Summary of Public Comment
Ionizing Radiation - Ionizing Radiation Rules Governing the Use of Radiation Machines ORR #2013-107 LR

The following captures the comments and questions received on the approved draft rule set through the close of business on the day of the public hearing. The hearing was held on September 17, 2015.

Organization	Karen Burgess, CEO Executive Director Michigan Dental Association
Comment and Response	Comment: In R333.5013(2), the weighting factor for calculating the effective dose equivalent for an organ or tissue, should utilize the updated 2007 International Commission on Radiation Protection (ICRP) Weighting Factors. The Organ Dose Weighting Factors in the current draft rules are based on the 1977 ICRP publication. Response: This issue is currently in flux. The NRC is considering changes to its part 20 regulations governing dose limits and methods of determining occupational dose. At present, the NRC and the Conference of Radiation Control Program Directors (CRCPD) utilize the 1977 tissue weighting factors (i.e. ICRP 30) for the purpose of computing occupational doses. If the NRC changes its basis for organ weighting factors, we expect the CRCPD to follow suit within a few years due to states obligations under the Agreement State program. The Department will consider changes to the weighting factors at a future time depending on the national consensus. At present, the Department believes that updating the weighting factors would not significantly affect the occupational dose levels in Michigan. We believe most registrants will be utilizing the deep dose equivalent as the assigned dose for their workers and the weighting factors will not apply.
	Comment: In regards to R333.5396, which requires users of handheld x-ray systems to complete a manufacturer-supplied training program, the MDA believes training should be addressed by a requirement that users have completed a course on radiology. This could be accomplished either in an approved institutional program or through continuing education courses. We make this request because, to the MDA's knowledge, not all manufactures supply a training program. Response: The Department has interpreted this rule to mean that employees are required to be instructed in the proper operation of the equipment as provided by the manufacturer. Our interpretation is based on FDA guidance. According to FDA regulation 21 CFR 1020.30(h)(1)(i) manufacturers must provide “adequate instructions concerning radiological safety procedures and precautions which may be necessary because of unique features of the equipment.” Since the FDA performance standards require manufacturers of equipment sold in the U.S. to provide such information, the Department believes this rule can be met by the registrant. The Department may consider changes to this rule during a future revision and would be open to specific suggestions at such time. Other commenters have requested specific training requirements for operators of x-ray equipment. The Department anticipates that operator training will be a topic for revisions once a machine only rule set is established.
Organization	R. Tod Van Wieren, Diagnostic Radiological Physicist Medical Physics Consultants, Inc.
Comment	Comment: I would like to give my comments on proposed Rule 717(4). This rule would require physics testing on a CT scanner before patient use if a scanner is moved, disassembled, or major components are changed or repaired.

and Response	Following are my concerns: • While a similar requirement is in place for mammography units, these units are not used in emergency situations like CT scanners are. The demand for immediate availability of a CT scanner in a hospital setting with one scanner is great. While service on these units is usually immediately available, consulting physics availability is not. This would mean a hospital could be without emergency scanning capability until schedule and travel can be worked out for a consulting physicist. This emergency consulting visit would be very costly and time consuming for the physicist and thus to the CT facility as well. • The CT service provider already insures proper calibration of this equipment after service. This includes radiation output accuracy which the CT scanner accurately displays for all patients. It is very likely that a physics survey would not find any issues in this situation. Without the proposed rule, experience has not shown any issues with a CT scanner due to disassembly, moving, or major component replacement. I would propose that a reasonable timeframe be substituted for the "before clinical use" in order to more reasonably accomplish the goal of documenting proper performance after changes to the scanner without loss of patient emergency response capability and/or taxing the limited consulting physics services. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Kimberly Grove, Diagnostic Imaging Manager McLaren Greater Lansing
Comment	Comment: I would like to comment on the proposed new rule requiring a medical physicist evaluation of a CT machine following a move or

and Response	a major component change. In regards to CT scanners that have been moved, I support a rule requiring an evaluation by a medical physicist prior to patient use. Such evaluation would validate that the unit is within proper operating specifications and ensure radiation safety to the patient. In regards to CT scanners that have had a major component change/service, I do not support this rule. I believe such language would negatively impact patient care due to delays in access while waiting for a medical physics clearance. CT scanners are used commonly for urgent and life threatening injuries/ailments and creating an obstacle for access to scanning would be detrimental to the patient. Most institutions do not have an on-site medical physicist, so getting an emergent medical physicist evaluation would take time (added to the down-time needed for the repair) and an added expense to facilities. Also of concern is the lack of scanner redundancy at many acute care settings, which with a down CT scanner would necessitate the need to transfer a patient with urgent medical needs. Finally, if no CT imaging is available an Emergency Room would close to EMS/ambulance traffic, which could be catastrophic. Please consider my comments in regards to the proposed rule change. This rule change will seriously impact our ability to provide patient care to those who need it most urgently. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Bob Green, Manager of Imaging, Cardio Diagnostic and Sleep Lab MidMichigan Medical Center – Gratiot
Comment and	Comment: R 333.717(4), 7/6/2015 draft, requires medical physics testing on a CT unit following a move or major equipment replacement prior to clinical use. I am concerned that this will increase the length of a downtime and no service for hospitals with one scanner.

Response	Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Rick Phillips, Radiology Manager St. Joseph Health System – Tawas City
Comment and Response	Comment: I am writing my concerns for the new proposal that would require a Medical Physicists evaluation of the CT Scanner after a major repair. In our community, we are very reliant on the services of our CT scanner and to delay the use of the CT scanner after the repair would/could cause a serious delay in care. We do not have an on-site Medical Physicist, which would require the Physicist to drive to Tawas to perform this post-service evaluation. Since the Equipment has Quality control testing after the repairs, would it be a more reasonable expectation to have a Physicist review within 7 days? Please take this into consideration, as the rural patients are the most affected by this. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose.

