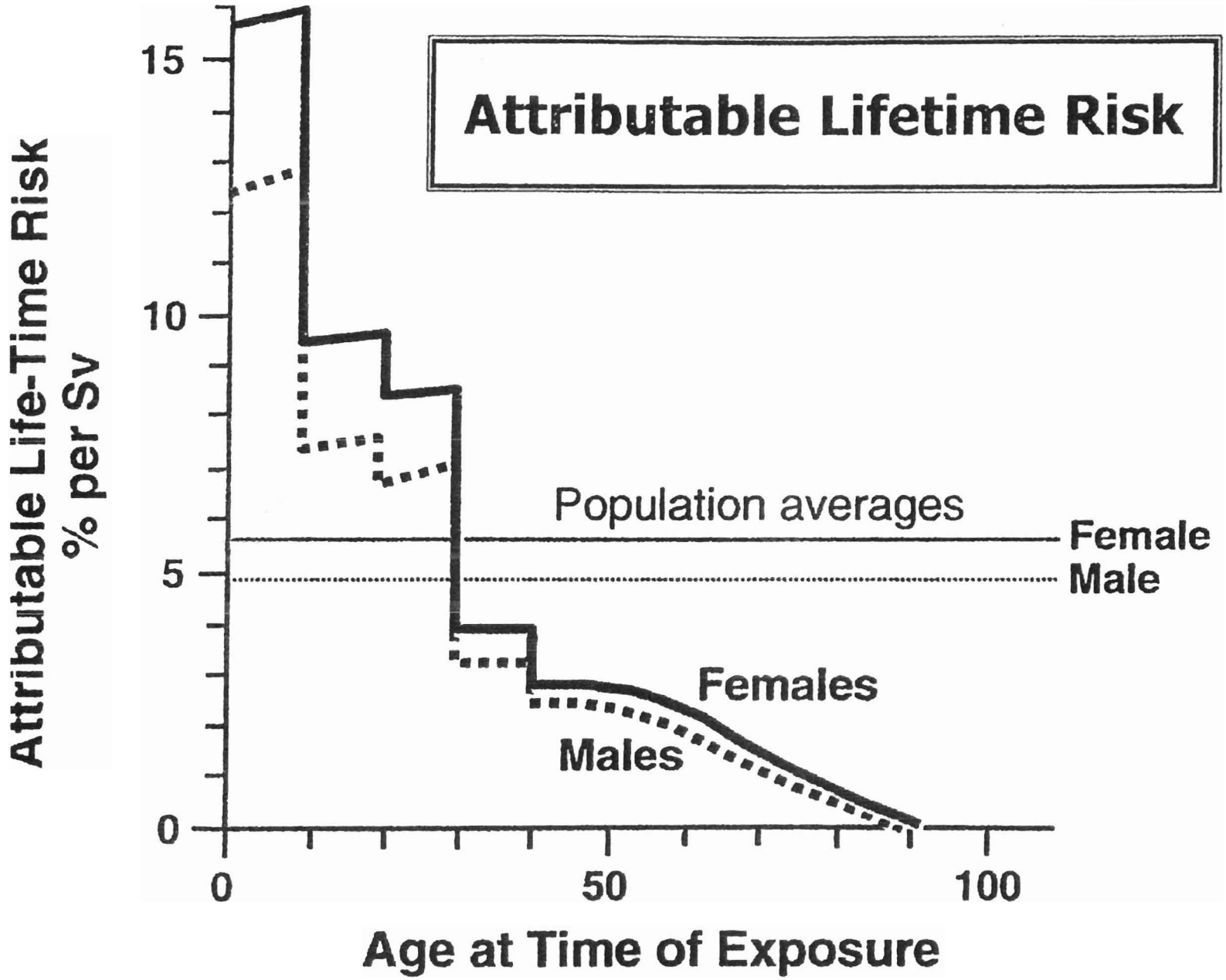
      2) Kind of CT exam

Following the ALARA concept is the responsibility of all of us!

