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Fundamental Q&A regarding mandatory radiation safety surveys by DHSS-recognized and approved Qualified Experts (QEs)

All facilities using regulated sources of ionizing radiation within the state of Missouri are required to have periodic radiation safety surveys conducted by, or under the direction of, a facility-contracted Qualified Expert in radiation safety who is registered and approved by the Missouri Department of Health & Senior Services (DHSS), in order to demonstrate required compliance with radiation safety standards.

19 CSR 20-10.010(17) defines the Qualified Expert as: “*an individual fitted by training and experience to perform dependable radiation surveys, to oversee radiation monitoring and to estimate the degree of radiation hazard. If the ability of a qualified expert is questioned, the department shall be the judge of his/her qualifications, in regard to which it may consider the testimony of other persons whom it deems expert.*”

19 CSR 20-10.050 further states:

(1) The user shall provide for radiation surveys and monitoring sufficient to assure compliance with other rules of this chapter. The radiation survey and monitoring shall be performed by, or under the direction of, a qualified expert using suitable instruments and methods for measuring radiation.

(2) Until an actual radiation survey can be performed, a written statement made by a qualified expert based on his/her analysis of the situation shall be acceptable as evidence of the absence of radiation hazard in a given area.

As a public service, prior to 2014 DHSS employed a number of staff to perform regulatory surveys in Missouri, to directly assist some facilities in meeting these requirements to assure compliance with radiation safety standards. However, as the number of facilities and radiation machines increased over time, the number of DHSS employees trained and available to perform these surveys decreased. It should be noted that Missouri is one of the few states that doesn't have the authority to charge a routine registration or inspection fee to support the radiation safety program for all x-ray producing machines. At the same time, the ongoing evolution of technology utilizing radiation made it increasingly more difficult to maintain the training and experience that allowed DHSS employees to adequately keep pace with new radiation equipment and imaging modalities. Therefore, beginning in 2014, DHSS no longer routinely provides this direct service to the majority of registered radiation facilities in Missouri (with the exception of mammography and complaint investigations).

In lieu of inspections conducted directly by DHSS staff, the results of a Qualified Expert survey must be provided to DHSS to demonstrate compliance with radiation safety standards. The initial due dates for mandatory Qualified Expert survey submission were gradually phased in over several years, depending on the facility type and radiological workload, to minimize impact on the regulated community while still providing assurance of protection of the public health.

As part of this process, DHSS formalized a registration and approval program for Qualified Experts (physicists/radiation safety consultants) working in Missouri. Registered radiation facilities are required to have these mandatory periodic radiation safety surveys conducted by, or under the direction of, individuals who have been officially recognized by the DHSS' Missouri Radiation Control Program (MRCP) as Qualified Experts.

This document provides further information and a detailed explanation about this process.

If you have additional questions or concerns that are not addressed below, please contact the MRCP (**Missouri Radiation Control Program**) preferably via e-mail at MRCP@Health.mo.gov

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Missouri Radiation Safety Qualified Expert (QE) Frequently Asked Questions

1. Are these new rules?

No. The rules that mandate QE surveys have been an existing provision in the radiation safety rules for many years. Prior to 2014, it had only been implemented/enforced on a selective basis (hospitals, ambulatory surgery centers, portable x-ray suppliers, etc). In years past, as a public health service, DHSS employed a staff of radiation safety professionals to carry out some of these surveys at some facilities. However, conditions changed, due to inability to collect fees, reduced DHSS workforce numbers, as well as a rapid evolution in technology that made it increasingly difficult to maintain adequate training and expertise for public health staff members. These evolving conditions made it necessary to fully implement this rule statewide at all facilities utilizing radiation equipment, and transfer the required radiation safety requirements back to the equipment owners.

References to Qualified Experts and requirements in the existing (1964) radiation safety rules (emphasis added):
-19 CSR 20-10.010 (17) Qualified expert is an individual fitted by training and experience to perform dependable radiation surveys, to oversee radiation monitoring and to estimate the degree of radiation hazard. If the ability of a qualified expert is questioned, the department shall be the judge of his/her qualifications, in regard to which it may consider the testimony of other persons whom it deems expert.

-19 CSR 20-10.030(1)...The [biennial] registration also shall give the name and address of the user(s) and *the name and address of the qualified expert*.

-19 CSR 20-10.050(1) The user shall provide for radiation surveys and monitoring sufficient to assure compliance with other rules of this chapter. The radiation survey and monitoring shall be performed by, or under the direction of, a qualified expert using suitable instruments and methods for measuring radiation.

-(2) Until an actual radiation survey can be performed, a written statement made by a qualified expert based on his/her analysis of the situation shall be acceptable as evidence of the absence of radiation hazard in a given area.