	(c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Andreas Koutouzos, Senior Director Imaging UP Health System - Marquette
Comment and Response	Comment: As Senior Director of Imaging, I have reviewed the proposed State of Michigan requirements for post repair CT scanners. I am opposed to this proposed rule for the reasons given below. Definition of disassembled is vague and can be construed to mean something as simple as a bed repair or complex as a tube replacement. To require a medical physicist to approve the repair before human use would require significant downtime and inevitably affect patient care. With 10 critical access hospitals in the Upper Peninsula with only a single scanner, the time required to comply with this rule would potentially be days before the CT scanner is up and running. The risk to patients and their subsequent care would be too great and may produce an adverse outcome. Repair typically is performed by the manufacturer of the CT scanner. In the process of repair, the clinical engineer performs routine QC on the unit after repair which coincides to manufacturer specifications. The OEM of these scanners has a vested interest to see that when a repair is complete, their units are safe and perform to published specifications. In many ways, given that most of the QC is controlled by software which monitors the unit's performance, the engineer is more qualified than the medical physicist in conducting these safety tests. The risk to patient care by creating a delay would be far riskier than the possibility of the CT scanner not functioning at peak performance. Please remember those hospitals on the fringe with vast areas to cover having to do without a vital tool in the management of a critically ill patient. A case in point for risk vs. benefit where the risk far outweighs the benefit of the proposed requirement. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection.

	(d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	James Tomlinson, Senior Vice President Medical Physics Consultants, Inc.
Comment and Response	Comment: R 333.5036 will a radiation survey be required following the installation of Department approved newly shielded room? Response: The Department's current practice is to require a radiation survey for CT rooms and radiation therapy rooms. In medical settings, these are the only examples of the Department routinely requiring surveys. Currently, R 325.5317(3) requires the survey of a radiation therapy room prior to routine use. While there is no specific rule requiring surveys for new CT rooms, the department feels that surveys should be performed on these rooms and cites the general requirement in R 325.5221 in making this request. The draft rules contain R 333.5063 which has the same general requirement for the performance of surveys as R 325.5221. The Department intends to continue the practice of requiring surveys of new CT rooms by citation of the new rule (R 333.5036).
	Comment: R 333.5063 requires that survey instruments used for quantitative radiation measurements be calibrated annually. This requirement conflicts with the biannual calibration frequency equipment used to assess the performance of CT and mammography equipment. Response: R 333.5063(2) requires that survey instruments used to demonstrate compliance with occupational and public dose limits (i.e. under part 3) be calibrated annually for the type of radiation measured "except as otherwise specified in another part:". Biennial calibration of mammography and CT ionization chambers is required for the instruments used to measure the radiation outputs and beam qualities used to determine patient doses or dose indices. These rules require that calibration of such ionization chambers be traceable to a national standard as defined in draft rule R 333.5012(1). These requirements are independent of one another. Rules 696 and 719 require biennial calibration which is "traceable to a national standard". Subrule 63(2) requires annual calibration of survey instruments but does not specify the method of calibration. The definition of "calibration" is given in draft R 333.5003(2).
	Comment: R 333.5087 requires immediate notifications if a shallow dose exceeds 250 rads, and 24 hours if shallow dose exceeds 50 rem. Does this apply to intentional medical exposure of patients? These skin dose levels can easily be exceeded in interventional radiography.

	Response: R 333.5087 does not apply to doses received by patients intentionally exposed for diagnostic or therapeutic purposes. This rule occurs in *Part 3. Standards for Protection Against Radiation for Users of Radiation Machines.* R 333.5052, the scope of Part 3, states "the limits in this part do not apply to doses due to background radiation, exposure of patients to radiation for medical diagnosis or therapy, exposure from individuals administered radioactive material, or exposure from voluntary participation in medical research programs."
	R 333.5337(15) limits the output of a fluoroscopic machine equipped with automatic exposure rate control to be limited to 5 roentgens per minute in the normal mode. This is contrary to the current FDA performance standard which allows a maximum rate of 10 roentgens per minute when operated in the normal mode. Response: The Department agrees. The subrule will be modified as follows: R 333.5337 X-ray equipment. … (15) Entrance exposure rate limits for fluoroscopic equipment shall be as follows: (a) Machines with automatic exposure rate control shall not be operable at a combination of tube potential and current which results in an a exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is provided. ~~When so provided, the equipment shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.~~ Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed. …
	Comment: R 333.5717(4) requires additional evaluations when a CT scanner is moved or when major components are repaired (I read "replaced"). Before clinical use. This is my biggest concern, especially for remote rural facilities with only one CT scanner. Equipment repairs involving a tube, detector, or collimator replacement are usually not planned. They are emergent. As a consultant, and with long distances to travel, I may not be able to drop everything, every time this happens, thereby creating an extreme burden on the facility. What we have experienced with mammography equipment evaluations is different, in that it is much easier for a facility to be down a few days until a physicist can get there. There are no "emergency mammograms". But a hospital's only CT scanner, down waiting for a physicist, would have serious negative impact on emergency patients. Since the proposed rule for the evaluation is to "determine compliance with (FDA) rules and facilities quality control limits before clinical use", I would like to pursue an alternative to requiring a physicist to conduct an on-site visit before clinical use. I find it reasonable to require the service engineer to follow FDA certification procedures for repairs and conduct testing to ensure compliance with manufacturer's specifications. The "evaluation" can be conducted under the direction of the medical physicist. Then have the CT quality control technologist conduct routine quality control to make sure there are no image artifacts and that the results are within QC limits. Finally, have that information reported to the physicist for review and approval and documented. I would like to propose this reasonable approach to satisfy this new requirement.

	Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Steve Henry, Medical Physicist Medical Physics Consultants, Inc.
Comment and Response	Comment: As it is currently worded, this proposed rule would require a medical physicist to evaluate/test a CT scanner when major components of the unit are repaired or upgraded. As many of these major repairs or upgrades are not planned, this would mean that medical facilities would be contacting us with little or no lead time asking us to come out and test their CT scanner so they can start using it again clinically. This is similar to the MQSA requirement for mammography units that requires in-person evaluations by a medical physicist for certain major repairs (a page from the MQSA website listing these repairs is also attached). The primary difference, however, is that there really aren't any emergency mammograms, which allows patients to be rescheduled without any immediate risk to their health, while there are obviously numerous emergency CT exams. This could, and probably will, lead to situations where emergency exams can't be performed because a scanner has not been tested yet after a major repair/upgrade. Therefore, I would instead suggest adopting language similar to what the ACR uses in their CT QC Manual FAQ, which is also attached. In it, the ACR lists different major repairs/upgrades that require in-person evaluations by the medical physicist. The difference, however, is that while the ACR says the evaluation should be completed as soon as possible, they allow 30 days for it to be completed. In my opinion, this would be a more reasonable requirement, and would avoid situations where emergency patients would have to be turned away because a repaired/upgraded scanner had not been tested yet. As an alternative, once the repair/upgrade has been completed, if a

	medical physicist can't perform their testing immediately, the facility could be required to perform their daily QC scan, and as long as the CT numbers are within range, and there aren't any clinically significant artifacts, then the scanner could be used clinically. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Suzanne Kasper, Radiology Manager Metro Health Hospital
Comment and Response	Comment: I am responding to the following proposal: A new rule requires a medical physicist evaluation of CT machines following a move or a major component change My currently role is, I am a manager in Radiology and directly oversee CT. I am responding to this rule due to the negative impact it will have on Radiology departments, and on daily/financial operations. Currently, in order to successfully schedule a physicist for yearly inspections and/or an inspection for a new piece of equipment, the process is started months prior to our need. If we do not do this then it is difficult to get a physicist scheduled to meet deadlines. A recent example: We replaced one of our CT scanners and the time line (de-install, construction, installation of new equipment) for the project did not go as planned. When notified about the delays I contacted the Physicist to reschedule the equipment inspection, and it took weeks to get this rescheduled. Due to the inspection delay we were not able to use the scanner which had an overall negative impact on the hospital. My concern is that the physicist are booked so far out, if this rule is put into place, CT facilities will be negatively impacted by the lack of turnaround time. The turnaround time for the follow up inspection will cause delays, and facilities will have to close the specific piece of equipment down until a physicist can inspect. This will also have a negative impact on patient care. There are metrics/standards that hospitals are held accountable for. If these standards cannot be met (due to the CT unit

	being out of service), then hospital's may be forced to "close" to specific types of patients, again negatively impacting patient care. This isn't even taking into consideration the cost that facilities are going to incur. Currently for yearly inspections, per CT unit cost is in upwards for $1,500. If this new rule is put into place, there will be additional cost that facilities were not planning on. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Scott Helms, Medical Physicist Medical Physics Consultants, Inc.
Comment and Response	Comment: I would like to comment on the proposed rule changes. My comment is directed toward the requirement that the CT scanner be inspected by a medical physicist before patients are scanned post repair. I agree with the LARA-RSS that such an inspection must be performed to ensure that the anticipated doses to patients are as expected. I don't accept the reasoning of the statement that the time for a physicist arrive to inspect the unit will put a hardship on the facility and their care to the public. Once a scanner as stopped functioning, a service engineer will be called in to diagnosis the problem that caused the unit to fail. Once the service engineer has determined the cause, parts are ordered for example say an x-ray tube. Service engineers have to call and have the x-ray tube shipped to hospital or imagining facility they don't have them stored locally. As a former CT technologist, I have seen the time from determining the cause of failure to the arrival of an x-ray tube. It's at least 8 hours. It's another 3-4 hours for install. The operator of the CT scanner then has ample time to notify the medical physicist to be ready to inspected the unit once its functional. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows:

	R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Nicholas Bevins, Imaging Physicist Henry Ford Hospital
Comment and Response	Comment: The current rule 333.5705 CT Operators defines those technologists that are deemed qualified to operate CT scanners. The currently allowed certifications, ARRT and CAMRT, do not fully encompass the population of technologists that have received CT-specific training as part of their certification process. Our proposed change is to R 333.5705(a)(i) (changes in bold): (i) Be currently registered by the American registry of radiologic technologists (ARRT), the Canadian association of medical radiation technologists (CAMRT), **the Nuclear Medicine Technology Certification Board (NMTCB) as a Nuclear Medicine Technologist (CNMT), or by the ARRT or the NMTCB in CT.** The justification for this rule is that CT education is a required element in current nuclear medicine programs. The Joint Review Committee on Educational Programs in Nuclear Medicine Technology (JRCNMT) has required CT as an educational element since January 1, 2011 and CT has been a component of the NMTCB exam since 2013. This far exceeds the requirements of the ARRT where CT education is not required and not a component of the ARRT radiography (R), nuclear (N), or therapy (T) exams. In addition, the both NMTCB and the ARRT have a certification exam in CT and that should be included. Response: The Department promulgated its CT rules in 2011 and used the accreditation standards of the American College of Radiology (ACR) as the basis. For initial qualifications, the current rules require that a technologist be registered with the ARRT or CAMRT and have