References

1. Slovis TL. Biologic effects of radiation on children. In: Kliegman RM, Behrman RE, Jenson HB, Stanton BF (eds) Nelson Textbook of Pediatrics, 18th ed. Saunders Elsevier, Philadelphia, 2007; Chapter 706, pp 2899-2906.
2. Slovis TL, Frush DP, Berdon WE, Hall EJ. Biological effects of diagnostic radiation on children (Chapter 1). In: Slovis TJ (ed) Caffey's Pediatric Diagnostic Imaging, 11th edn. Elsevier, Philadelphia, 2007 (*in press*).
3. Adelstein SJ, Hall EJ, Brenner DJ, et al. Evaluation of the linear-nonthreshold dose-response model for ionizing radiation. National Council on Radiation Protection and Measurements Report No. 136 (2001).
4. Brenner DJ. Estimating cancer risks from pediatric CT: going from the qualitative to the quantitative. Pediatr Radiol 2002; 228-231.
5. Brenner DJ, Elliston CD, Hall EJ, Berdon WE. Estimated risks of radiation-induced fatal cancer from pediatric CT. AJR 2001; 176:289-296.
6. Pierce DA, Preston DL. Radiation-related cancer risks at low doses among atomic bomb survivors. Radiat Res 2000; 154:178-186.
7. Radiation & Pediatric Computed Tomography: A Guide for Health Care Providers (2002). National Cancer Institute and The Society for Pediatric Radiology. www.cancer.gov or www.pedrad.org