2. How does the DHSS apply and implement the QE regulatory requirement(s)?

The basic QE survey requirements are spelled out in the existing rules. However, the language of the standards is less than overly descriptive. Therefore, the implementation expectations are largely based on presumptive standards already widely accepted in the radiation safety community; they are expectations of how the rule will be met. In general, MRCP has described general expectations, and if already in place, MRCP considers the requirements met. MRCP has left considerable latitude to the professional judgment of the QE. In some cases, there may be alternative methods of compliance that are outside the presumptive standards. These methods, upon written request to the DHSS, may be examined to determine equivalency with the presumptive standards. The burden of evidence is on the petitioner requesting the alternative standard. In some cases, MRCP may write regulatory interpretive guidelines, which further detail and clarify how the rule is or will be interpreted and implemented. Presumptive standards may evolve over time due to introduction of new technology, protocol, or consensus view of professional bodies.

3. Are these presumptive standards for QE's similar to other states and nationally-recognized programs?

Yes. In the development of these presumptive standards, to identify common elements, DHSS reviewed both national radiation safety programs (CRCPD, ACR, AAPM), and programs from the following states: AR, FL, IA, IL, KS, KY, MD, NE, NJ, TX, VA, WV. The basis of this review in part represents what is referenced in 19 CSR 20-10.010(17) as "*testimony of other persons whom [MRCP] deems expert.*"

4. What does the language in 19 CRS 20-10.050(1) specifying "User shall provide for Radiation surveys" mean?

The registered radiation facility is responsible for arranging (and paying for) radiation safety surveys by a recognized QE, the frequency of which is dependent upon the facility Class (See Question 8).

5. ***What was the timeframe for implementation of the QE requirements, and what is MRCP's Role after the full implementation?***

--October 2012: Formal registration and recognition process for Qualified Experts was initiated.

--December 2012: Mass mailing to all 4,900 registered facilities announcing the implementation of the QE survey process. As part of this announcement, MRCP made available to facilities a list of the current officially recognized Qualified Experts. At that time, MRCP also sent the announcement to installers, equipment vendors, and other associated stakeholders.

--January 1, 2014: Transition complete and requirements fully enforced. Submission of periodic QE surveys, dependent on facility class, were required incrementally over the next six years for already registered facilities. In addition to periodic survey requirements for existing radiation facilities, all NEW radiation facilities beginning service on or after 2014 have to meet these standards.

The role of the MRCP also transitioned, becoming more administrative and registration-driven. Regulatory actions for the MRCP are now largely based on survey findings of the Qualified Expert. MRCP (other than mammography) onsite radiation safety surveys are limited: MRCP conducts audit surveys and validation of surveys conducted by or under the direction of QEs; ensures that appropriate corrective actions are taken based on findings of the QE survey; perform onsite visits of problematic registrations and facilities with poor compliance histories; finally, MRCP performs complaint investigations.

6. ***What constitutes a radiation safety survey as defined in CSR 20-10.050(1) that is "Sufficient to Assure Compliance"?***

The scope of the required survey includes not only determination of full compliance with existing state rules and the FDA's federal performance standard for radiation equipment as described in 21 CFR Parts 1010-1050, but also the Radiation Protection Law 192.430, which requires *Radiation sources to be kept safe*: "All sources of radiation shall be...used and kept so as to prevent all users thereof and all persons within effective range from being exposed to unnecessary radiation." It is largely left to the professional judgment of the QE to apply generally-accepted professional standards of radiation protection to determine if radiological conditions are safe. Each QE have some leeway to develop their own survey protocol appropriate to the facility conditions and equipment, but are expected to follow generally-accepted standards of measuring radiation safety and radiation machine performance.

7. ***When the rules refer to a "survey" does that mean a unit survey (testing of the performance parameters of a specific radiation machine) or an area survey (testing of either a controlled or uncontrolled area around a radiation machine to see if radiation shielding, signage, and leakage is sufficient and appropriate to protect the facility staff, members of the public, and others from exposure to unnecessary radiation)?***

It depends on the situation, how the equipment is used, and the professional judgment of the Qualified Expert. The required radiation safety survey may include unit survey, area survey, or both. If the radiation machine is a medical machine used on human patients, then in almost all cases a unit survey testing variable parameters and performance of the machine will be necessary, because the patient is the member of the public most at risk for unnecessary radiation. This would include radiation not necessary to produce an optimal image or treatment, or radiation used in diagnostic exams performed so poorly (through either machine problems or user misuse) that the exam could likely lead to missed diagnoses. If the machine is not medical, then the exposure to the patient is not a consideration, and only occupational exposure and exposure to members of the general public is of significant concern. In this case an area survey may be more appropriate. For new medical facilities, both a unit survey and an area survey (to evaluate shielding, signage, etc.) would in almost all cases be necessary. However, on surveys of that same facility in the future, if the equipment or usage of the area has not changed, an area survey may not be needed, although a unit survey would still be necessary to ensure that the equipment is still being maintained and used in a safe manner. In most cases, the evaluation of the Qualified Expert of the situation will determine what areas of radiation safety are most appropriate to be tested.