	20 hours of training in operating CT equipment or the advanced certification in CT from the ARRT. We are aware that the ACR has added registration with the NMTCB to its list of acceptable initial training requirements. We agree with the comment and will modify the rule as follows: R 333.5705 CT operators. Rule 705. All CT examinations shall be performed by a radiologic technologist who meets all of the following requirements or by a physician or osteopathic physician licensed under article 15 of the act. (a) Initial qualifications. Before beginning to perform CT examinations independently, a technologist shall meet both of the following: (i) Be currently registered by the American registry of radiologic technologists (ARRT)**,** ~~or by~~ the Canadian association of medical radiation technologists (CAMRT)**, or the Nuclear Medicine Technology Certification Board (NMTCB)**. (ii) Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection or have the advanced certification in computed tomography from the ARRT. ...
	Comment: We propose the addition of a new rule to the Radiation Safety Rules, Part 7 (Medical X-Ray Installations), section R 333.5337 pertaining to the x-ray equipment associated with fixed fluoroscopic installations: Visual, beam-on indicator(s) are required inside the fluoroscopy/procedure room whenever x-rays are being produced. These caution lights/indicators (usually of amber color) must be positioned inside the procedure room, in multiple locations if necessary, so that they are clearly visible to all staff working anywhere in the procedure room. Note that the FDA Code of Federal Regulations Title 21 Part 1020 requires the use of visual beam-on indicators whenever x-rays are produced. From a radiation safety standpoint, it is logical to assume that the beam-on indicator should be visible to the x-ray beam operator (e.g. interventional radiologist) AND ALL OTHERS present in the procedure room. Furthermore, NCRP report 168 (Radiation Dose Management for Fluoroscopically Guided Interventional Procedures) outlines widely accepted standards of protection involving fluoroscopic procedures. According to this report, “caution lights (amber) of universal design are required in the procedure room, in multiple locations if necessary, so that they are visible to all staff working anywhere in the room.” See paragraph below from NCRP Report 168 for more details. NCRP Report 168, page 62 “All staff present in the procedure room need a clear indication when x rays are being produced so they may adequately protect themselves. Since some fluoroscopy equipment does not emit noise during the production of x rays and is not designed to produce an audible tone as described in Section 3.1.2, staff in the procedure room cannot rely on an audible indication of the production of x rays. The presence of static or dynamic patient images on the display monitors cannot be used as a visual indication of the production of x rays since patient images remain after x-ray production ceases. In many cases staff cannot see the image monitors. In some installations, the room lights can be automatically dimmed during the production of x rays, and may be switchable within a given room to address the preferences of different operators. For all these reasons, caution lights (amber) of universal design are required in the procedure room, in

	multiple locations if necessary, so that they are visible to all staff working anywhere in the room. These lights are continuously illuminated while x rays are produced." Response: As you noted, the FDA performance standards require fluoroscopic machines to have beam-on indicators. At this time the Department does not want to create requirements without the input of the regulated community and is reluctant to add such a rule. We anticipate a promulgation of new machine rules in the near future. This issue will be taken up at that time.
	Comment: We applaud the department's efforts in standardizing the definition section of the radiation rules. However, we have concerns over how existing rules will be interpreted in this new framework. For instance, in the existing CT rules, the term "annual" in reference to annual physics testing means in the same calendar month each year (per the CT rule guidance). However, for mammography, per MQSA, annual means on or before the same day in the following year. There is a bit of ambiguity here, and we would like some clarification on how this will be handled when sites are inspected by the state. To be clear, we are not interested in changing the current interpretations, rather we are only interested if these combined rules will force that. Perhaps the best change would be to use the phrase "within 365 days of the previous test" when the very tight federal definition applies (i.e., for mammography). Response: We believe there is some misunderstanding on this point. Prior to the 2013 amendments to part 14, annual surveys and inspections needed to be performed within 365 days of the previous survey. The MQSA does not have a definition of annual. It states that a medical physicist shall perform a survey "at least once each year". Under this scheme a physicist could perform a survey on January 1st of one year and December 31st of the following year and meet this requirement. This is the reason the FDA needed to issue guidance stating that physicist surveys must be performed every 14 months. In Michigan, when part 15 (Computed Tomography Installations) was promulgated in 2011, a definition of annual meaning 12 months was created for that part. In 2013 when the mammography rules were amended, the same definition of annual was created for that part. This relieved the Department and the regulated community from needing to perform surveys within 365 days of the previous survey. This rules draft will create the same definition for all parts of the rules.
Organization	Karl Fischer, Health Physicist University of Michigan
Comment and Response	Comment: Consider including definitions for "permanent" and "continuous," as they apply to personnel monitoring. Response: The Department believes the typical understandings of the words "permanent" and "continuous" are sufficient in the context noted. Occupationally exposed individuals are to be provided with "permanently" assigned monitoring equipment and monitoring shall be "continuous" for the duration of employment. The current rules do not define these terms and we are not aware of a situation where there has been uncertainty about what is meant.
	Comment: A definition for "radiation worker" is purposely not created in the draft rule set. However, "radiation worker" continues to be used throughout the draft rule set, notably as it applies to continuous monitoring (Rules 294, 317, 333, 348, 366, 409, 418, 439, and 713). Consider clarifying the affected rules.

	Response: In the current rules, a person defined as a "radiation worker" is equivalent to an individual for whom monitoring is required under rule 222(1). Excepting the provision for minors, the definition (with the personnel monitoring requirement citations inserted) is: "A radiation worker means an individual assigned to work with or around sources of radiation **[rule 222(1)(c) and (e)]** or who, during the performance of his assigned duties is likely to receive a dose in any calendar quarter in excess of 300 millirems **[rule 222(1)(a)]**" We agree that rules you cite in your comment probably intended to point to the definition of "radiation worker". However, we believe the definition is not necessary because (1) its meaning can be inferred by context and (2) this definition is duplicative of the rule requiring monitoring (R 325.5222 in the current rules and R 333.5064 in the draft rules).
	Comment: Consider incorporating the guidance from HFS-105 (https://www.michigan.gov/documents/mdch/bhs-hfs-105_317334_7.pdf) into the draft rule set, to prevent confusion. Response: We do not plan to incorporate this guidance into the current rules draft. The material in the guidance document will continue to be relevant but will need to be updated to reflect the newly promulgated rules.
Organization	Gary Duehring Michigan Society of Radiologic Technologists
Comment and Response	Comment: The State should exercise its statutory authority and establish minimum training requirements for x-ray operators. Response: The Department is in favor of establishing formal minimum training requirements for x-ray operators. We do not intend to develop training standards for the current draft but anticipate draft rules for this purpose in the near future. We would anticipate the involvement of affected organizations and individuals in such a development.
Organization	Mitch Goodsitt, Professor of Radiological Sciences Emmanuel Christodoulou, Diagnostic Physicist Sandra Larson, Diagnostic Physicist University of Michigan Medical Center, Department of Radiology
Comment and Response	Comment: R 333.5005 (1): If the State wants to use "Effective dose equivalent (HE)" then the individual wT weighting factors must refer to the values of ICRP publication 26, 1977. According to R333.5013 (2) this is what the State intends to continue using. If the State would like to use the weighting factors of ICRP publication 60 or even the new weighting factors of ICRP publication 103, then they must use "Effective dose (E)". We strongly recommend the use of Effective dose (E). In this case the State should also use wR for "equivalent dose (H)" instead of the quality factor Q that was used for the "dose equivalent". Response: This issue is currently in flux. The NRC is considering changes to its part 20 regulations governing dose limits and methods of

