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Comments on the Second Draft Report: Patient Safety Measures

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
1	James A. Brink, MD	Yale Diagnostic Radiology	Public	PSM-043-10: Participation in a Systematic National Dose Index Registry	Commonly used dose indices (CTDIvol and DLP) are measures of the radiation output of the CT scanner, not the radiation dose absorbed by an individual patient. These measures vary greatly according to body habitus. A large person is expected to have values that are much greater than a small person. When analyzed for a large group of people, variations based on body habitus are averaged, and meaningful comparisons can be made. Similarly, estimates of the effective dose human beings rely on conversion factors that are applied to these measures of machine output and generate a dose estimate for a standard size human, not for a specific patient. Thus, I support measure PSM-043-10 (Participation in a Systematic National Dose Index Registry) as it reflects the population-basis of these measures. I also support measure PSM-044-10 (Radiation Dose of Computed Tomography) so long as it is made clear that the reported measures are not indicative of the dose absorbed by an individual patient.	Measure developer's response: We appreciate the commenter's support.	NQF's response: Language in report may need to be modified for additional clarity. For SC consideration-suggested language for draft report below. "Steering Committee members expressed concerns about the age cut-off for children and the lack of stratification of patients by weight. The developer noted that while children's radiology results tend to be linked to data on weight, this is rarely the case for adult radiology results. The developer suggested that collecting such data would pose a substantial burden for providers."

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2	James A. Brink, MD	Yale Diagnostic Radiology	Public	PSM-044-10: Radiation Dose of Computed Tomography (CT)	Commonly used dose indices (CTDIvol and DLP) are measures of the radiation output of the CT scanner, not the radiation dose absorbed by an individual patient. These measures vary greatly according to body habitus. A large person is expected to have values that are much greater than a small person. When analyzed for a large group of people, variations based on body habitus are averaged, and meaningful comparisons can be made. Similarly, estimates of the effective dose human beings rely on conversion factors that are applied to these measures of machine output and generate a dose estimate for a standard size human, not for a specific patient. Thus, I support measure PSM-043-10 (Participation in a Systematic National Dose Index Registry) as it reflects the population-basis of these measures. I also support measure PSM-044-10 (Radiation Dose of Computed Tomography) so long as it is made clear that the reported measures are not indicative of the dose absorbed by an individual patient.	Measure developer's response: I appreciate Dr. Brinks support of measure 044-10. The measure is intended to assess the quality and safety of CT and doses used at the machine, and facility level.	NQF's response: Addressed in previous comment-language in report may need to be modified for additional clarity. Language suggested for draft report below: "Steering Committee members expressed concerns about the age cut-off for children and the lack of stratification of patients by weight. The developer noted that while children's radiology results tend to be linked to data on weight, this is rarely the case for adult radiology results. The developer suggested that collecting such data would pose a substantial burden for providers."

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3	Ms. Tanya Alteras, MPP	National Partnership for Women & Families	Consumer	Comments on the general draft report	The Consumer-Purchaser Disclosure Project appreciates the opportunity to provide comments to NQF on the second set of patient safety measures currently being recommended for endorsement. Overall, we are very disappointed with the five measures that are now out for comment. Regarding the three colonoscopy measures, we feel that these reflect standard-of-practice activity, and that the NQF endorsement process should not be a means of enforcing basic standards. Standards related to colonoscope cleanliness and reprocessing guidelines should be certainly be enforced, but through other oversight and accreditation bodies, not through the quality measurement enterprise. The bigger question here is where does this type of measurement activity end? If NQF endorses these types of colonoscope measures in the name of patient safety, does that open the door to discrete measures for every type of medical equipment used in practice for which special training and		NQF's response: Submitted measures met the conditions for consideration. The SC evaluated each measure against NQF's measure evaluation criteria. For SC consideration. In particular, note the highlighted portion.

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					guideline updates are the norm? Regarding the two radiation dosing measures, it is not clear how these passed the importance test, given the statements in the report that radiation indices are not reflective of actual radiation dosing. Further, it is unclear how these measures would be useful to consumers, purchasers or other stakeholders, without a better sense of what the radiation index means for patient safety. Overall, while the first set of infection measures to come out of this project added value to the patient safety portfolio, we do not believe that the measures being recommended for endorsement in this second phase of the project meet the high bar that NQF endorsement represents.		

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4	Ms. Tanya Alteras, MPP	National Partnership for Women & Families	Consumer	PSM-014-10: Colonoscope Processing Personnel Instruction	The three colonoscope measures reflect activity that should be standard of practice, and at the very most, may be appropriate for internal quality improvement. While the goal of reducing the rates of viral infection associated with colonoscopy is certainly one that we support, we do not feel that the best method of doing so, within the quality enterprise, is by endorsing structural measures of whether an office or Ambulatory Surgery Center a) receives colonoscope operating instruction updates annually, b) reviews colonoscope device reprocessing guidelines annually; or c) documents that their staff are competent at reprocessing colonosopies and/or changes made in the equipment or recommendations. As noted in the report, issues of adherence to training and cleaning guidelines are more appropriately addressed through state and medical licensing bodies. When we consider measures for NQF endorsement, we must consider whether we believe the measures	Measure developer's response: The AAAHC Institute for Quality Improvement thanks the National Partnership for Women & Families for the comments on the three AAAHC Institute colonoscope processing measures. We respectfully disagree with the comments and would like to address them point by point. (1) Regarding a ""standard of practice"" and ""internal quality improvement:"" we agree that the concepts encompassed in these measures are so important that they should be expected and thus a ""standard"" of practice. If in fact these activities were more uniformly practiced, we would be able to treat them as standards, and internal quality improvement activities	

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					should be linked to public reporting or payment programs, and in this case, we believe the answer is no. In addition, these measures are yet further removed from evidence-based linkage to outcomes; they are not even measuring adherence to cleanliness and equipment sterilization standards, but, rather, whether proper training has taken place.	would suffice. However, it has been amply documented that lapses in these practices adversely affect thousands of people each year. The evidence we cite shows the serious problems associated with colonoscope processing competency, standard operating procedures, and training in the Veterans Administration (VA); we are aware of similar issues in private centers; and, direct discussions with leading authorities (writers of the CDC 2008 guidelines, Drs. Rutala & Weber), indicate that their research and experience point to these as the most critical areas of failure. (2) Regarding the roles of medical and state licensing bodies: leaving the issues of adherence to colonoscope processing guidelines,	

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						training, and competency testing to medical licensing bodies begs the question of who has the responsibility--this is a facility level obligation, not an individual's (please see the note in response to the comment from the PCPI re PSM-015-10)--medical licensing bodies address issues associated with the provision of care by individual medical practitioners. Neither inspection of ambulatory facilities by state licensing bodies nor requirement for accreditation has been effectively closed the gap in care cited for these new performance measures. (3) With regard to whether these measures are appropriate for payment and public reporting: these are facility level measures that speak to critical,	

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						well supported processes--they do not need to be risk adjusted and do not have special exclusions. As noted above, these measures address critical patient safety issues, and failure has been associated with serious adverse events. (4) In response to the comments that the measures are ""further removed"" from evidence-based linkages to outcomes: GAO ""root cause analyses"" of the VA issues point directly to issues raised in the measures as the causes of the serious preventable events that occurred. The VA has reported that the disastrous outcomes that occurred were from failure to establish standard operating procedures, and ensure that competency is achieved and maintained	

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						through regular instruction and testing. Further, the CDC HICPAC guidelines include evidence ratings that place the issues addressed in the AAAHC Institute measures as high as many of the ratings for specific aspects of reprocessing and higher than some of these. In sum: yes, everyone should be complying with these measures, but no, not everyone is and this has led to mass notifications of possible exposure to chronic and life-threatening diseases, large outlays for notification and testing, and actual exposure (mortality and morbidity) for patients. We cannot rely on state and medical licensing bodies to ensure compliance with these measures. These are	

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						well-constructed measures (with no need for risk adjustment, nor exclusions) appropriate for facility level measurement and they have received direct support from national guideline recommendations and national experts in this field.	