8. ***How often must the radiation safety survey be conducted?***

All radiation facilities must re-register their equipment every two years, and dependent on the facility Class, must have periodic radiation safety surveys performed by a QE. In determination of Class and the inspection period for the facility, MRCP considers likely public health hazards associated with various types of radiation-producing equipment, the facility workload, as well as the facility's past compliance history. Based on the hazards, MRCP initially applied statewide incrementally staggered inspection period, taking into account factors such as the impact on small entities, and the available population of likely QEs. The first full cycle of mandatory QE survey submission was phased in over several years. Facilities are divided into Classes as follows:

Class A: Annual surveys: These include licensed Hospitals; licensed Ambulatory Surgery Centers; any facility with the following type of equipment: CT, fluoroscopy, radiation therapy, mammography; Specifically Designated Facilities w/high risk equipment (some non-medical); or facilities with a history of radiation safety compliance problems, as determined by the MRCP. *Note: Of the total 4,900 registered radiation facilities in Missouri, approximately 550 (11%) are Class A.*

Class B: Biennial surveys: These include routine x-ray; radiology; chiropractic; podiatry, CMS-Certified Portable X-ray suppliers, and others designated by the MRCP. *Note: Of the total 4,900 registered radiation facilities in Missouri, approximately 900 (19%) are Class B.*

Class C: Four (4) year survey cycle: These include radiology facilities with services or equipment normally designated Class B, that provided initial written evidence (prior to 2014) of a *very low workload: [300 or fewer exams/year (25 a month)]*; veterinary facilities without fluoroscopy or CT, others designated by the MRCP. *Note: Of the total 4,900 registered radiation facilities in Missouri, approximately 725 (15%) are Class C.*

Class D: Six (6) year survey cycle: These include dental offices *without* CBCT; Bone Density DEXA; non-medical facilities not Specifically Designated as Class A. *Note: Of the total 4,900 registered radiation facilities in Missouri, it is estimated that approximately 2,100 (42%) are Class D.*

Class E: Dental Facilities with CBCT—split 3 year/6 year inspection cycle: Per 2017 changes in state law 192.500, dental facilities utilizing Cone Beam CT (CBCT) equipment are now designated Class E. This means that CBCT equipment must be inspected every 36 months/3 years; all other dental equipment in use at the facility must be inspected every 72 months/6 years. *Note: Of the total 4,900 registered radiation facilities in Missouri, it approximately 375 (7.5%) are Class E.*

9. ***What does the language in 19 CSR 20-10.050(2) indicating a “Written Statement” mean, and what are the requirements for an Initial Survey by Qualified Expert?***

In some cases, until an onsite radiation survey can be conducted by the QE, the QE may issue a written statement to the facility with a preliminary evaluation of probable radiation hazards, assessing to what degree additional testing or monitoring is necessary to assure safe use. In many (but not all) cases, this statement may be what is commonly referred to as a “radiation shielding plan.” QE’s should use generally-accepted standards in the development of the written statement; i.e., various radiation shielding guidelines published by the National Council of Radiation Protection (NCRP). However, the QE is given some flexibility to exercise his/her professional judgment in the formulation of recommendations in the written statement. The following are expectations of the written statement and initial survey:

--New Class A facilities: Shielding plan evaluation and onsite survey of new facilities by QE prior to routine clinical use.

--New Class B, C, & D facilities: Shielding plan and/or written statement from QE *should* be prior to use, and *must* be no later than the onsite survey required within 90 days of beginning use of the radiation equipment.

--Newly Installed CBCT Units must have shielding evaluations and be inspected within thirty (30) days from installation per 192.500.

--For *existing* facilities, if additional equipment (either new or used, +1 to the facility inventory) is added between routine survey cycles, the facility will need a written shielding evaluation from a QE, as well as an onsite survey of new equipment will need to be done: (Before routine clinical use for Class A equipment, within 30 days for CBCT, and within 90 days for all other equipment). There is no specific format for the written shielding evaluation statement, but it must be retained by the facility, and provided to the DHSS as evidence of compliance with registration requirements. *Note: this is part of the requirement at 19 CRR 20-10.030 to notify the MRCP in writing of any change in conditions which could substantially increase the radiation hazards.*

10. What testing/evaluation is required for additional equipment or rooms added between survey cycles, versus replacement equipment (the same type of is being repaired or replaced in an existing radiation room)?