	determining occupational dose. At present, the NRC and the Conference of Radiation Control Program Directors (CRCPD) utilize the 1977 tissue weighting factors (i.e. ICRP 30) for the purpose of computing occupational doses. If the NRC changes its basis for organ weighting factors, we expect the CRCPD to follow suit within a few years due to states obligations under the Agreement State program. The Department will consider changes to the weighting factors at a future time depending on the national consensus. At present, the Department believes that updating the weighting factors would not significantly affect the occupational dose levels in Michigan. We believe most registrants will be utilizing the deep dose equivalent as the assigned dose for their workers and the weighting factors will not apply.
	Comment: R 333.5006 (1): Dose equivalent or Effective dose equivalent? If it is dose equivalent, then which part of the body does this refer to? As above, we recommend the use of "equivalent dose" and "Effective dose". Response: The definition of "high radiation area" uses "dose equivalent". The part of the body referred to is that which may be exposed. The definitions of both terms are identical with the regulations of 10 CFR 20 and the CRCPD SSRCR.
	Comment: R 333.5009 (4): Recommendation as above. Response: As discussed above, the Department intends to adopt the methodology of ICRP publication 26 until such time as a national consensus is reached.
	Comment: R 333.5013 Rule 13 (2) To reiterate, we recommend the adoption of the new weighting factors of ICRP 103 along with the adoption of effective dose E. Therefore, we recommend that the organ dose weighing factors in the table on pages 5 and 6 be updated to those in ICRP Publication 103.* ORGAN WT Gonads 0.08 Bone marrow, breasts, colon, lung, stomach 0.12 each Bladder, liver, thyroid, esophagus 0.04 each Skin, brain, bone surface, salivary gland 0.01 each Remainder 0.12 (sum) (adipose, adrenals, connective, gall bladder, heart wall, lymphatic, muscle, prostate, uterus airways, pancreas, SI wall, spleen, thymus)

	*Protection." Annals of the ICRP. ICRP publication 103 37 (2-4). 2007.ISBN 978-0-7020-3048-2 Response: As discussed above, the Department intends to adopt the methodology of ICRP publication 26 until such time as a national consensus is reached.
	Comment: 5) R 333.5057 Rule 57 (3)(b)(iii) (Page 16) If the State accepts the above recommendations for using effective dose, then for the estimation of the Effective dose using 2 individual monitoring devices, the number 1.5 should be replaced by 0.5 and the number 0.04 should be replaced by 0.025 according to the recommendation in NCRP report 168, 2010. If the State decides to stay with the Effective dose equivalent, then the numbers 1.5 and 0.04 must remain. We recommend use of an even more up-to-date equation for converting double badge dosimetry readings to effective whole body dose than the proposed "Webster" method. For example, use E=0.84 x deep dose equivalent under-apron + 0.051x deep dose equivalent over-apron (collar) (Equation 1) instead of E=1.5 x deep dose equivalent under-apron + 0.04 x deep dose equivalent over-apron (collar) (Equation 2 = "Webster" method)) (E=effective dose) Equation 1 is from von Boetticher, Heiner; Lachmund, Jörn; Hoffmann, Wolfgang AN ANALYTIC APPROACH TO DOUBLE DOSIMETRY ALGORITHMS IN OCCUPATIONAL DOSIMETRY USING ENERGY DEPENDENT ORGAN DOSE CONVERSION COEFFICIENTS Health Physics: December 2010 - Volume 99 - Issue 6 - pp 800-805 Response: As discussed in response to your other comments and recommendations, the Department plans to use the older ICRP methodology.
	Comment: 6) Part 2. Registration of Radiation Machines R 333.5036 Shielding plan review Rule 36 (5) – this rule requests a great deal of information be included on the scale drawing of the room. As it can be difficult to squeeze all of this information legibly on one drawing, we request that the rule state that this information is provided "with" the drawing rather than "on" the drawing. Response: The Department agrees that this rule may require too much information to be contained in a legible drawing. The draft rule will be changed to allow some information to be contained in an attachment and proposes R 333.5036(5) be changed as follows: R 333.5036 Shielding plan review.

	... (5) For machines installed after the effective date of this part, the registrant shall maintain for inspection by the department a scale drawing of the room where a stationary radiation machine system is located. The drawing **or accompanying attachments** shall ~~show~~ **indicate** the use of areas adjacent to the room and ~~contain~~ **include** an estimate of the occupancy in each area. In addition, the drawing **or attachment** shall include at least 1 of the following: (a) The type and thickness of materials, or lead equivalency, of each protective barrier. (b) The results of a survey for radiation levels at the operator's position and at pertinent points outside the room under specified test conditions. ...
	Comment: 7) R 333.5063 Rule 63 (2) (Page 17) requires that equipment used for quantitative radiation measurements be calibrated annually. Because this equipment rarely drifts out of calibration, an annual calibration would be excessive, not to mention expensive. Current ACR/MQSA recommendations allow for calibration every 2 years, so a 2-year time frame would not increase the financial burden of most facilities unnecessarily. We recommend a change to every 2 years. According to MQSA "(xx) Traceable to a national standard means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within +/- 3 percent of the national standard in the mammography energy range." See: http://www.fda.gov/RadiationEmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110906.htm Response: R 333.5063(2) requires that survey instruments used to demonstrate compliance with occupational and public dose limits (i.e. under part 3) be calibrated annually for the type of radiation measured "except as otherwise specified in another part:". Biennial calibration of mammography and CT ionization chambers is required for the instruments used to measure the radiation outputs and beam qualities used to determine patient doses or dose indices. These rules require that calibration of such ionization chambers be traceable to a national standard as defined in draft rule R 333.5012(1). These requirements are independent of one another. Rules 696 and 719 require biennial calibration which is "traceable to a national standard". Subrule 63(2) requires annual calibration of survey instruments but does not specify the method of calibration. The definition of "calibration" is given in draft R 333.5003(2).
	Comment: 8) R 333.5325, R 333.5362, and R 333.5405 FIXED RADIOGRAPHIC INSTALLATIONS Most references to "film" should also refer to a "digital detector" Response: The Department agrees. The following changes will be made to the draft rules: R 333.5325 X-ray equipment. ... (15) For radiographic procedures resulting in multiple views on a single ~~x-ray film~~ **image receptor**, the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the ~~radiographic film~~ **image receptor**