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5	Ms. Tanya Alteras, MPP	National Partnership for Women & Families	Consumer	PSM-043-10: Participation in a Systematic National Dose Index Registry	It is unclear what value this measure would add to the NQF portfolio as currently described in the report or in the measure submission form. The report notes (in line 264) that dose indices are not directly related to the amount of radiation absorbed by patients, which begs the question of why being able to compare dose index levels will be useful to consumers, purchasers, or providers. We would appreciate NQF explaining in greater detail how being able to compare and benchmark CT dosing levels which is the argument for why this measure is important -- will lead to patient safety improvements related to radiation absorption. We ask that the pre-voting report from this committee discuss this with more clarity and detail so that consumer and purchaser members can make an informed voting decision.	Measure developer's response: As mentioned in response to previous comments above: If dose indices are at optimal levels, then absorbed dose is also optimized. Dose indices measure radiation output of the scanner, i.e. CTDIvol or DLP. Gathering data on the amount of radiation used on patients during an exam – while also examining the associated image quality – can help standardize lower dose techniques on a majority of patients. Measuring actual absorbed dose for each individual patient is logistically and technically difficult, thus "effective dose" has been used as a proxy. Effective dose is calculated by converting scanner output factors (CTDIvol, DLP) to an	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						estimated dose for a standard size patient, not specific to each patient. The goal of the national dose index registry is to collect and compare dose index information across facilities using standard methods of data collection in order to establish national benchmarks for comparative and improvement purposes. With a national registry/database available to accept data, aggregated data can be derived by body part, exam type, scanner type as well as by facility demographic characteristics. This data will be used for developing the much needed national benchmarks for CT dose indices. Facilities that participate in such a national registry will be able to	

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						compare their specific dose indices (by exam type, body part, scanner, etc.) to national averages through frequent reports. This provides a means to set targets for quality improvement and bringing dose indices in line through protocol refinement. Attesting "yes" to such participation indicates the facilities QI efforts. Additionally, local quality improvement efforts that sites are likely to implement based on benchmark comparison reports from the registry should help develop improved exam protocols. Well-honed protocols will provide higher quality images, reducing the need for re-imaging due to poor quality. A second generation of such a measure may be to indicate a facility's	

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						compliance with certain well-established benchmarks, but at this time it is premature to do so.	

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6	Ms. Tanya Alteras, MPP	National Partnership for Women & Families	Consumer	PSM-044-10: Radiation Dose of Computed Tomography (CT)	We have similar concerns with this measure as we do with PSM-043-10, and would like more explanation as to why measuring the radiation dosing index would be meaningful to consumers and purchasers, given the statement in the report about lack of relationship between the index quantity and how much radiation is absorbed by patients. We are supportive of the measure developers statement, noted in the report on line 323, that transparency around dosing information is important for fostering accountability and driving improvement. But as currently described in the report, we do not see how this measure achieves that goal.	Measure developer's response: The doses used for CT are currently highly variable and doses are higher than they need to be for diagnostic accuracy. The purpose of this measure is to reduce both the variability of the doses used in clinical practice and reduce the magnitude of the doses used in clinical practice. These will be brought about by collection and assessment of doses and a reduction in the doses will improve the safety of CT. Thus the measure will not only increase dose awareness, but by asking facilities to compare their doses to national standards, we will encourage creation of benchmarks for quality that will be widely implemented. The statement that there is a lack of relationship between the indices that	

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						will be collected, and the radiation absorbed by the patient is false. There is a very strong relationship between the dose emitted by a machine and the dose absorbed by a patient. Further there is a strong relationship between the dose absorbed by the patient and the radiation detriment (ie harm from that radiation.) Thus these measures of dose are highly associated with measures of safety and harm. The strength of this relationship does not mean it is a simple relationship and that is why , on an individual patient level, its insufficient to just know the dose, but you also need to know weight, height, etc of the patient to fully understand their absorbed dose and the detriment from that dose and the subsequent	

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						estimation of risk of cancer. However, it is very easy to assess if doses are in the normal range, high or very high or dangerously high. The doses that we have found are used in patients are substantially higher than they should be in any circumstances. This same finding of grossly abnormal doses that are sometimes 10 times higher than they should be and sometimes 100 times higher than they should be, and this is the problem that this measure is trying to address. The measures of dose that are presented in this measure are simple to collect, will be extremely useful and will be highly correlated with absorbed dose and are more easily collected. Further, these metrics are those that are widely used as measures of	

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						quality in other countries quality assurance programs around CT	

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7	Stephen Vastagh on behalf of David Fisher	Medical Imaging & Technology Alliance	Public	PSM-043-10: Participation in a Systematic National Dose Index Registry	National Quality Forum Public Comments Docket - Submitted via the NQF Web Portal Re: Support of PSM-043-10: Participation in a Systematic National Dose Index Registry The Medical Imaging Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the collective voice of medical imaging and radiation therapy equipment manufacturers, innovators, and product developers, including companies that manufacture x-ray, computed tomography (CT), diagnostic ultrasound, nuclear medicine, magnetic resonance imaging (MRI), and medical imaging informatics equipment. CT manufacturers have developed a new standard for an important new dose notification feature, the CT Dose Check Standard (http://www.nema.org/stds/xr25.cfm#download). The availability of dose index data assists the hospitals and other providers in the implementation and utilization of this feature. Further, MITA also	Measure developer's response: We appreciate MITA's support of the measure as well as their continued efforts to assist in standardization of communication and the data associated with digital images.	

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					manages the DICOM Standard, the international standard for the communication of digital images and related data . The DICOM standard includes provisions for the reporting of dose index data; dose index databases facilitate the utilization of data recorded to the DICOM reporting specifications. Therefore, MITA supports the Systematic National Dose Index Registry proposal by ACR. Sincerely, Dave Fisher Executive Director		

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8	Ms. Samantha Burch	Federation of American Hospitals	Provider	Comments on the general draft report	The FAH appreciates the opportunity to comment on the five Patient Safety Measures in the 2ndReport recommended for endorsement by the steering committee. We are generally concerned that these five measures will not strengthen the NQF portfolio and do not meet the evaluation criteria for endorsement. We have provided specific comments on each of the measures that further outline our concerns.		No action necessary.

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9	Ms. Samantha Burch	Federation of American Hospitals	Provider	PSM-014-10: Colonoscope Processing Personnel Instruction	The FAH believes that patient safety related to colonoscopy is an important area to focus on, however, we are concerned that the three colonoscope measures fall more within the purview of compliance with accreditation standards and are not true quality measures. If the research shows a concrete, scientific link between colonoscope reprocessing and viral infections (which would be helpful to have had presented in more detail in the report), we believe it would be more appropriate to seek development of a measure with a stronger focus on outcomes rather than create dual tracking of standard practices. We believe these measures illustrate the reason why we have accreditation standards in place and we do not support them as quality measures. We are further concerned, based on the discussions of the Steering Committee, that endorsement of these measures could open the door to similar accreditation-style measures for other devices. We believe this is the wrong approach to promoting quality improvement.	Measure developer's response: Please see the response to AHIP re PSM-014-10 re standards versus quality measures. The research does show that keeping up-to-date on changing technology and colonoscope processing recommendations is a significant issue. Failure in scope processing has been an ongoing issue over the last two decades, during which a very large number of adverse outcomes have been amply documented. Tracking outcomes has not led to a reduction in the gap in care; rather, failures continue to occur. As noted in response to AHIP PSM-014-10 comments, accreditation surveys do not have the frequency or depth to reach issues like these. These measures provide an	

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						opportunity to stop or at least put a significant dent in the occurrence of adverse outcomes caused by improper colonoscope reprocessing.	