To some degree, the scope of the survey is determined by the professional judgment of the QE. State rule 19 CSR 20-10.030 requires that users notify the department of any change with respect to the radiation sources that will increase the potential for personnel exposure, so the department can determine any testing or monitoring needed. Our presumptive standard on compliance is as follows:

--If radiation equipment of the same type, usage, and location is being replaced or repaired, DHSS recommends that the facility should contact a QE to consult whether the QE believes additional testing of the machine's performance would be warranted, but is QE survey is not mandated. For example, if a facility has a routine radiographic machine in Room A, and that machine is being replaced or repaired, it may be prudent to consult with a QE to determine if additional radiation safety testing should occur, but an additional survey is not mandated by MRCP in these cases.

--However, if a facility is adding additional radiation machines or rooms (+1 to the facility's inventory) or moving to a new location, the facility must consult with a QE and have the +1 unit inspected. This inspection (both shielding evaluation and unit survey) needs to be done: prior to routine usage if Class A equipment (radiotherapy, mammography, CT, or fluoroscopy); within 30 days if CBCT; all other equipment within 90 days.

11. Our facility was assigned a specific Qualified Expert survey "due date". Can the survey be done before that date, to be more in consistent with the schedule we have already established in the past?

Yes. The initial round of required QE survey submissions were tied to a specific "due by" date, and were incrementally staggered over a 1-6 year period. However, facilities were also encouraged not to wait until the last minute, particularly if they did NOT have a QE on permanent retainer or employment status. If a hospital, for example, as a Class A facility was assigned 10/31/14 as a QE survey due date, that means that by said date, DHSS would be expecting a submitted copy of survey results, but the survey itself can be completed at any point in the 12 months prior (10/31/13-10/31/14 [364 days]). Staggering the due dates over each month of a multiple year period avoided an unmanageable rush at the end of each year as facilities made arrangements for QE surveys. Survey results were due for submission to DHSS for Class A facilities over a 12 month period beginning in 1/1/2014, for Class B a 24 month period beginning in 1/1/2015, for Class C a 48 month period beginning in 1/1/2016, and for Class D a 72 month period beginning in 1/1/2017.

12. May a facility utilize multiple QE's?

-Yes, as long as the facility meets the timeframes for survey as defined by their Class (See Question 8). For example, a hospital (Class A) may have one QE recognized for Therapy, and another for Diagnostic Radiology. The Hospital could arrange for the therapy QE and diagnostic QE to both perform annual surveys of the equipment for which they are Qualified Experts. It is the choice of the facility as to which QE or group of QE's are utilized, as long as said individual(s) are officially recognized by DHSS as QE. Although permitted, a facility is not required to keep a QE on permanent retainer or contract; they may utilize a different QE each time a radiation survey is required, either due to the required time expiring, or the addition of equipment.

13. Does a Qualified Expert utilized to conduct the required survey have to be a third party (non-employee) or may the survey be done by an individual who is fully employed by a single registered facility?

The owner of the x-ray equipment must make arrangements with a Qualified Expert recognized by DHSS. How this is arranged, whether contract, fee-for-service, formal employment, or on a pro bono volunteer basis is between the owner of the radiation equipment and a QE. In the situation you describe, those employees would indeed be able to perform the surveys, as long as they are recognized and approved as Qualified Experts by DHSS. DHSS will be auditing the work of all types of QE, regardless of the employment arrangements.

14. *Our facility is a large research university department. We have some x-ray equipment designed for medical use on humans; however it is used only on phantoms & cadavers for research. Our in-house physicists don't have the equipment needed to do proper medical surveys on the equipment, and not sure they would qualify to perform medical physics testing. Will this facility REALLY be necessary to classify as Class A?*

Not necessarily. It depends on several factors: Question #2 of this document indicates that much of the initial transition was based on presumptive standards; circumstances that fit the majority of facilities. However, there are 4,900 facilities, and some of them are outliers that don't fit neatly into a box. "Non-medical" equipment is frequently such an outlier, and research universities are another, where the usage of radiation is so varied that the determination of the hazard classification may need to be made on a case by case basis. As indicated in Question #2: "*In some cases, there may be alternative methods of compliance that are outside the presumptive standards. These methods, upon written request to the MRCP, may be examined to determine equivalency with the presumptive standards. The burden of evidence is on the petitioner requesting the alternative standard.*"