	with radio-opaque material is not a substitute for proper x-ray field limitation. ... R 333.5362 X-ray equipment. ... (10) For radiographic procedures resulting in multiple views on a single ~~x-ray film~~ **image receptor**, the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the ~~radiographic film~~ **image receptor** with radio-opaque material is not a substitute for proper x-ray field limitation. ... R 333.5405 X-ray equipment. ... (9) For radiographic procedures resulting in multiple views on a single ~~x-ray film~~ **image receptor** the beam-limiting device shall limit the x ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the ~~radiographic film~~ **image receptor** with radio-opaque material is not a substitute for proper x-ray field limitation. ...
	Comment: 9) R 333.5368 PART 9. DENTAL X-RAY INSTALLATIONS – update to refer to digital detectors as well as film. Response: The Department agrees. The following changes will be made to the draft rules: R 333.5373 X-ray equipment. ... (8) For intraoral ~~film~~ exposures, means shall be provided to limit the source-skin distance to not less than 18 centimeters with apparatus operable above 50 kVp, and not less than 10 centimeters with apparatus not operable above 50 kVp. Open-ended cones are recommended to reduce scattered radiation. ... R 333.5376 Conditions of operation. … (2) The operator or the assistant shall not hold the ~~film~~ **image receptor** in place for the patient during the exposure. … ~~(9) X-ray film with a minimum sensitivity of 12.0 to 24.0 reciprocal roentgens as specified in American standards association speed group D (A.S.A. PH 6.1-1961) shall be used for routine dental radiography.~~ ~~(10)~~**(9)** The x-ray beam and the ~~film~~ **image receptor** shall be aligned very carefully with the area to be radiographed. ~~(11)~~**(10)** ~~Film p~~**P**rocessing materials and techniques shall be those recommended by the ~~x-ray film~~ manufacturer **of the image receptor** unless otherwise tested to ensure maximum information content of the ~~developed film~~ **final image**. Sight developing **of film** is not permitted

	except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient. ~~(12)~~**(11)** A radiographic x-ray system shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons. R 333.5384 X-ray equipment. ... (2) For purposes of this rule, "image receptor" means that portion of the x-ray film **or digital receptor** instantaneously exposed by the x-ray beam subtended by a beam-limiting diaphragm immediately adjacent to the front of the radiographic film **or digital receptor**, if the panoramic technique requires this diaphragm. ... R 333.5389 X-ray equipment. ... (7) For radiographic procedures resulting in multiple views on a single ~~x ray film~~ **image receptor** the beam-limiting device shall limit the x ray field size to the recorded radiographic image within 2% of the SID. Covering a portion of the ~~radiographic film~~ **image receptor** with radio-opaque material is not a substitute for proper x ray field limitation.
	Comment: 10) R 333.5337, and R 333.5411 FIXED FLUORSCOPIC INSTALLATIONS -These sections should be updated to refer to digital detectors as well as image intensifiers. Response: The Department believes the use of the term “image intensifier” is generic enough in its use that no confusion arises from its use. Adding descriptions and definitions of digital detector technologies is beyond the scope of the current rulemaking. Future rule revisions will address changes to technology.
	Comment: 11) R 333.5351 and R 333.5421 MOBILE OR PORTABLE DIAGNOSTIC X-RAY EQUIPMENT – These sections should be updated to refer to digital detectors as well as film/screen and image intensifiers. Response: The Department believes the use of the term “image intensifier” is generic enough in its use that no confusion arises from its use. Adding descriptions and definitions of digital detector technologies is beyond the scope of the current rulemaking. Future rule revisions will address changes to technology.
	Comment: 12) R 333.5675(c) Medical Physicists (Page 84.) We have some concern about the lack of availability of courses to obtain the required “3 continuing medical education credits in stereotactic breast biopsy during the 36 months immediately preceding the date of the facility’s annual inspection.” There have been no refresher courses or sessions devoted to the physics of stereotactic breast biopsy systems at recent RSNA and AAPM meetings. We would prefer this requirement be changed to 3 continuing medical education credits in

	x-ray breast imaging. This would be more consistent with the FDA's requirements for specific areas that are acceptable for CME for MQSA approved medical physicists. From the FDA Website: " May medical physicists count general medical physics continuing education not related to mammography or general continuing education in mammography unrelated to medical physics? Yes, all continuing education credits related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography may be acceptable toward meeting the continuing education requirement. Diagnostic medical physics continuing education not directly related to mammography or general continuing education in mammography unrelated to medical physics would also be acceptable." See: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm138349.htm Response: The Department intends to leave this draft requirement unchanged. These requirements are founded on the personnel requirements of the ACR stereotactic breast biopsy accreditation standards which are identical to the existing standard.
Organization	Dennis Palmieri, Health Physicist
Comment and Response	Comment: At the outset, I want to state that I am commenting as an individual regarding provisions in the proposed amendments to the State of Michigan Ionizing Radiation Rules (R325.5001 et seq). These comments do not represent the position of my employer nor am I acting in representation of the University of Michigan. Second, I want to thank you for the opportunity to make these comments. In general, I look forward to the revisions proposed. I am writing this because of what I perceive to be a serious flaw in the provisions of the proposed Ionizing Radiation Rules. The proposed rules amend existing R325.5046 as new R333.5023 by adding a new civil money penalty provision. It justifies this by citing MCL 333.13535 out of Article XII of the Public Health Code. MCL 333.13535 does not grant the Department any authority to promulgate a schedule of civil money penalties. It is a criminal penal statute. The correct provision for doing so is in MCL 333.2262. That provision limits the amount of the penalty to $1000 per violation per day. MCL 333.2262 is from Article II of the Code which outlined the general powers of the Department. Those applicable powers in Article II under the Public Health Code transferred from the original Michigan Department of Public Health to the successor departments through the several Executive Reorganizations issued by the Office of the Governor since 1996. Analysis: The State passed 1978 Public Act 368 as a comprehensive, unified Public Health Code and it remains that way under the statutes of the

