**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0739

**Measure Title**: Radiation Dose of Computed Tomography (CT)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 2/10/2014

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome:

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Part A: distribution in radiation dose metrics (i.e. mean, median 75% and 95% in distribution of the following specific CT radiation dose metrics: CTDIvol, DLP, Effective Dose and SSDE) associated with computed tomography (CT) examinations of the head, chest, and abdomen/pelvis performed among children (within specified age strata) and adults. This is the first part of a two-part measure, and these metrics are calculated at the facility or health plan level.

Process: Part B: The proportion of CT examinations where a measure of dose is included in the final medical report. This is the second part of a two-part measure)

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

**Brief Summary:** Radiation is a well-studied carcinogen. Radiation is used for CT scanning, but because it is a known carcinogen, it must be used in the safest way possible. Facilities are currently using higher doses of radiation for medical imaging with CT then needed for diagnosis *(Smith-Bindman JAMA Int Med 2009; JAMA 2012; JAMA Pediatrics 2013.)* Further, they are in general unaware of the doses they routinely use for their patients. The adoption of a standard metric for summarizing dose at the facility level would allow facilities to compare their performance to other facilities, and pooling dose data created can further be used to generate benchmarks for CT. This process of assessment of dose and comparison to benchmarks would enable facilities to lower the doses they use and thereby reduce this important potential harm of imaging. Miglioretti et al (*JAMA Pediatrics 2013*) has estimated that the reduction in the outlier doses (i.e., doses > 75th percentile in distribution) could reduce the burden of radiation related cancers in children by 40%. Radiologists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted and, therefore, there is great potential for practice variation that could introduce unnecessary harm from excessive radiation dosing. Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for radiologists to standardize their practice. Currently, radiologists do not know the typical radiation doses received by their patients. Almost certainly non-radiologists who are conducting CT studies also do not know the radiation doses delivered to their patients. Facilities that complete the data analysis as part of this measure would rapidly understand the doses they use and how they compare to other facilities, and would motivate improvement. Further, if this measure was adopted by quality organizations, assessment of facility processes of reviewing dose could further improve quality.

The second part of the measure, reports the proportion of CT examinations with the reporting of dose in the medical record. This second part of the measure similarly seeks to increase dose awareness. Reporting the radiation dose in the medical record is required per California Law that went into affect June 2012, and currently all practices where CT is performed in California report the dose in the medical record.

**Details of Rational for Measure**

Radiation can be harmful: Radiation is one of the most heavily studied carcinogens, and extensive epidemiologic and biological evidence supports that radiation doses in the range delivered by medical imaging with CT increase cancer risk. The epidemiologic evidence comes from studies indicating cancer development among survivors of environmental and accidental exposures, populations repeatedly irradiated for benign conditions or diagnostic imaging, patients receiving radiotherapy for malignant disease, and people who received occupational exposure, such as radiologists and nuclear power workers. *(BEIR VII Report)*. The literature on the health effects of exposure to ionizing radiation is summarized in the BEIR VII phase 2 report (Board of Radiation Effects Research Division on Earth and Life Sciences "Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington, D.C." The National Academies Press, 2006. The BEIR VII committee, the most widely sited source on the topic, concluded after an exhaustive review of the literature that no dose of radiation should be considered completely safe, and attempts should be made to keep radiation doses as low as possible. As part of their report, The BEIR VII report presented the best risk estimates for exposure to low-dose, radiation in human subjects, which largely rely in large part on results of the Life Span Study (LSS), the study of the 120,000 survivors of the atomic bombings in Hiroshima and Nagasaki Japan. Organ specific radiation doses are linked with organ specific risks of cancer and cancer mortality. Researchers have used these data to estimate the risk of exposure to a single medical imaging study. For example, Einstein and colleagues estimated the risk of cancer associated with the radiation exposure from a single 64-slice computed tomography coronary angiography was as high as a 1/114. Smith-Bindman found in our work that the risk of cancer could be as high as 1/80. (JAMA Internal Medicine 2009)

Direct studies of CT Two studies have directly assessed cancer risk associated with CT. Retrospective, population-based cohort studies by Pearce et al. *(Lancet 2012)* compared children in the UK who received two or more CTs to children who underwent a single CT. Those with multiple CTs had a small but significant increased risk of leukemia and brain cancer. Matthews et al. *(BMJ 2013)* compared children and adolescents in Australia who were exposed or not exposed to CT. Over ten years, exposed children had a 24% greater chance of developing cancer. Thus Radiation in the same dose range as used with Computed Tomography is known to be carcinogenic.