--One of the presumptive standards that may differ on a case-by-case basis is the initial assignment of Facility Class. Based on the type of equipment, a facility may look like (and be presumed to be) Class A, but taking other factors into account, it may be more appropriate to make it a Specifically Designated Facility in another Class. In this specific case, the medical equipment is not used on humans and there is a significant degree of routine oversight by radiation safety personnel, so there is a case to be made that this is actually more of a Class C or D facility. Although MRCP is certainly concerned with occupational exposure, from a public health standpoint, it is an equal or greater concern with patient exposure and to members of the general public. As a point of comparison, this is similar to presumptive designation of Class C for veterinarian offices. Although the equipment is similar to medical, it is not used on humans. In a sense, it is closer to a non-medical application that would typically be Class D. However, over many years of field surveys, MRCP found that many vet facilities provide minimal training to their operators, and often facility personnel end up holding the animals and stand near (or in) the primary radiation field during the exam. In this case, the occupational exposure, and possibility of unnecessary exposure is of higher risk than most non-medical applications. For this combination of reasons, veterinarian facilities are normally considered Class C. Following the same logic, an argument may be made that the University could more reasonably (and from a public health risk standpoint) be considered a Class C or D. Again, these will be evaluated on a case by case basis.

--Initial Classification of facilities was made based on presumptive standards. However, as indicated in Question #2, each facility is also afforded an opportunity to request in writing that an alternative standard be applied, one that provides an equivalency of public health protection for the operator, patient, and general members of the public. If, upon review, DHSS concludes that the alternative standard is adequate, MRCP considers the requirement met. As always, the burden of showing this rests on the person or facility applying for the alternative standard.

15. *What are the survey requirements for radiation machines being brought into the state for temporary use?*

Equipment being brought into the state must be registered at least four (4) days prior to entry. The owner/user should attach registration information and evidence of the most recent radiation safety survey completed in the state where the equipment is normally housed. DHSS *may* require survey prior to use in Missouri for some types of equipment. DHSS may also accept evidence of safety inspection in another state on a case by case basis. Temporary usage is limited to a max of ninety (90) days. If the machine is to be used in excess of 90 days within Missouri, it must be permanently registered and at that point a survey/evaluation would be required.

16. *Do only individual machines have to meet survey timeframes? For example, if a facility has both a CT and a radiographic machine, could the CT machine be surveyed annually and the radiographic machine surveyed every two years?*

No, survey timeframes are based on the Class (see Question 8) of the *entire* registered facility as a whole, which is dependent on the most significant potential radiological public health hazard registered to the facility, or past compliance history issues. In the case above, this would be considered a Class A facility, and all radiation producing equipment in the facility would need to be surveyed annually. The only exception to this is Class E dental (per 192.500) where CBCT equipment is inspected every three years, and all other dental equipment every six years. Beyond that, only in very limited circumstances, when the facility requests and can provide adequate justification (including distinct difference in ownership/control of the equipment) can the registration be split when it exists on the same physical location/campus/premises.

17. What are the requirements to be recognized as a Qualified Expert?

There are four (4) Pathways available to determine official recognition of Qualified Expert status:

A. Pathway 1: Approval by a Nationally-recognized Certifying body:

- o The American Board of Radiology; or
- o The American Board of Medical Physics; or
- o The Canadian College of Physicists in Medicine; or
- o The American Board of Health Physics.

OR

B. Pathway 2: Masters or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university.

-AND (2-A) documentation of a minimum of one (1) year of full time training and one (1) year professional, clinical and/or technical full time work experience under appropriate supervision.

-AND (3-B) Evidence of at least two (2) radiation surveys in the last two (2) years.

OR

C. Pathway 3: Bachelor's degree with 30 credit hours in physical or biological sciences or mathematics from an accredited college or university.

-AND (3-A) Four (4) years of applied radiation protection experience, of which at least one (1) year shall include applicable survey experience under supervision acceptable to the Department.

-AND (3-B) Evidence of at least two (2) radiation surveys in the last two (2) years.

OR

D. Pathway 4: Alternative Standard/Recognition by Petition. Petitioner for QE recognition does not meet the qualifications of paths 1,2, or 3; however, as an alternative, professes and can demonstrate to the department that the petitioner is competent to act in the category(s) for which they are applying, via equivalent educational, professional, clinical, technical, employment, or relevant experience, or have equivalent certification to the certifying agencies named above. Petitioner will submit third party documentation of education and experience or certification, and explain how that is applicable and equivalent to meet the intent of the Qualified Expert standard. Burden of evidence is on the petitioner.

-AND (4-A) Four (4) years of applied radiation protection experience, of which at least one (1) year shall include applicable survey experience under supervision acceptable to the Department.

-AND (4-B) Evidence of at least two (2) radiation surveys in the last two (2) years.