	State of Michigan. Provisions applicable can be found in statutes within Articles I, II and XII of the Act. See: http://www.legislature.mi.gov/(S(ifk5nhc3zu3k3seyp0btjgma))/mileg.aspx?page=getObject&objectName=mcl-Act-368-of-1978 I) MCL 333.1353 is a Criminal Penal Statute—Not a Grant of Departmental Authority MCL 333.13535 is a criminal penal statute. It never mentions the Department nor does it instruct the Department to do or enact anything. It serves strictly to define violations of the Public Health Code—as proven in court of law—to be a misdemeanor crime under the laws of the State of Michigan with maximum sentences of $10,000 and/or 180 days imprisonment. Crimes must be prosecuted in a court of law under the Constitution of the State of Michigan. Those crimes can only be prosecuted by county prosecutors or the Attorney General upon criminal information or indictment. It cannot be done via a Notice of Violation or other administrative means. MCL 333.1299 vests the authority to prosecute violations of the Public Health Code as misdemeanors with either the Attorney General or a county prosecutor with jurisdiction stemming from where the violation occurred. It grants no powers or authorities to the Department. See Article I of the Public Health Code 1978 Public Act 368. II) MCL 333.2262 -- Correct Authority to Promulgate Civil Money Penalties Article II of the Public Health Code outlines the general authorities and powers of the Department. These include MCL 333.2262. That statute grants the Department the discretionary authority to promulgate a schedule of civil money penalties in amounts up to $1000 per violation per day. It includes the manner in which those citations are to be noticed and served and provisions for hearings and a right to an appeal. III) Summary In short, Article I vests authority to prosecute criminal violations under the code with the Attorney General or a county prosecutor. Article II specifies the general powers of the Department and includes a provision to promulgate civil money penalties. Article XII of the Code defines additional specific powers and duties of the Department to regulate and register sources of ionizing radiation. It also defines violations of those rules and laws to be a criminal misdemeanor and sets the required and maximum sentences a court may order upon conviction. There is a fundamental constitutional difference between a civil money penalty and a criminal sanction. Crimes are prosecuted in courts of law. Charges are brought by prosecutors or the Attorney General. The defendant has a right to trial, the right to confront witnesses, have a jury, remain silent, the right to innocence until proven guilty, etc. The prosecutor must prove his case beyond a reasonable doubt--a very high standard of proof. IV) Conclusion:

The proposed rule R325.5046 is legally flawed. It should be amended to cite the Department's authority under MCL 333.2262 and to set the penalty amounts and establish procedures in accordance with the provisions of that statute.

V) Applicable Statutes from the Public Health Code (1978 Public Act 368)

333.1299 Violation as misdemeanor; prosecution.
Sec. 1299.
(1) A person who violates a provision of this code for which a penalty is not otherwise provided is guilty of a misdemeanor.

(2) A prosecuting attorney having jurisdiction and the attorney general knowing of a violation of this code, a rule promulgated under this code, or a local health department regulation the violation of which is punishable by a criminal penalty may prosecute the violator.

333.13535 Violations; penalties.
Sec. 13535.

A person who violates this part or a rule promulgated under this part or who fails to obtain or comply with conditions of licensure or registration under this part is guilty of a misdemeanor, punishable by imprisonment for not more than 180 days, or a fine of not more than $10,000.00, or both. A court may fine a person not more than $2,000.00 for each violation of this part. Each day a violation continues shall be a separate violation.

333.2262 Violation; rules adopting schedule of monetary civil penalties; issuance, contents, and delivery of citation.
Sec. 2262.

(1) The department may promulgate rules to adopt a schedule of monetary civil penalties, not to exceed $1,000.00 for each violation or day that a violation continues, which may be assessed for a specified violation of this code or a rule promulgated or an order issued under this code and which the department has the authority and duty to enforce.

(2) If a department representative believes that a person has violated this code or a rule promulgated or an order issued under this code which the department has the authority and duty to enforce, the representative may issue a citation at that time or not later than 90 days after discovery of the alleged violation. The citation shall be written and shall state with particularity the nature of the violation, including reference to the section, rule, or order alleged to have been violated, the civil penalty established for the violation, if any, and the right to appeal the citation pursuant to section 2263. The citation shall be delivered or sent by registered mail to the alleged violator.

Response: The commenter is correct. We appreciate the commenter's alertness in raising this issue. The rule will be changed as follows:

R 333.5023 Violations.
Rule 23. (1) Under authority of MCL 333.13536, the department may obtain an injunction or other court order prohibiting a violation of the act, a rule, an order, or a registration condition issued under the act.