The risk of radiation induced cancer, is widely believed to be approximately proportional to the level of radiation exposure. Reduction in radiation exposure will be associated with reduction in cancer risk *(BEIR VII Phase 2, 2006; JAMA Internal Medicine 2009, Berrington de Gonzales 2009; Miglioretti JAMA Pediatrics 2013)*

Currently no formal program of oversight

Although radiation dose information is not currently collected in the US, programs exist in many European countries, Canada and Asia, for collecting the dose information using the indices specified in this measure. They have found the doses can be reduced through data collection and reporting. These programs have collected and reported dose information for many years, largely using voluntary programs, and this has resulted in a lowering of typical radiation dose. The most well-known and published program is run through the National Radiological Protection Board (NRPB) in the United Kingdom. The most recent report, NPRB-W67, describes a snapshot of patient CT dose. (Doses from Computed Tomography (CT) Examinations in the UK - 2003 Review. Shrimpton PC et al. National Radiological Protection Board, Childton, Didcot, Oxon, ISBN 0 859515567, http://www.mendeley.com/research/nrpbw67-doses-from-computed-tomography-ct-examinations-in-the-uk-2003-review/) The doses described in this report are on average approximately 50% lower than the doses used in the US. The near absence of widely collected data on current doses in the US, agreed upon standards for how the CTs should be programmed (meaning how these complex machines should be instructed to conduct the examinations), or an agreed upon metric whereby data could be collected and analyzed across facilities has led to the current situation where each facility decides on how to set up their individual CT scans. Further, the absence of widely published guidelines for acceptable ranges of dose in the US would make it difficult for an institution to know if they are doing well in minimizing this important harm of CT.

Oversight of CT is limited and highly fragmented, with no single organization assigned responsibility to ensure the standardization of CT dose when used in clinical practice. For example, while the FDA monitors the manufacture of CT machines, they do not assess how they are used in routine practice and they do not collect information on actual clinical practice. However, the FDA, have recently highlighted in their white paper on minimizing radiation dose the pressing need to collect dose information associated with the most common types of diagnostic CT and to use these data to generate standards for targeted dose.

Radiation doses used in clinical practice are highly variable: CT radiation doses are higher and more variable than widely reported,and can vary up to 50-fold across institutions for patients imaged for the same clinical reason *(Miglioretti JAMA Pediatrics 2013; Smith-Bindman JAMA 2012; Smith-Bindman JAMA Internal Medicine 2009)*. We have published extensively on this variation. For example, we found a range of 4.8 to 137 mSv in effective dose for an abdominal CT in children aged 1-4 years. Only a small part of the variation is due to appropriate accommodation of patients of difference sizes; most variation reflects physician and technologist preferences, rather than doses needed for improved diagnosis.

The doses used for CT can be readily reduced, thereby reducing the risks of imaging, by 40% or more without loss of diagnostic accuracy.

The first step towards reducing dose is for facilities to quantify their doses. The NQF endorsed measure provides the only simply way for facilities to compare their doses to national norms, and thereby reduce the high doses they use in their patients. The comparison to benchmarks had been done in the UK as part of the National Health Service Health Protection Agency Program for over 10 years. Two recent papers used the endorsed NQF measure as the framework for assessing the doses they used *(Keegan Journal of the American College of Radiology 2014; Miglioretti, Journal of the American College of Radiology 2014*)

Adoption of a simple standard for collection of radiation dose information would help facilities understand their current practice, would allow comparisons to local and national standards, and would indicate to facilities whether there is a need to improve. There is currently a high level of interest in this area - facilities are being asked by their patients and governing boards to report whether they are performing CT safely - and this measure is an ideal starting point for facilities to assemble this information to answer these questions. If facilities collect dose information, it is the first step towards trying to compete on a measure of safety and I envision facilities will begin to do all they can to lower the doses they use.

The measure will facilitate to the creation of regional and national diagnostic reference levels, improve dose awareness and inevitable improvements, as it will enable physicians to consider dose as an important measure.