Note: "grandfathering" in recognition by Petition. Evidence should include documentation that the petitioner was actively engaged in radiation safety activities, and had a reasonable history of conducting surveys of the type they are requesting recognition for, prior to 2014. After that date, requirements for recognition default to the non-alternative presumptive standards described in Pathways 1,2 or 3.

18. Are QE's required to periodically reregister their status?

Yes. QE status will be renewed every two (2) years. Renewal will primarily be based on:

--Continued Experience: Evidence of at least 2 applicable radiation safety surveys in the last 2 years in the recognized modality/specialty.

--Continued Education: Upon renewal, evidence of approved credits pertinent to the recognized area(s) of expertise.

19. *I wish to apply as a QE, but have been serving in a supervisory/reviewer role for the past two years. I have trained/mentored/reviewed the work of other physicists or radiation safety professionals, but have not performed hands-on surveys in the last two years. Could that review work of those surveys be counted in lieu of the two (2) surveys performed in the last two years?*

Yes, depending on the scope of the survey(s) reviewed. After initial recognition, when QE status is renewed in two years, MRCP typically does not allow review only, but will expect ongoing education & experience, to normally include at least two (2) surveys. However, for initial recognition of QE status, MRCP take this situation of supervising individuals and review of work into account. For those that qualify for recognition via Path 1, MRCP does not require that evidence initially, but will on re-application. MRCP also applies a similar standard in this specific instance. However, MRCP will ask for some specific details about your role as a supervisor or reviewer; for example, a letter from a superior or the owner of the firm describing expectations in terms of review of surveys, surveys have performed in the past (outside the two year window), how many surveys you reviewed and signed off on over the last two years.

20. *For what reasons would the recognition of Qualified Expert status be revoked?*

Recognition as a Qualified Expert may be denied or revoked or limited to certain services due to problems regarding the reliability of the consultation/survey(s) resulting from issues including (but not limited to):

---Falsification of data/information, either on the application for recognition or survey/consultation documents;

---Negligence in the performance of radiation consultation/surveys such that significant errors result;

---Utilization of methods or procedures that do not conform (when applicable) to existing accepted professional standards (such as those described in documents published by AAPM, ACR, or other recognized standards);

---Lack of adequate oversight/direction of individual(s) performing tests or gathering data under review/signature of the QE;

---Failure to provide adequate survey documentation to the MRCP, including the QE summary form within 30 days of completing the survey;

---Failure to provide adequate evidence of initial or (upon re-registration every two years) continuing professional education and experience.

---Other problems that impact on the reliability of the consultation services provided by the Qualified Expert.

21. *What does the language in 19 CSR 20-10.050(1) mean that states the QE must utilize “Suitable Instruments & Methods” to conduct the radiation safety survey?*

--Survey equipment used to measure radiation safety should be used as the manufacturer indicates, following generally-accepted professional standards, and calibrated per manufacturer specifications.

--Suitable Methods means that the QE should follow accepted professional standards & protocol for radiation equipment evaluation; i.e., follow guidelines published by recognized professional organizations such as AAPM, ACR, etc. QE's are allowed significant leeway to develop and alter survey protocols, depending on their professional judgment and the individual circumstances of the facility. However, they should be prepared to scientifically justify any deviations from common radiation safety protocol.

22. *What does the language in CRS 20-10.050(1) indicating that surveys must be “Conducted by or under the direction of a Qualified Expert” mean in terms of supervision of the survey process?*

--Survey of Class A facilities must be conducted personally by a Qualified Expert, or under their *direct supervision* (on site, in the building, available to observe and correct for training purposes).

--Survey of Class B, C, D, and E facilities may be conducted by QE or under their direction. The QE can utilize another individual to conduct measurements and gather data for the survey, but the QE is ultimately responsible for the quality and oversight of the survey process, including protocol & measurements. In addition, the results must be reviewed and approved by the QE, and the QE must provide a signed report summarizing the results of the survey.

-Both the *survey frequency & level of QE supervision take into account public health risk, as well as recognizing existing numbers of QE's available to handle expanded workload & responsibility.*

23. What are the requirements for individuals that the QE may utilize to collect survey information/data under the QE's direction (QE Assistants)?

For Class A facilities, the radiation surveys must be conducted directly by the QE, or under their direct supervision while onsite (for training purposes). However, for Class B, C, D, and E facilities, the data & measurements for the radiation safety survey may be gathered under the direction of the Qualified Expert (QE determines survey protocol, reviews results, and produces a signed final report summarizing findings and recommendations). For those individuals (QE assistants) the QE may use to assist in collecting data and making measurements, there are no formal standards at this time. The QE is given leeway to utilize individuals they choose, but are required to provide adequate training and oversight of those individuals, as well as review the data and create the signed report of findings and recommendations under the signature of the QE. Consensus standards may be developed in cooperation with the QE community to outline presumptive standards for QE assistants.