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10	Ms. Samantha Burch	Federation of American Hospitals	Provider	PSM-043-10: Participation in a Systematic National Dose Index Registry	The FAH is unclear how, with a focus on dose indices and not the amount of radiation absorbed, this measure would provide useful information to clinicians, hospitals, or patients. Further, the FAH continues to be concerned about introducing additional check the box measures that track only participation in a given type of registry. While participation in a registry could lead to quality improvement, we believe it is misleading to consumers to suggest that registry participation is an absolute indication of quality. Hospitals use a variety of methods for tracking their performance and improvement, including internal data capture and analysis within their institution. With the implementation of electronic health records, hospitals will greatly increase their capacity to do much of the measurement and analysis that registries perform today.	Measure developer's response: If dose indices are at optimal levels, then absorbed dose is also optimized. Dose indices measure radiation output of the scanner, i.e. CTDIvol or DLP. Gathering data on the amount of radiation used on patients during an exam – while also examining the associated image quality – can help standardize lower dose techniques on a majority of patients. Measuring actual absorbed dose for each individual patient is logistically and technically difficult, thus "effective dose" has been used as a proxy. Effective dose is calculated by converting scanner output factors (CTDIvol, DLP) to an estimated dose for a standard size patient, not specifically that patient.	

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						Learning about radiation dose output better enables clinicians to optimize the amount that is delivered. The educational element is critical for adjusting exam protocols so that the lowest dose possible is given while still maintaining image quality. In regards to comment on the registry measure as a "check the box" measure, please see previous response to Comment #24. Additionally, as far as the measure suggesting to consumers that registry participation is an absolute indication of quality – the same could be argued about the public reporting on clinician/provider submission of quality data, as in the CMS Physician Quality Reporting System (PQRS), where currently	

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						the Physician Compare website only reports that an eligible provider reported data, not actual performance. Granted, that is not optimal information to provide to consumers or other interested parties, but measures of participation may serve alternatively as a starting point, particularly to begin decreasing variation in practice. Setting optimal radiation dosing for imaging procedures is complex, technical, with a multitude of factors and parameters to take into consideration, as previously described. At this point, describing levels of radiation dosing quality/safety in absolute terms of patient absorbed doses for certain imaging exams is not possible, feasible or appropriate and could potentially result in harm through	

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						misinformation. A second generation of this measure may be to indicate a facility's compliance with certain well-established benchmarks, but at this time it is premature to do so.	

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11	Ms. Samantha Burch	Federation of American Hospitals	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	The FAH reiterates our concerns related to the usefulness of this measure to providers and patients as, per the report, dose indices are not directly related to the amount of radiation absorbed by the patient. This is an area where additional clarification would be extremely useful prior to voting on these measures.	Measure developer's response:The doses reflected in the metrics proposed will very much reflect the doses that patients are exposed to. Thus these measures are highly relevant to the patient.These measures are highly correlated with the doses patients receive; higher DLPs, CTDIs and Effective doses are associated with higher absorbed dose to the patient's organs and higher patient detriment (harm). If these doses were lowered (using any of these three metrics), patients would be exposed to lower doses of radiation, have correspondingly lower absorbed organ doses and would be expected to have less detriment from these exposures to radiation. Estimating absorbed organ doses would be the most	

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						precise way to compare doses between patients, however, it is much more complicated to estimate these parameters, as they would be influenced by the size of the patient. However, not only is it more complex to make these measurements , the technologist/radiologist cannot directly influence these measures, and there would be way to practically compare organ doses as there are too many organ doses to compare (30 or more); this is the reasons that organ dose was not proposed as a metric. The output of radiation from the machine is far simpler to measure and in fact is the important variable, as this is what the radiologist and the technologist can influence. As pointed out by Dr Brink, Chair of Radiology at Yale who	

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						wrote a comment, the measures are primarily proposed to reflect the average CT dosing at the institutional level and small variations in patient size will average out across institutions.	

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12	Ms. Maureen Dailey, DNSc, RN	American Nurses Association	Health Professionals	Comments on the general draft report	The Steering Committee advocated for the creation of broader medication safety measures with far reaching impact on patient health outcomes (line 502-503, pg. 21). The American Nurses Association (ANA) respectfully submits the following comments: Medication safety in computer provider order entry (CPOE) has been noted to be problematic to clinicians without adequate training on the health care professional team (e.g., e.g., physicians, nurses), which may negatively impact patient safety outcomes (i.e., may increase errors of omission and commission related to lack of evidence-based practice) ANA supports the development of broader cross-cutting medication safety measures as identified by the Steering Committee in the Additional Comments section (line 510-511)		No action necessary.

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13	Ms. Rabia Khan, MPH on behalf of Michael Rapp	Centers for Medicare and Medicaid Services	Purchaser	Comments on the general draft report	I agree with the Committee that cross cutting measures for medication safety are needed and more measures are needed for perinatal care.		No action necessary.

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14	Ms. Rabia Khan, MPH on behalf of Michael Rapp	Centers for Medicare and Medicaid Services	Purchaser	PSM-014-10: Colonoscope Processing Personnel Instruction	The following comments refer to all of the Colonoscope measures: It is a great topic area, as it is high cost and high volume to Medicare. The data source for these measures is problematic, because they rely on survey methods or self reporting by the provider. Surveys only capture a snapshot in time. Capturing all of the requirements of the measures would be burdensome, especially to ASCs who have limited resources and staff. According to line 215, it appears that reprocessing standards may not exist to the extent that facilities or individual providers can be held accountable. Are there evidenced-based guidelines developed by specialty societies that can work together to create these standards? Not all facilities use the same scopes/equipment to do their procedures. Therefore, each individual manufacturer specifications would need to be taken into account, as they would more than likely have their own maintenance recommendations. Time-limited endorsement is appropriate in order to facilitate		No action necessary.

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					collection of feasibility and testing data in the ASC and office settings, and provide data on variation and opportunity for improvement.		

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15	Ms. Rabia Khan, MPH on behalf of Michael Rapp	Centers for Medicare and Medicaid Services	Purchaser	PSM-043-10: Participation in a Systematic National Dose Index Registry	This measure supports decreased radiation levels and improved quality of images that facilitate successful interpretation and diagnosisboth patient safety issues. Feasibility for this measure is strong, supported by electronic image archiving and communication by most radiology practices. This is an attestation measure, indicating whether the reporting facility participates in a national dose index registry or standard data collection program, similar to the national registry of the ACR, which will be ready for use mid-late 2011. Specifications state this data would come from the medical record, is this something that is normally recorded in the medical record?	Measure developer's response: We appreciate the commenter's recognition that the measure/registry supports quality improvement and safety of imaging procedures. We would like to confirm the feasibility of the measure and the registry. The ACR Dose Index Registry is completing Phase II pilot and will roll out to all interested participants in May 2011. The registry will provide for consistent, standardized, automated data collection with anonymization of patient data and aggregated data available to sites through regular reports. This will eliminate need for data entry and reduce errors and burden. The measure itself is a straightforward attestation of participation. Lists of	

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						participating facilities can be provided. The data elements used in the registry are data that is associated with the exam image. The image and associated data is most often stored in a Picture Archiving and Communication System (PACS) but may be also stored on the scanner, other server or EHR. In all cases, the data/image is considered to be part of a patient's medical record.	