Figure 1



Hall Pediatric Radiology Apr 2002 pg 226

Attachment A

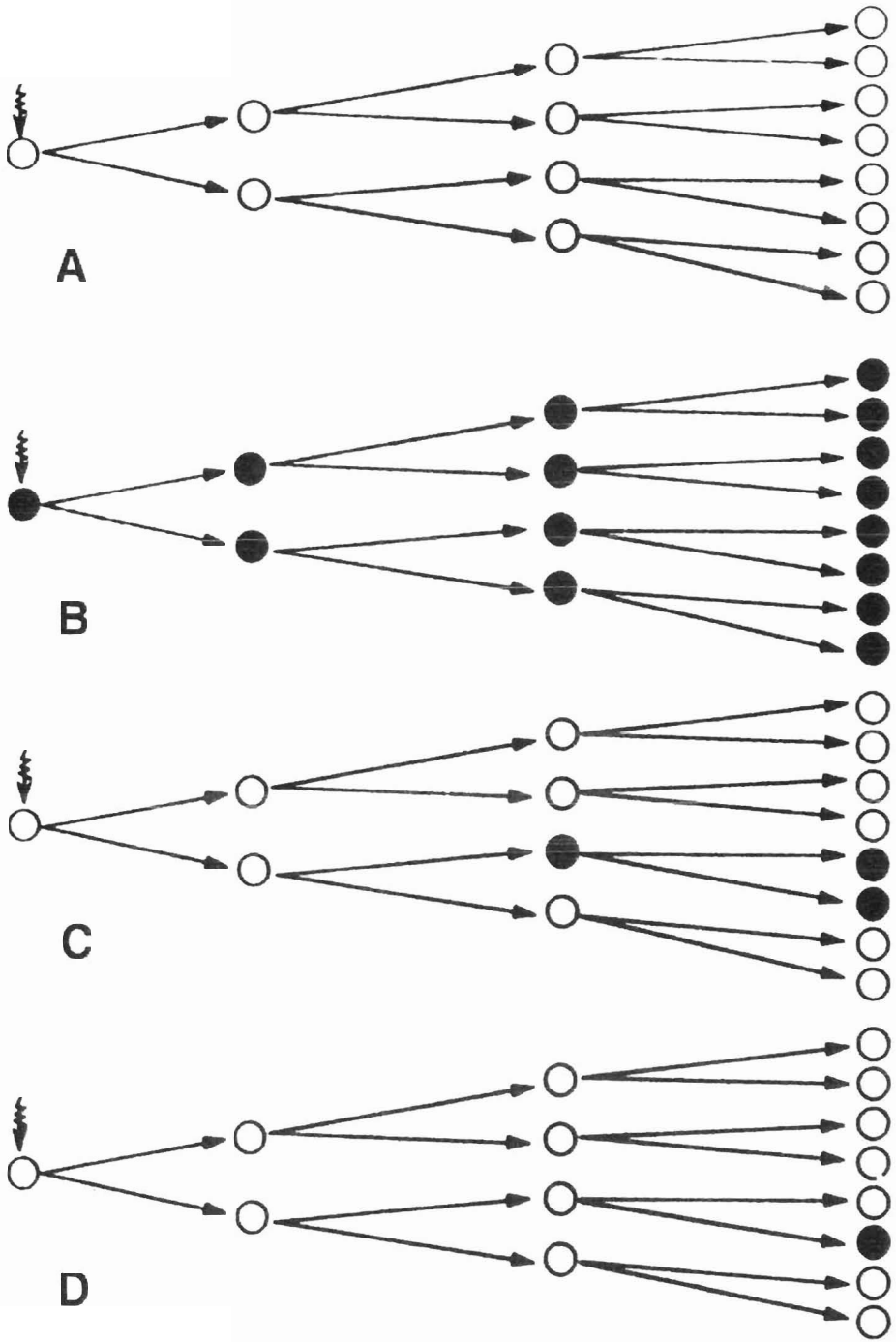
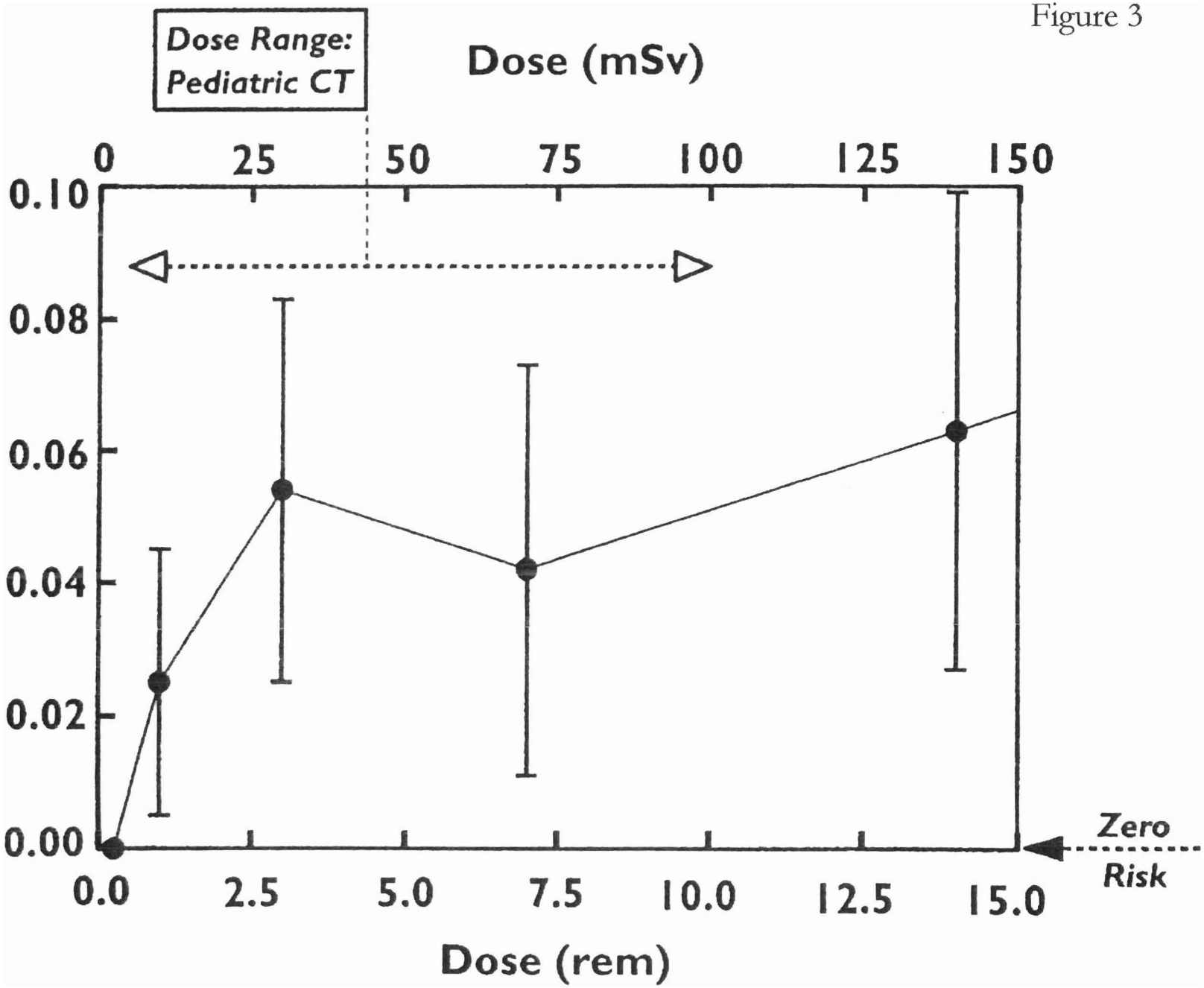