24. What specific areas of Expertise will be recognized?

QE's should indicate his/her areas of Expertise, and upon request be able to provide evidence of both training and experience for each specific type of equipment for which they are requesting Qualified Expert status. Expertise in the following areas will be recognized:

1. Health Physics Consultation
2. Shielding Design
3. Routine Radiographic (Medical/Chiropractic/Podiatric/x-ray machines)
4. Mammography (qualifications must conform to the FDA's MQSA requirements.)
5. Fluoroscopy/interventional radiology
6. CT (includes CBCT)
7. Bone Density/DEXA
8. Non-medical/Industrial/Academic/Research
9. Veterinary Radiology (machine type similar to medical, but public health risk is occupational only).
10. Dental (non-CBCT)
11. Therapy/Linear accelerators
12. OTHER radiation safety expertise: applicant will be asked to describe specifics more fully.

25. Will DHSS communicate with the Qualified Experts as a single group to help assure consistency?

DHSS provides ongoing, routine communication with the QEs via periodic emails, not only with individual QE's, but with periodic email "blasts" to all registered QEs, as well as with formal representatives and professional entities of the radiation safety/health physics community, such as local chapters of the AAPM and HPS.

26. If I am recognized as a Qualified Expert, and am claiming an area of expertise in mammography, is there additional documentation I must include along with my application to be recognized as a Qualified Expert?

Yes. As noted on the application for recognition as a Qualified Expert, to claim the area of expertise in mammography, the applicant must demonstrate that he/she conforms to the federal requirements to be a medical physicist under the FDA's Mammography Quality Standards Act (MQSA). Many physicists have already had their initial qualifications approved in Missouri to be a mammography physicist in years past. However, that approval as a physicist was only based on a review of the initial qualifications. To be recognized as a Qualified Expert in mammography, the applicant must also conform to the continuing qualification requirements, namely education (15 CEUs in the last 36 months) and experience (2 facilities & 6 units in the last 24 months). This documentation must be provided as part of the QE application if you are claiming an expertise in Mammography. Since Qualified Expert status must be renewed every two years, once you are registered as a QE, MRCP will request updated continuing education and experience at each renewal (at a minimum). However, your QE certificate will be the only document you need to show at mammography facilities in Missouri (other states' requirements may differ). For your reference, the federal requirements for mammography physicists may be found on the FDA's MQSA website at:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm>

27. ***My dental practice utilizes a Cone Beam Computed Tomography machine (CBCT). It is my understanding that this equipment puts out less radiation than a typical standard CT machine. Does the usage of a CBCT in a dental office really raise the classification of the radiation facility to Class E, requiring radiation safety surveys every 36 month?***

Yes. Per state law 192.500, any dental facility utilizing CBCT is a Class E facility, and the CBCT unit must be surveyed by a Qualified Expert every 36 months. The other x-ray equipment in use by the Class E facility must be inspected every six years. A more detailed discussion follows.

In the past decade, cone beam computed tomography machines (CBCT) have become more widespread in use in dental facilities. This is a relatively new technological development, and extensive studies on the radiological impact, radiation dose, as well as detailed utilization and protocol optimization guidelines, are still under development in the CBCT industry and health physics community. However, a current understanding of the technology and risk indicates that although the radiation exposure is less than a typical medical CT, on average it is far in excess of routine dental radiographic and panoramic x-rays. Further, CBCT is inherently prone to artifacts and other technical issues than can negatively impact diagnostic quality and unnecessary exposure. Additionally, studies and surveys have indicated that that training and usage has not been consistently applied across the dental field. In other words, penetration of CBCT technology into the dental community has, to some degree, outpaced the understanding of its optimization and potential health impacts. Finally, the consensus guidelines of most professional and technical advisory bodies suggest that CBCT be treated like typical CT, and similar radiation protection standards be applied. Relevant references:

--Radiation doses and risks from dental CBCT are considerably higher than conventional dental radiography, although lower than typical conventional muscular-skeletal CT. Although specific radiation dose delivery will vary, CBCT dose is 10-450 times greater than a standard intraoral radiograph, and 5-50 times greater than a panoramic radiograph.—*Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology, Evidence Based Guidelines (2011). Sedentex CT.*

--CBCT is considered “Advanced Diagnostic Imaging” under CMS’s MIPPA accreditation requirement, and all facilities providing this service and billing Medicare after 1/1/2012 must be accredited, including dental facilities. Part of accreditation standards are periodic quality testing of the imaging equipment. Other insurance companies such as Aetna, Anthem, and Humana are implementing similar requirements for accreditation for facilities billing for CT services, including CBCT. — *CMS.gov*