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16	Ms. Rabia Khan, MPH on behalf of Michael Rapp	Centers for Medicare and Medicaid Services	Purchaser	PSM-044-10: Radiation Dose of Computed Tomography (CT)	Who would this measure be attributable to? Would it be the ordering physician or the radiology tech that performs the scan? Is it normal practice to record the data elements required for the measure? A minimum sample size (number of scans for adults and children) is needed; therefore, the measurement period for the numerator will vary depending on the facility. Also, the measure addresses dose indices rather than dose levels sustained by the patient. An advantage is the increased transparency regarding dosing and accountability for improvement at the facility level. Also, the measure facilitates aggregate data collection and public reporting, and feedback and comparison by facilities to regional and national practices.	Measure developer's response:The dose indices will reflect physician and technologist and to some degree the equipment. Thus the measure is specified within machine strata. Two of the elements that are needed for this measure are routinely displayed on all CT examinations (DLP and CTDI) and Effective Dose can be easily calculated from these measures (its requires multiplying the DLP by coifficients that vary by anatomic region and for children, by age). Most CT scanners in the US operate at very high daily volumes (to maximize the number of examinations that can be conducted) thus while the measurement period will vary by facility size, and by how many different types of CT	

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						scanners they have, the largest different will be in the frequency with which they scan children. As explained elsewhere in my responses to comments, the dose indices will very much reflect the doses the patients will absorb. The dose indices that will be collected are highly correlated with the doses patients receive; higher DLPs, CTDIs and Effective doses are associated with higher absorbed dose to the patient's organs and higher patient detriment (harm). If these doses were lowered (using any of these three metrics), patients would be exposed to lower doses of radiation, have correspondingly lower absorbed organ doses and would be expected to have less detriment	

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						from these exposures to radiation.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
17	Ms. Rabia Khan, MPH on behalf of Michael Rapp	Centers for Medicare and Medicaid Services	Purchaser	Comments on measures not recommended	PMS-010-10, 11, 12, 13agree with not endorsing these measures, as they are check box measures. Comments on Medication Safety Measures (017-10 through 031-10): Related to the importance criterion, evidence-based support for these measures was not grounded in studies or clinical trials to provide guidelines for appropriate monitoring. Adverse events related to the medications and conditions is lacking in formal documentation, but in general is considered low volume. These measures would be improved if re-considered and re-specified under a Prevention theme for medications with better evidence-based support for measure concept, measurement period and opportunity for improvement.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
18	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	Comments on the general draft report	On behalf of our more than 5,000 member hospitals and health systems the American Hospital Association (AHA) appreciates the opportunity to comment on the National Quality Forums (NQF) National Voluntary Consensus Standards for Patient Safety Measures, Second Report. We commend the NQF for recognizing the importance of ensuring proper protocols around colonoscopy equipment and consideration of dosing levels associated with certain imaging services. We are not providing specific comments on the colonoscopy measures because the denominator population does not include patients seen in hospitals. The measure developer specifically noted that these measures only apply to patients in ambulatory surgical centers and office-based practices. We have included specific comments on the imaging services below.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
19	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	AHA fully supports measuring radiation doses associated with imaging services. However, we have several concerns with the current construct of this measure concept. We request that the Steering Committee (SC)/measure developer provide more detailed information on the typical range of radiation associated with each of the CT procedures (head, chest, abdomen/pelvis and lumbar spine). Since the measure is currently based on a sample of these procedures, it is critical to understand the range of dosing associated with each type of procedure. Oversampling of one type of procedure may make a particular facility look like an outlier when in fact the problem is over-sampling of a higher dose procedure.	Measure developer's response:Several references are provided for the range of doses observed for CT procedures. For example, in the description of our metric, we cite our paper Radiation dose associated with common CT examinations and the associated lifetime attributable risk of cancer published in the Archives of Internal Medicine in 2009, where the range in observed dose for several CTs was provided. For example, the range in dose for head CT was 0.3 msv – 56 mSv; the range in chest CT was 2.0 mSv – 39 mSv, and abdominal CT was 3 – 90 mSv. Other organizations, such as the ACR dose registry has found even more profound variation (cited in Dr. Morin's letter of support.) The	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						attached paper describing the UK dose quality assurance program, NRPB-SR250: Normalized Organ Doses for X-Ray Computed Tomography Calculated Using Monte Carlo Techniques, describes in great detail the range of dose for many types of examinations. Measure PSM-044-10 has been designed to reflect the collection of a consecutive sample of all head, all chest, all abdomen and pelvis and all lumbar spine exams. There will be no sampling within these groups. Thus the types of procedures (if the comment is referring to the specific protocols used) will be sampled in proportion of the degree to which that particular type of protocol is used at that institution. As described in section 4, by	

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						collecting all examinations, rather than just collecting a sample within each category, facilities will more accurately reflect the doses to which most patients are exposed when they get a head, chest, abdomen or spine CT and thus the measure will be useful and representative. If a facility chooses to use these high dose protocols in the majority of cases, the dose metrics will reflect this, and they are probably exposing their patients to much higher dosing than necessary.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
20	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	We request that the measure developer provide more detail on the testing process this measure has endured. The measure application states that the measure is fully developed and tested, but neither the report nor the measure application provide any additional details. How many facilities was the measure tested in? What types of facilities was the measure tested in? Further, the report states that minimum sample size for this measure to generate sufficient accuracy for adults is 100 scans and the minimum sample size for children is 50. How were these numbers derived? Why is the minimum threshold for these populations so different?	Measure developer's response:The CT dose indices that are proposed (CTDI, DLP, and effective dose) will be collected within anatomic area strata and have been used for many years by diverse quality assurance programs, including the ACR, European quality assurance programs and the FDA. The dose indices that are specified (DLP and CTDIvol) are available on nearly all (>95%) of CT scans conducted in the US. The FDA collects dose data on a sample of imaging examinations every year as part of a collaborative effort with state radiological protection boards called the NEXT survey (Nationwide Evaluation of X-ray Trends). The last year data were collected on CT exams was in 2005.	Part 2 of preceding comment.

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						These data are collected based on phantom studies (ie CTs conducted on sophisticated plastic phantoms rather than patients, thus providing data different from, although complimentary to, the proposed metric). However, as part of that survey the FDA documented that he vast majority of CT machines in operation will document DLP and CTDIvol. (unpublished, information provided by Dave Spelic, FDA). The last proposed index, Effective Dose, can be calculated easily by multiplying the DLP by a factor specific to patient age (child or adult) and anatomic area (head, chest, abdomen/pelvis, spine) and is thus easily calculated from the DLP. Thus the proposed data	

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						have been collected across hundreds of radiology facilities in the US through the NEXT survey. A report published by the National Radiological Protection Board in he UK entitled, "Doses from CT Examinations in the UK - 2003 Review" provides the distribution in dose using the CTDI and DLP and Effective Dose metrics, collected across every facility in the UK and includes descriptive statistics of these metrics across facilities, patients, anatomic areas imaged, manufacturers and machine types and demonstrates the value of these data. The sample size of 100 adults was chosen as an approximate minimum sample size to give a stable estimate of the mean dose used for CT	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						within defined age and machine strata. These values could then be compared within facility over time and could be compared with referent overall population estimates within those strata, assuming a two tailed comparison, with an effect size of .5 standard deviations (a clinically relevant difference in means to detect) with an alpha level of .05 and 80% power. This number of cases was also feasible given the average number of cases performed on most CT scanners (i.e. most facilities would accumulate sufficient cases to report within a week.) Because children are scanned much less frequently than adults and because many more strata are necessary in children because of the	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						dramatic difference in size, this minimum sample size would not be feasible for many facilities. The lowered number per group will allow an effect size of 1 standard deviation to be detected (still a highly relevant difference) with a more realistic size per group.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
21	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	The absence of benchmarking information available for this measure is problematic. The report states the measure will lead to the creation of diagnostic reference levels, this will lead to dose awareness and inevitable improvements as it will enable physicians to consider dose as an important measure. The report also states 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. These two statements from the measure developer speak volumes about the measures readiness for improving patient care. The purpose of measurement is to address gaps in care delivery. Without clearly established diagnostic reference levels, providers will not know if a modification in his/her ordering/rendering of CT scans is warranted. The report states this measure is initially proposed for internal quality efforts, and thus reduction in average doses over	Measure developer's response:Benchmarking on a broader level cannot move ahead without generating information about current practice on which benchmarks can be created. Thus there is a bit of a catch 22; without collecting such data, no represenatative or meaningful benchmarks can be created. Thus while I agree it would be highly useful to have existing and endorsed benchmarks, this will happen only after the creation of agreed upon metrics that this measure will help to create. However, while no agreed upon benchmarks in the US exist, there are data regarding current performance through the FDA, the American College of Radiology published through their certification program and	Part 3 of preceding comments.