Figure 2

Little JB: Ionizing Radiation in Cancer in Medicine 2003

Attachment A

Figure 3



Pierce, Preston, Rad Res 154 pg 178-186: 2000 Brenner Pediatric Radiology Apr 2002 pg 230

Attachment A

Table 8. Risks of Death from Various Activities*

Activity	Risk of Death (per million/year)
Being a person age 55 years (all causes)	10,000
Smoking a pack of cigarettes daily (all causes)	3,500
Rock climbing for 2 h (accident)	500
Canoeing for 20 h (accident)	200
Motorcycling for 1,000 miles (accident)	200
Traveling 1,500 miles by car (accident)	40
Being a pedestrian (accident)	40
Working 1 week as a firefighter (accident)	15
Working 1 week in agriculture (accident)	10
Fishing (drowning)	10
Eating (choking on aspirated food)	8
Skiing for 10 h (accident)	8
Working 1 month in a typical factory (accident)	5
Traveling 5,000 miles by air (accident)	5
Having a chest radiograph (radiation-induced cancer)	1
Visiting Denver for 2 months (cancer from cosmic rays)	1
Living in the vicinity of a nuclear power plant (radiation-induced cancer)	< 0.1

* Little JB: Ionizing radiation. In: Kufe DW, Pollock RE, Weichselbaum RR, Bast RC, Gansler TD, Holland JF, Frei E (eds) Holland-Frei Cancer Medicine, 2nd ed. Ontario, BC Decker, 6th ed, chapter 19, pages 289-301, 2003, with permission.

Figure 4

Draft Standards Changes for Dental CT Exemption

Section 2. Definitions

Modify definition of CT scanner as follows:

(i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gama ray emitters, positron annihilation CT systems, magnetic resonance, ~~and~~ ultrasound computed tomographic systems, **AND SYSTEMS USED EXCLUSIVELY WITHIN THE PRACTICE OF DENTISTRY, AS DEFINED IN MCL 333.16601(1)(d), THAT GENERATE A PEAK POWER OF 5 KILOWATTS OR LESS.**

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.16601 Definitions; principles of construction.

Sec. 16601. (1) As used in this part:

(a) "Assignment" means that a dentist has designated a patient of record upon whom services are to be performed and has described the procedures to be performed. The dentist need not be physically present in the office or in the treatment room at the time the procedures are being performed.

(b) "Dental laboratory" means a dental workroom operated as a part of a dental office or otherwise, by a person, other than a dentist, who is engaged in, or holds himself, herself, or itself out as being directly or indirectly engaged in, constructing, repairing, or altering prosthetic dentures, bridges, orthodontic or other appliances, or structures to be used as substitutes for or as a part of human teeth or jaws or associated structures, or for the correction of malocclusions or deformities.

(c) "Dentist" means an individual licensed under this article to engage in the practice of dentistry.

(d) "Practice of dentistry" means the diagnosis, treatment, prescription, or operation for a disease, pain, deformity, deficiency, injury, or physical condition of the human tooth, teeth, alveolar process, gums or jaws, or their dependent tissues, or an offer, undertaking, attempt to do, or holding oneself out as able to do any of these acts.

(e) "Practice as a dental assistant" means assistance in the clinical practice of dentistry based on formal education, specialized knowledge, and skill at the assignment and under the supervision of a dentist.

(f) "Practice as a dental hygienist" means practice at the assignment of a dentist in that specific area of dentistry based on specialized knowledge, formal education, and skill with particular emphasis on preventive services and oral health education.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code and part 161 contains definitions applicable to this part.

History: 1978, Act 368, Eff. Sept. 30, 1978

Compiler's note: For transfer of powers and duties of certain health-related functions, boards, and commissions from the Department of Licensing and Regulation to the Department of Commerce, see E.R.O. No. 1991-9, compiled at MCL 338.3501 of the Michigan Compiled Laws.

Popular name: Act 368

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PROPOSED LANGUAGE FOR REDEFINING "DENTAL PROCEDURES"

Proposed by CT SAC member Dr. Sharon Brooks

Current language (page 2 of 15, draft 9-28-07, line 66-67)

Section 2, Definitions

(M) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

Proposed language

(M) "Dental procedures" means procedures used to treat conditions of the teeth, jaws and maxillofacial complex. ~~They include, but are not limited to, dental implants, third molar (wisdom teeth) surgical procedures, mandibular or maxillary surgical procedures; and temporomandibular joint evaluations.~~