-- “[A]lthough CBCT technologies have advanced rapidly across time, concerns have been expressed about whether the information acquired with CBCT imaging warrants the additional exposure risk, as well as about the level of training, education and experience required to interpret the CBCT data set...Dentists must abide by applicable federal and state regulations in the provision of dental imaging modalities. This includes following regulations or guidance to ensure a safe working environment for both the staff and the public in relation to CBCT equipment and other sources of ionizing radiation...Facilities considering the installation of new CBCT devices should consult a health physicist (or other qualified expert) to perform a shielding analysis based on NCRP reports 145 and 147. Facilities using CBCT systems should consult a health physicist (or other qualified expert) to perform equipment performance and compliance evaluations initially at installation and then follow a schedule in compliance with local, state and federal requirements. The Council recommends that a performance evaluation be completed at least annually. The evaluations should include patient dose estimation to assist the facility with patient dose management.”-- *Use of cone-beam computed tomography in dentistry--An advisory statement from the American Dental Association Council on Scientific Affairs—8/1/12*

--“At this time, all CBCT equipment produce dose levels and beam energies that are higher than conventional dental radiography, requiring extra practical protection measures for office personnel. Appropriate qualified experts should be consulted prior to and after installation to meet state and federal requirements, and manufacturer’s recommended calibration routines should be conducted at the recommended intervals.”--*Joint Position Statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology—2010*

-- Although the radiation doses from dental CBCT exams are generally lower than other CT exams, dental CBCT exams typically deliver more radiation than conventional dental X-ray exams. Concerns about radiation exposure are greater for younger patients because they are more sensitive to radiation (i.e., estimates of their lifetime risk for cancer incidence and mortality per unit dose of ionizing radiation are higher) and they have a longer lifetime for ill effects to develop. —*fd.gov*

--CBCT is prone to significant imaging artifacts (noise, scatter, motion, etc) that can negatively impact diagnostic quality and an accurate diagnosis. —*Dentomaxillofacila Radiology, July 2011, Vol 40:5, pp. 265-273*

--[A]ny practice undertaking medical exposure should have access to the advice of a qualified expert for advice on radiation protection and a medical physics expert for advice on patient dose optimization and equipment testing. ... the relative radiation dose implications of some CBCT systems [outline the need] to have a formal arrangement to obtain [qualified expert] advice...both when the equipment is first installed and then on a regular basis throughout the life of the equipment. [Maximum values for testing frequency for CBCT per the SEDENTEX Evidence based guidelines is 12 months.] --

SEDENTEX CT, 2011

28. Are QE's required to utilize and submit any standard survey forms to MRCP?

Yes. QE's have considerable flexibility to develop and utilize his/her own survey protocol. However, as part of the expectation of recognition of Qualified status, the QE is required to use a standardized survey summary results form, consistent across all facility Class types. QE's are also required to provide to MRCP, upon conclusion of the required radiation safety survey, basic information about the survey so that MRCP staff can track and follow up on problems as needed. The form is available on the MRCP website.

<http://health.mo.gov/safety/radprotection/xls/QE-SurveySummaryForm.xls>

The form includes basic information about the survey such as:

--Facility identification

--Who performed the survey (data collection, as well as final QE conclusions/recommendations)

--Date the survey was completed

--Listing of Radiation Equipment Reviewed (to ensure that all facility radiation equipment was surveyed)

--Summary of Results for each machine reviewed:

----Triage Code 0—No problems;

----Triage Code 1—Suggestions Only;

----Triage Code 2—items requiring corrective action within 30 days;

----Triage Code 3--Significant Problems/Safety issues that must be corrected prior to additional usage.

--The QE must provide the Radiation Safety Summary Results Form to MRCP within thirty (30) days after completion of the survey, and a copy of the summary along with a detailed report to the facility also within thirty (30) days. MRCP reviews the survey results and QE recommendations, and seeks additional information as needed (corrective actions, etc.) from the facility or QE, to ensure that facilities correct any significant problems found. **NOTE: For any unusual or Triage Code 3 findings, the QE is expected to contact/notify MRCP at the time of the inspection.**

29. What if a physicist does not wish to be registered or recognized as a Qualified Expert?

There is no regulatory mandate that an individual physicist or radiation safety consultant be recognized as a Qualified Expert. The mandate is on the radiation facility itself. Each registered facility must utilize a recognized Qualified Expert to conduct their periodic radiation safety surveys. If you are contracted as a physicist with a facility, but are not registered and recognized as a QE, the facility will have to utilize someone else who IS a recognized QE to provide the periodic radiation safety survey.