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					time is the goal. Reduction to what dose level? Over what time period?	several European Programs, such as the UK NHS Health Protection Service data. These provide very concrete examples of acceptable dose limits. Thus these existing data will provide a place to start comparisons for any institution that begins assembling their data. Thus each facility can review their data and compare their performance to these imperfect benchmarks and will clearly see if their average doses exceed these standards. This first pass will allow assessment of gross errors in dosing, and differences in dosing that are dramatic. For example, if a facility sees that their typical CTDI for a head CT is 80 – substantially higher then the 50-60 maximum CTDI endorsed by	

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						existing programs – they can see that their dosing is too high. It will take at least one cycle of collection of dose data to create more nuanced guidelines and benchmarks in the US. However, helping facilities become aware when their typical dosing varies dramatically from these existing normative data is probably the largest, and most beneficial aspect of this measure.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
22	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	In addition to the concerns raised above, we were limited in the feedback we are able to provide because the documentation did not include a reference to the detailed measure specifications. Further, the report states that if a multi-phase study is done, the doses will be higher than if a single-phase study is done. This seems like a situation in where a measure exclusion would be warranted, but we cannot tell of if this step is built into the measure without access to the detailed measure specifications.	Measure developer's response:The measure was developed from the perspective of collecting data within broad anatomic area categories that would align with safety concerns – ie when a patient goes to a facility to get a brain, chest, abdomen or spine CT, will the dose she will receive be within a reasonabl and appropriate range. Within these anatomic area categories there are many ways to conduct the examinations – the number of passes, the scan lengths, etc, and these will strongly influence the resulting dose the patient receives. However, as explained in detail in section 4, if the categories are parsed into very small categories (such as single phase abdominal CT, double phase abdominal CT,	Part 4 of preceding comments.

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						multiple phase abdominal CT, single phase abdominal and pelvic CT) this will not be helpful as one would need to know both the dose within those strata as well as how frequently a facility uses each of those protocols, to understand the typical doses a patient might receive when they went to a particular facility. Further, the results would be extremely misleading. If patients are routinely exposed to multiple phase studies in a particular facility, then the overal doses reported for that facilities should reflect those doses - and the choice to use particular protocols. This is precisely the type of decisions that the facility makes. The measure is specified in the proposal and the simplicity of the measure will both falitate	

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						easy data collection and will provide the most useful data to assess radiation safety and quality at a given facility, and will encourage choosing lower dose protocols when ever necessary. There are very few data to support using the high dose protocols, or to suggest they improve patient care or diagnostic accuracy. Thus measure PSM-044-10 was designed to reflect the collection of a consecutive sample of all head, all chest, all abdomen and pelvis and all lumbar spine exams. There will be no sampling within these groups. Thus the types of protocols a facility uses will be sampled in proportion of the degree to which that particular type of protocol is used at that institution. As	

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						described in section 4, by collecting all examinations, rather than just collecting a sample within each category, facilities will more accurately reflect the doses to which most patients are exposed when they get a head, chest, abdomen or spine CT and thus the measure will be useful and representative. If a facility chooses to use these high dose protocols in the majority of cases, the dose metrics will reflect this, and they are probably exposing their patients to much higher dosing than necessary.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
23	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-044-10: Radiation Dose of Computed Tomography (CT)	Finally, the measure application form does not include enough information on the burden associated with collection of this measure. The report states a busy facility center can abstract data on scans that were conducted over a few days to have sufficient sample size, whereas smaller centers may compile date from a month, 6 months or a year to generate sufficient data within each anatomic area/age/machine type category. We are very concerned that this measure may be overly burdensome for small and rural providers. Further, the report states the costs should be minimal. How does the developer define minimal? We request additional detailed information on the actual cost of implementing this measure.	Measure developer's response:Based on the most recent FDA Next survey (conducted across all US states in 2004/2005) the measures specified in this report were available for the vast majority (>95%) of scanners in the US. This number has only increased over the last 5 years. These data are captured in the CT stored PACS images and can be viewed directly by the technologist at the time of scanning, or can be abstracted later by pulling up the exam for viewing. To collect the data, a medical abstractor would have to sit at the PACS workstation, open up clinical examinations, and record several numbers. Each examination will take at most a minute or two to abstract.	Part 5 of preceding comments.

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						Further, the second part of the measure calls for recording the dose information metrics in the radiology report. If a facility chose to do this, the dictating physician could record this dose information (a number) at the time of interpretation of the study and this would take a matter of seconds, as the radiologist would be reviewing the images where this information is stored. At UCSF, for example, we currently dictate the dose information into the report at the time the study is interpreted and the work is trivial. If facilities recorded information in this way, the work to compile dose would be very easy (they could just print out copies of all CT reports and an abstractor could review these dictated	

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						reports and write down the numbers from these records.) Additionally, for all new CT scanners, and for many older scanners that are currently undergoing upgrades, the manufacturers are providing a feature to easily export these data to a data base. Thus the data can be assembled in many ways and its possible to extract the information to comply with the measure in a very short period of time. An advantage of this metric (over the ACR dose registry) is the ease with which even small rural facilities can comply.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
24	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-043-10: Participation in a Systematic National Dose Index Registry	Though we recognize the need to collect imaging procedure dosing data, we do not support a quality measure for participating in a national dose registry. Participation in a dose registry is not tightly linked to improving quality and patient care. For many quality measures, such as providing beta-blockers upon discharge to heart attack patients, there is a great deal of scientific evidence that providing that particular process of care can improve patient outcomes. The dose registry participation measure fails to meet that standard. There is no established connection between whether provider answers yes or no to registry participation measures and the quality of the care provided.	Measure developer's response: Evidence of data driven improvement through registry participation does exist. As mentioned, the measure on providing beta-blockers upon discharge to heart attack patients is included in the well-known Society of Thoracic Surgeons National Adult Cardiac Database 1. Beginning from the early 1990's, data from that registry offered evidence that prescribing beta-blockers for such patients improved outcomes and subsequently became best practice. Although the ACR Dose Index Registry is in preliminary stages, even in a short time measured data elements have improved. Additionally, analysis of data from the Michigan Cardiac	

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						Computed Tomography registry has shown a decrease in radiation doses (Dose Length Product) following implementation of dose reduction techniques2. The goal of the national dose index registry is to collect and compare dose index information across facilities using standard methods of data collection in order to establish national benchmarks for comparative and improvement purposes. Most registries begin with this goal, as did the STS registry. There is a great need for such an effort to reduce the variability in radiation doses delivered to patients, particularly during CT exams. There is much room for quality improvement but there are not enough evidenced-based	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						benchmarks and clinical reference levels at this time. The preliminary work of developing the ACR Dose Index Registry has brought about solutions to a number of problems that previously have prevented a method for determining appropriate levels of radiation for a given exam – benchmarks. Those problems include: • Recording of dose information that was delivered during an exam, i.e. CTDIvol or DLP, has not been widely available on CT scanner reports (specific dose information in a standard format). • Lack of standards for describing an imaging exam type for comparison purposes across facilities, i.e. Head1 Brain_without (Adult) vs. Head	

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						^1_HEAD_WO_Adult as the same exam. • Is recorded dose information by exam or individual scans that are included in entire exam • Adjustment for patient size when that information is not generally included in scanner report • Requirement for vendor involvement for updating scanner reports/capabilities to include data elements needed for comparison • Method for collecting standard data from legacy scanners not capable of creating/ transmitting digital information. With these issues addressed and a registry/database available to accept data, aggregated data can be derived by body part, exam type, scanner type as well as by facility demographic	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
						characteristics. This data will be used for developing the much needed national benchmarks for CT dose indices. Facilities that participate in such a national registry will be able to compare their specific dose indices (by exam type, body part, scanner, etc.) to national averages through frequent reports. This provides a means to set targets for quality improvement and bring dose indices in line through protocol refinement. Attesting "yes" to such participation indicates the facilities QI efforts. A second generation of such a measure may be to indicate a facility's compliance with certain well-established benchmarks, but at this time it is premature to do so.	