The second part of the measure, reports the proportion of CT examinations with the reporting of dose in the medical record. This second part of the measure similarly seeks to increase dose awareness. Reporting the radiation dose in the medical record is required per California Law that went into affect mid 2012.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Click here to enter date range

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

The evidenced is compelling for a strong association between radiation exposure and cancer risk. The risk is based on a large number of observational studies, case control studies, and cohort studies.

Information that radiation dose can be summarized comes from several large observational studies, including several included with this application.

There is uncertainty regarding the exact quantification of the risk associated with radiation associated with medical imaging but widespread belief in the need to lower and standardize dose. All radiology professional organizations (such as the American College of Radiology, ACR) physics professional organizations (such as American Association of Physicists in Medicine) and oversight organizations (such as National Council on Radiation Protection and the FDA) have endorsed the goal of lowering radiation dose from CT. See the American College of Radiology published a White Paper on Radiation Dose in Medicine (Amis SE, et al, JACR 2007).

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

Radiation dose associated with CT has been studied and standardized in the UK and Europe for over 10 years, although no comparable work has been done in the US. The metrics to measure dose have been well established, and data in the UK has been collected in a format that parallels the method proposed in this measure.

The recommended measure is a technique for summarizing dose and is simple and straightforward. Facilities summarize the doses they use in consecutive patients so that they can compare their doses to normative data. Currently there is relatively little published data, although do not exceed levels are published by the American College of Radiology. Further, we have, and will continue to publish papers describing benchmarks using the NQF endorse measure as a method to report dose.

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

Amis ES, Jr., Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol 2007;4:272-84.

Hausleiter, J., T. Meyer, et al. (2009). "Estimated radiation dose associated with cardiac CT angiography." JAMA 301(5): 500-7.

Hricak H, Brenner DJ, Adelstein SJ, et al. Managing Radiation Use in Medical Imaging: A Multifaceted Challenge. Radiology 2010.

Board of Radiation Effects Research Division on Earth and Life Sciences National Research Council of the National Academies. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington, D.C.: The National Academies Press; 2006.

Einstein AJ, Henzlova MJ, Rajagopalan S. Estimating risk of cancer associated with radiation exposure from 64-slice computed tomography coronary angiography. JAMA 2007;298:317-23.

Keegan, DL Miglioretti, R Gould, LF Donnelly, N Wilson, R Smith-Bindman. Radiation Dose Metrics in Computed Tomography: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. In press, Journal of the American College of Radiology 2014.

Mathews J, Forsythe A, Brady Z, al. e. Cancer risk in 680 000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. BMJ 2013;346 doi: <http://dx.doi.org/10.1136/bmj.f2360>

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311 2013.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure from Computed Tomography. In press Journal of the American College of Radiology 2014.

Nationwide Evaluation of X-ray Trends: NEXT 2005-2006. This presentation was given by David Spelic, physicist with the Food and Drug Administration (FDA), to the 39th Conference of Radiation Control Program Directors (CRCPD) annual meeting, held in Spokane Washington, May 21-24, 2007.

Morin, R. L. (2006). "CT dosimetry--an enigma surrounded by a conundrum." J Am Coll Radiol 3(8): 630.

Morin, R. L. (2006). "What are the national radiation doses?" J Am Coll Radiol 3(12): 956.

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet 2012;380:499-505.

Preston DL, Ron E, Tokuoka S, et al. Solid cancer incidence in atomic bomb survivors: 1958-1998. Radiat Res 2007;168:1-64.

Preston RJ. Update on linear non-threshold dose-response model and implications for diagnostic radiology procedures. Health Phys 2008;95:541-6.

Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. Arch Intern Med 2009;169:2078-86.

Smith-Bindman R. Is computed tomography safe? N Engl J Med 2010;363:1-4.

Smith-Bindman R. Environmental causes of breast cancer and radiation from medical imaging: findings from the Institute of Medicine report. Arch Intern Med 2012;172:1023-7.

Smith-Bindman R, Miglioretti DL, Johnson E, et al. Use of diagnostic imaging studies and associated radiation exposure for patients enrolled in large integrated health care systems, 1996-2010. JAMA 2012;307:2400-9.