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25	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	Comments on the general draft report	Finally, we wanted to support a recommendation made by the SC regrading the overall NQF consensus development process. The report states: Committee members challenged the current way of thinking about quality improvement by placing measures within a certain spectrum related to their intended use or their relevance for different objectives within health care. The Committee suggested categorizing measures into classes or tiers base on their place in this spectrum. For instance, standards could be split into three groups: 1) measures suitable for public accountability and reporting; 2) measures geared towards quality improvement; and 3) practice guidelines, or baseline standards of care. The Steering Committee recommends further study of this idea and possible development of a framework or system for classifying measures. We support the notion that different measures may be useful for different purposes and we echo the Steering Committees recommendation that		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
					NQF develop a framework for classifying measures.		

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
26	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-014-10: Colonoscope Processing Personnel Instruction	We are not providing specific comments on the colonoscopy measures because the denominator population does not include patients seen in hospitals. The measure developer specifically noted that these measures only apply to patients in ambulatory surgical centers and office-based practices.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
27	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-015-10: Colonoscope Processing Currency	We are not providing specific comments on the colonoscopy measures because the denominator population does not include patients seen in hospitals. The measure developer specifically noted that these measures only apply to patients in ambulatory surgical centers and office-based practices.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
28	Ms. Lisa M. Grabert, MPH on behalf of Nancy Foster	American Hospital Association	Provider	PSM-016-10: Colonoscope Processing Competency	We are not providing specific comments on the colonoscopy measures because the denominator population does not include patients seen in hospitals. The measure developer specifically noted that these measures only apply to patients in ambulatory surgical centers and office-based practices.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
29	Dr. Mark S. Antman, DDS, MBA on behalf of Ardis D. Hoven, MD	American Medical Association	Health Professional	Comments on the general draft report	The American Medical Association (AMA) appreciates the opportunity to comment on the National Quality Forums (NQF) National Voluntary Consensus Standards for Patient Safety Measures, Second Report: A Consensus Report. As we have noted previously, the AMA strongly believes in improvements in patient safety. The development of performance measures for patient safety is an important step in improving patient care and in ensuring adverse events are minimized.		No action necessary.

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
30	Dr. Mark S. Antman, DDS, MBA on behalf of Ardis D. Hoven, MD	American Medical Association	Health Professional	PSM-014-10: Colonoscope Processing Personnel Instruction	Measures PSM-014-10 and PSM-015-10 are being put forward as appropriate for accountability at all level. While these measures address important areas of care, we cannot support them as accountability measures at the clinician level to be used for public reporting. There are other factors beyond the care directly provided by clinicians, including the efforts of other health care professionals, that would affect the care of those patients who would be impacted by these measures. We believe that performance measures are only appropriate at the clinician level when it has been consistently shown that the measure is directly dependent on the clinician, and not when such results are dependent on other healthcare professionals or other factors exogenous to the care a clinician provides. Accordingly, this type of measure is best represented at higher levels of data collection or aggregation. Reporting of these measures at higher levels of collection or aggregation does not take away from their value to individual	Measure developer's response: We agree that these are NOT clinician level measures. We thank you for noting that the reporting of these measures at higher levels of collection (ASC or office) does have value to individual clinicians and those who are part of the care team.	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
					clinicians and others who are part of the team of care. We recommend that the measure developer remove can be measured at all levels from the level of analysis.		

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
31	Dr. Mark S. Antman, DDS, MBA on behalf of Ardis D. Hoven, MD	American Medical Association	Health Professional	PSM-015-10: Colonoscope Processing Currency	Measures PSM-014-10 and PSM-015-10 are being put forward as appropriate for accountability at all level. While these measures address important areas of care, we cannot support them as accountability measures at the clinician level to be used for public reporting. There are other factors beyond the care directly provided by clinicians, including the efforts of other health care professionals, that would affect the care of those patients who would be impacted by these measures. We believe that performance measures are only appropriate at the clinician level when it has been consistently shown that the measure is directly dependent on the clinician, and not when such results are dependent on other healthcare professionals or other factors exogenous to the care a clinician provides. Accordingly, this type of measure is best represented at higher levels of data collection or aggregation. Reporting of these measures at higher levels of collection or aggregation does not take away from their value to individual	Measure developer's response: We agree that these are NOT clinician level measures. We thank you for noting that the reporting of these measures at higher levels of collection (ASC or office) does have value to individual clinicians and those who are part of the care team.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
32	Dr. Mark S. Antman, DDS, MBA on behalf of Ardis D. Hoven, MD	American Medical Association	Health Professional	PSM-043-10: Participation in a Systematic National Dose Index Registry	The AMA is in support of a measure, such as this, that recommends that facilities which utilize imaging technology participate in a national dose index registry. However, as we have stated elsewhere, it is important to distinguish between the overuse of imaging from instances when there is a true necessity to re-image. Measures related to the use of imaging technologies should provide a means for clinicians and other healthcare professionals to distinguish between these two. We caution that the omission of opportunities to distinguish necessity and medical judgment can lead to undue punitive actions against clinicians and other healthcare professionals.	Measure developer's response: Inappropriate imaging is certainly a contributing factor to unnecessary medical radiation exposure; it should be and is beginning to be addressed through other measures. The focus of this measure is to increase the safety of imaging procedures, e.g. optimized radiation exposure, rather than to specifically address the overuse of imaging itself. There is no assessment as to the appropriateness of exams for which data is submitted to the registry. Additionally, local quality improvement efforts that sites are likely to implement based on benchmark comparison reports from the registry should help develop improved exam protocols. Well-honed	

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						protocols will provide higher quality images, reducing the need for re-imaging due to poor quality.	

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33	Dr. Mark S. Antman, DDS, MBA on behalf of Ardis D. Hoven, MD	American Medical Association	Health Professional	PSM-044-10: Radiation Dose of Computed Tomography (CT)	The AMA has previously recommended that patients have a radiation exposure record similar to a vaccination and thus we are in support of this measure. However, we believe that in addition to efforts to track patient exposure to radiation on the part of clinicians and other healthcare professionals, it is important that manufacturers of imaging technologies collaborate to achieve uniformity through calibration standards. Such uniformity on the part of manufactures will reduce variability in patient exposure to radiation and will make the assessment of patient exposure more systematic.		NQF's response: For SC consideration. Addition of a recommendation to the report may be beneficial. Suggested language for draft report below. "In addition to close monitioring of radiation dose by healthcare providers, it is of note that manufacturer standardization of calibration techniques would be useful in achieving dose index standardization and ultimately the goal of reduced patient exposure to radiation."

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34	Ms. Judy Burleson	American College of Radiology	Health Professional	PSM-044-10: Radiation Dose of Computed Tomography (CT)	The ACR supports the concept of measure PSM-044-10 Radiation Dose of Computed Tomography (CT), in that it encourages acquiring and analyzing radiation dose levels associated with CT procedures. This addresses a real safety concern and is a step forward in reducing variation of the dose indices associated with CT and ultimately unnecessary exposure to ionizing radiation. Using this measure and the resulting data in local quality improvement programs can enable facilities to optimize dose levels. However, the ACR believes that the measure does not adequately address the issue of patient size in the calculation of estimated dose. The second part of the measure -- reporting a measure of radiation dose, i.e. DLP, CTDIvol or Effective Dose in the radiology final report-- is particularly concerning. Reporting DLP or CTDIvol may be technically correct, but providing such information without context to patient size and exam has little meaning and is difficult to act	Measure developer's response:The metrics of DLP, CTDI vol and Effective Dose are all highly relevant, and useful, as all will reflect the settings that the radiologists and technologists use and will all reflect the doses that patients receive and the corresponding radiation detriment. One factor that influences the radiation dose in CT is patient size, and in general higher dosing may be used in larger patients to maintain the same image quality as can be achieved with lower doses in smaller patients. However, the difference based on patient size is small compared to the differences in CT dosing due to other factors. The variation in the doses that patients currently receive (based on our	

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					upon. Reporting effective dose is more problematic. The determination of ionizing radiation dose to humans is very complex.	published work as well as many other sources included data collected through the ACR Dose registry, and described in the application, and described in Dr. Morin's letter of support) can vary tremendously – by 10, 50 fold or 100 fold and this does not have anything to do with patient size. It is this profound and clearly harmful variation in dose that this metric seeks to reduce. It is possible to account for patient size in estimating dosing to patients. However it would require knowledge of patient weight and much more complex assessment of absorbed doses that are not readily available. This seems outside what seems feasible and outside what is necessary. I do not believe the ACR dose	

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						registry accounts for variation in dose by patient body habitus; I do not believe the ACR accreditation program accounts for variation in dose by patients size; and none of the European quality assurance programs account for variation in dose by patient size. Thus the imprecision that is introduced through ignoring patient size is a small price to pay for the capacity to assemble large amounts of data. Of note, we are accounting for patient size in our research efforts, but the amount of work to do so does not seem worth the small gain in precision.. The primary level of assessment of this measure is at the facility level. If a facility sees a very high proportion of obese patients, their doses may be slightly	

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						higher than a facility that sees very thin patients (and this variation in dose may be acceptable.). This issue will be important if and when facilities compare their dose indices to normative data (i.e. to benchmark data, that will be used to create the diagnostic reference level data), as they should compare their actual observed data to facilities that see similar patients. In practicality, geographic dose benchmarks will likely be sufficient to account for this variation by patient size. This is the reason that facilities should note the state where their facility is located when and if they submit their data to a national organization. Diagnostic reference levels should be generated at a local	

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						enough level (state, or region of the country) so they are most useful and relevant. However, each facility can compare their performance to their previous year's performance. The average doses would hopefully continue to decrease over time. The second part of the measure calls for recording of a measure of dose in the patient's medical record. This is widely done in many countries and would go a long way towards increasing dose awareness (among radiologists, referring clinicians and patients) and make completion of the first part of the metric (collecting dose data) more feasible for small facilities (ie they could just look at printouts of all CT reports to find and	

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						abstract the relevant dose information.). The effective dose metric would reflect the dose used and absorbed in a patient. While higher doses are frequently used in larger patients, there are no data to support that it makes sense to increase the dose 5-10 fold because a patient is very large. Maintaining imaging quality may be a good goal, but maybe not a desirable goal if the doses a patient receives have to go up dramatically to achieve the same level of imaging quality (ie, it may be preferable to accept lower image quality.) These sorts of questions need to be addressed in research settings to best understand the tradeoff between dose and accuracy. It is only by beginning to assemble	

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						the called for dose data, that we can understand current practice, that we can we begin to make choices about what doses should be used. I agree that patients and referring physicians will need to be educated to understand the dose information that will be included in the medical record so that these data can have the best influence on patients. The usefulness of Effective Dose (even though it is similar to DLP) is that it is a measure that can be calculated from all radiologic tests associated with ionizing radiation (xrays, fluoroscopy, angiography, nuclear medicine, etc), making it an easy measure to understand and compare between different types of tests.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
35	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Professional	Comments on the general draft report	Thank you for the opportunity to provide comments on the NQF Patient Safety Measures, 2ndReport. We support NQFs efforts to advance the measurement of patient safety and focus specifically on patient outcomes. We recognize that preventable medical errors represent a significant public health concern and cost to the U.S. health care system and appreciate efforts to promote measures that focus on these key areas.		No action necessary.

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36	Ms. Judy Burleson	American College of Radiology	Health Professional	PSM-044-10: Radiation Dose of Computed Tomography (CT)	comment continued: To determine the absorbed radiation dose, the initial exposure and the absorption in each organ must be known. It is impossible to estimate the total radiation dose absorbed by a patient without detailed information of the patient habitus and the many technical factors that go into the production of the image. It is important to understand that the reported numerical values for individual radiation doses may vary by factors of 5 to 10 depending on individual patients and the manner of image acquisition.Thus the ACR does not support this part of the measure. We would like to provide clarification regarding the reference to the American College of Radiologys relative small and new CT Accreditation Program as stated in the PSM-044-10 measure evaluation form. Our first CT facility accreditation was completed in 2002; there are currently close to 5,000 actively accredited CT facilities. Recent analysis of the CT accreditation program statistics has shown a	Measure developer's response: The doses used in current practice vary profoundly within and between institutions. The variation is based on the technical factors used, the type of machine, and patient size. While some variation is inevitable, and desirable, the 5- 10 fold cited by the ACR (that may be attributable to patient size) is almost certainly not ideal practice, and the 100 fold variation observed is completely unacceptable. Thus the reporting of the doses used in actual patients will go a long way towards both increasing awareness and incentivizing physicians to lower the doses to the degree possible The ACR Accreditation program does not collect doses used in consecutive patients, but rather asks facilities to	This comment is part 2 of comment 34.

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
					decrease in dose levelsat sites that are renewing their 3 year accreditation, indicating the educational aspect of the program. In 2008, based on previous year statistics, the program implemented a dose reference level pass-fail criterion. Subsequently, facilities are submitting images with lower doses.	submit a handful of optimized cases. The relationship between these best-case scenarios, and actual doses most patients who go to a facility will receive, is completely unknown, and these "best cases" may bear no resemblance to the doses patients routinely receive. actual patients. There are many reasons to suspect this is a substantial problem and not just a theoretical problem. For example, if a facility frequently use complex protocols (such as the brain perfusion scans associated with high doses and radiation overdoses reported at Cedar Sinai ;or the increasingly popular multiphase studies) these would almost certainly not be reflected in the handful of cases submitted. And yet if a facility used these	

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						protocols often, the dosing patients might receive when they go to these facilities could be unnecessarily high or unsafe. The potential for very misleading results based on such a small sample is real and is described in detail in section 4 of PSM-044-10 Thus the proposed measure will have far more impact on measuring actual current doses used in CT in comparison to the ACR Accreditation program. Further, none of the doses seen in the ACR are made publically available (there is no public reporting) making it impossible to assess the impact of accreditation on dose. Further, in some instances, when the ACR observed high doses, the ACR simply raised the doses for passing (the	

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						benchmarks were based on usual and customary care, and when that demonstrated high doses, the allowable limits were increased, and made higher than applied in many European programs). Thus while doses may have gone down, they have also sometimes gone up. In summary, while patients size is certainly an important factor when setting settings, it is in no way the only or dominant factor in explaining dose, and the measure as submitted remains highly valuable without consideration of patient size.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
37	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	PSM-014-10: Colonoscope Processing Personnel Instruction	NQF should consider whether this measure may be more appropriate as a guideline for processing personnel, as it may have the unintended consequence of causing centers that currently provide more frequent instructions to drop back the frequency to annual.		NQF's response: NQF appreciates that there may be unintended consequences for endorsed measures, as suggested in the comment. NQF now has an implementation comment period for all measures undergoing maintenance in order to learn more about any potential consequences of measure use.

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38	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	PSM-015-10: Colonoscope Processing Currency	Given the evidence showing the potential for a colonoscope to carry contaminates, processing currency of the colonoscope needs to be carefully monitored. As this measure has received time-limited endorsement, it would be important to ascertain the correlation of infections and perforations in relationship to the measurement score.	Measure developer's response: We entirely agree that colonoscope processing needs to be carefully monitored because of the potential for colonoscopes to carry contaminates. A quick review of recent literature in PubMed does not speak to colonoscope processing, bowel perforations, and risk of infections. Reported colonoscope perforation rates are relatively low (1/1500 for therapeutic colonoscopy, 1/6000 for diagnostic colonoscopy: http://fightcolorectalcancer.org/research_news/2009/06/colonoscopy_perforation_rates_low_and_decreasing). Although infections are certainly serious outcomes, there are high costs associated with patient notification and patient testing, when a failure in scope	

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						processing is found.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
39	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	PSM-016-10: Colonoscope Processing Competency	The measure specifications need to clarify the process for which reprocessing personnel at ambulatory surgery centers and office based practices are documented to be competent at reprocessing. More specifically, the specifications should define who determines competency (these specifications are presumably the ones used in the 2010 Colonoscopy Study of the AAAHC, but they should be specified here).	Measure developer's response: The process for documenting reprocessing competency is having the reprocessing personnel demonstrate the skill level required to independently and appropriately perform all assigned reprocessing tasks or responsibilities, including new skills or knowledge required because of changes made in colonoscope equipment or in manufacturers' recommendations, documented within the last 12 months. As described in the definitions in the NQF Measures Submission Form, 2.a.8. "colonoscope reprocessing" is the preparation of a colonoscope after patient use to prepare for next patient use, via "method	

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						to ensure the proper disinfection or sterilization; [tasks or responsibilities] can include: cleaning, inspection, wrapping, sterilizing [or disinfecting], and storing." [Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control and Prevention. 2008]. As with any reporting of health care performance, it is most appropriate that someone who officially represents the unit of measure (in this case the administrator of the ASC or office-based practice) designates, takes responsibility for, and ensures this is assigned to a person with appropriate qualifications to perform	

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						these tasks. This person may be the administrator, another person within the organization, or an expert consultant hired for this purpose.	

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40	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	PSM-044-10: Radiation Dose of Computed Tomography (CT)	Although the ACR measure as currently specified, only tracks participation in a registry, it would be helpful to clarify how radiation dosing is measured in the ACR registry and if it aligns with the measure proposed by the University of California, San Francisco. We feel this is a positive step in assessing the level of radiation patients receive, as it places the radiologist in the position of monitoring the radiation, just as other physicians monitor the dosage of pharmaceuticals.	Measure developer's response:The two measures take different approaches towards patient safety. Measure PSM-044-10 calls for directly recording dose indices at the facility level which will encourage facilities to review the doses they are using. It also will permit the creation of dose benchmarks. It is less clear how participation in the dose registry will directly influence the doses that facilities use, although I believe they will also assess the same DLP and CTDI dose metrics per conversations I have with the ACR measure developer. Measure PSM-044-10 will encourage collection and assessment of these measures of radiation dosing at essentially every facility in the US	

						that conducts CT, as >95% of machines generate these data on their existing machines, without the need for any other additional work, data linkages, etc. Dr. Morin (who drafted the ACR CT dose metric and who is the lead of the ACR Dose Registry) wrote a strong letter of support for PSM-044-10, emphasizing the broad consistency of the measures.	

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#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
41	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	Comments on measures not recommended	We received a variety of comments from our members regarding NQFs Medication Safety Measures, and have summarized some of the key themes below. These comments do not represent an industry consensus position but member-specific comments on these measures. Concerns with the lack of scientific evidence associated with these measures. Focus efforts to measure patient safety on patient outcomes. Suggestion that the measure developer assess the feasibility of creating a medication safety composite measure, which could be integrated into a checklist for the management of patients with chronic disease. The focus could then be placed on examining the success of such monitoring on patient outcomes measures such as measuring renal, hematologic or hepatic complications or ER visits.		

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42	Ms. Carmella Bocchino, MBA, RN	America's Health Insurance Plans	Health Plan	PSM-014-10: Colonoscope Processing Personnel Instruction	General Comments on Proposed Colonoscope Measures We request that additional clarification be provided on whether these measures intend to be reported as a composite. Additional clarification is also needed on how these measures align with existing accreditation standards, for both the ambulatory care and office-based settings. It would be helpful for NQF to request that the developer provide greater clarity with respect to the feasibility of implementing the three Colonoscope measures, particularly as to the Committees request for clarification regarding the differences between existing standards required as part of ambulatory surgical centers accreditation process and these proposed performance metrics.	Measure developer's response: Please see the NQF response below with regard to composite versus paired measures. Existing AAAHC (Accreditation Association for Ambulatory Health Care) accreditation standards include standards that generally discuss using national guidelines and manufacturers' recommendations, ascertaining competency, and providing education. The accreditation standards do not reach the specificity nor are they applied with the periodicity of the AAAHC Institute measures and there is a clear gap in care for these areas. Surveys generally occur every three years and substantial changes in technology and	NQF's response: The Steering Committee recommended that measures # PSM-014-10, PSM-015-10, and PSM-016 be endorsed as grouped measures. Grouped or paired measures, as defined in the notes section of the report, refer to two or more measures grouped together for the purpose of public reporting. The measures maintain separate scores."

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						competency can occur in that interval. Initial results from the 2010 AAAHC Institute Colonoscopy study indicate that the proposed measures are feasible to implement. NQF's response: The Steering Committee recommended that measures # PSM-014-10, PSM-015-10, and PSM-016 be endorsed as grouped measures. Grouped or paired measures, as defined in the notes section of the report, refer to two or more measures grouped together for the purpose of public reporting. The measures maintain separate scores.	

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43	Michael McNitt-Gray, PhD, DABR, & Cynthia McCollough, PhD, DABR	American Association of Physicists in Medicine		PSM-044-10: Radiation Dose of Computed Tomography (CT)	While this measure is well intended, we believe there are problems with this approach that will not allow it to be used as intended, primarily because size of the patient is NOT taken into account. That is, as described below, it is entirely appropriate for dose indices to vary with patient size; however if one only looks at the dose index value - without any information about patient size - it is impossible to determine whether variations in the dose indices between patients for a given exam type are due to appropriate adaptations of system output to differences in patient size or inappropriate variation in protocols. This has tremendous implications for making appropriate adjustments for patient size, such as reducing tube output for pediatric patients. If a site is looking to reduce the variation in a dose index value, without any information about patient size, then this could lead to a lack of adjustment for patient size or diagnostic task. This would result in a one size fits all approach to	See response letter from developer.	

#	Submitter	Organization	Member Council/ Public	Comment Type/ Measure Name	Comments	Measure Developer Response	NQF Response
					adjusting scanner output - which may lead to the same technical factors being used for both pediatric and adult patients - and which goes against what we know is appropriate clinical practice. Therefore, we recommend that this proposal either be modified or delayed until it can implemented with appropriate information recorded (i.e., some index of patient size); otherwise, variations in dose indices that are entirely appropriate may be (and already have been) interpreted as being inappropriate variations within a clinical practice.		