	(2) Under the authority of MCL **333.2262** ~~333.13535~~, the department, in addition to taking other enforcement action, may impose a civil penalty, not to exceed **$1,000** ~~$10,000~~ for each violation, on a person who violates the act, a rule, an order, or a registration condition issued under the act. Each day that a violation continues shall constitute a separate **violation** ~~offense~~. (3) A person who ~~willfully~~ violates the act, a rule, an order, or a registration condition issued under the act may be guilty of a **misdemeanor** ~~crime~~ and, on conviction, may be fined, imprisoned, or both, as provided by law.
Organization	Laura Appel, Senior Vice President Strategic Initiatives Michigan Health & Hospital Association
Comment and Response	Comment: Thank you for the opportunity to comment on the proposed Ionizing Radiation Rules Governing the Use of Radiation Machines (rulemaking number 2013-107). The Department of Licensing and Regulatory Affairs (LARA) rule comparison document is helpful to understanding the proposed changes. LARA staff did an outstanding job to make this rule change clear to commenters. The Michigan Health & Hospital Association represents all Michigan acute care hospitals. It is likely that every Michigan hospital uses several pieces of equipment affected by the proposed rule. It is also likely that every Michigan hospital has and uses a CT scanner. CT scans are a reliable and frequent diagnostic tool for physicians. This service is used daily and extensively in our member hospitals. Section R. 333.5707 [sic] Medical Physicist proposes that a medical physicist evaluate "a CT scanner when it is disassembled and reassembled at the same or new location or when major components of the unit are repaired or upgraded." As proposed, the rule does not define "major component." The MHA is concerned that this portion of the rule could be interpreted broadly and lead to lengthy wait times for medical physicist services. This, in turn, could cause delay in availability of this necessary service. Many Michigan hospitals are small enough that there are not numerous machines available. The MHA recommends that this section of the rule be rewritten to more specifically identify when a CT scanner must be re-evaluated to minimize the disruption in service. The MHA is not suggesting that any CT scanner be used in an unsafe manner. We are suggesting that only certain repairs or replacement parts could result in a change in the safety of the machine and that a re-evaluation should only be required in these circumstances. Thank you for your kind consideration of this suggestion. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose.

	(c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
Organization	Ralph Lieto, Radiation Safety Officer Saint Joseph Mercy Health System
Comment and Response	Comment: I am Ralph Lieto, the Radiation Safety Officer for the Saint Joseph Mercy Health System. I am an American Board of Radiology certified medical physicist with over 35 years of medical radiation safety and regulatory compliance experience. It is understandable that the Department (LARA) has determined that it needs to establish a separate rule set governing radiation machines only. Removal of language, and definitions referring to radioactive material and deleting allowances for lower standards for machines manufactured prior to 1975 were reasonable and a major clean-up of these archaic rules. However, the Department has not maintained its commitment as stated in the announcement of this hearing to do this "with little or no change" to existing law. Some of the proposed changes are substantial and will have a significant impact - in allocation of resources, time and money and in some cases patient care. These proposed rules do not clearly indicate that an implementation time period is being allowed. On the contrary, it would appear that this comprehensive rewrite of the ionizing radiation rules will have immediate effect. Response: The commenter is correct in that some portions of the rules will be significantly updated from the current 40 year old rules. The Department has indicated as such in its communications to registrants both through its web page and its January 6, 2015 announcement of the availability of these draft rules for comment. The web page described that portions of the rules dealing with general provisions, registration of radiation machines, standards for protection against radiation, and notices and instructions to workers were based on the CRCPD SSR and, in those cases, would be a significant update from the current rules. The web page goes on to describe how these parts of the draft rules received input from members of the regulated community during the agreement state effort of 2007 through 2009. The drafts of parts 1 through 4 were developed at that time with the Agreement State Advisory Committee (ASAC) providing expertise. The remaining parts of the draft rules (6 through 15) are little changed. As stated previously, the main goal is to separate radioactive material rules from radiation machine rules. Where there are significant deviations from the current rules, the Department has tried to point them out through the documentation on its web page. The draft rules will be effective immediately following promulgation.
	Comment: The public should have been provided strikethrough/underline version of changes to compare the current and proposed new rules. At least the proposed rules should have some indication of the changes, additions, or language modifications in some

	bold/underlined version. Instead the public had to use three separate documents. One of which was called the "rules comparison" gave only vague, nondescript statements such as "The language of this rule is modified for style in the new rule set." It gave absolutely no assistance to assess if substantive changes have occurred. This is a serious due process concern. Response: The Department published the draft rules in keeping with the Office of Regulatory Reform standard. Under the promulgation process, these are “new rules”. That is the reason for no strikethrough/underline version having been created. The promulgation process will result in all current radiation machine rules being rescinded. The Department has followed the Administrative Procedures Act in this promulgation.
	Comment: The creation of the definition for "Declared pregnant woman" was unneeded. The existing wording in the current rules has been adequate and worked well for 40 years. If the Department insists on a new definition, it needs clarification and revision. The new definition states, "a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception." The proposed rule should clarify that it is not any woman but an occupationally exposed radiation worker. Remove the requirement for documenting date of conception. It is has little practical value and does nothing to improve worker safety. The Conference on Radiation Control Program Directors (CRCPD) does not suggest such a definition in its Suggested State Regulations. Response: The definition of “declared pregnant woman” and treatment in the rules is identical to that of the NRC and the CRCPD SSRs. We intend to incorporate this definition. .
	Comment: I commend the Department and MIOSHA for the change of the dose limits so that they will be consistent with current national standards. In addition, I support the elimination of quarterly limits. However, the dose limit to members of the public is changed by a factor of five to 1 millisievert from the current limit of 500 mrem. A concern is this limit being applied to a member of the general public (e.g., parent, caregiver) who must enter a room for patient assistance. Either add this circumstance as an exemption to the general public limit or keep the 500 mrem (5 millisievert) dose as a limit for such situations. Response: The NRC limit for the dose to members of the public has been 100 mrem (1 mSv) since 1991. While the Department has not yet changed this limit in rule, it has used the 100 mrem limit in shielding evaluations and in other applicable situations. We are aware that the NRC and the CRCPD SSRs contain a provision to allow a licensee to expose a member of the public to doses up to 0.5 rem (5 mSv). This rule would only come into play for the caretaker of a radioactive patient. Protection of the public and workers from radiation produced by radioactive material is beyond the Department’s jurisdiction. We note that the NRC/CRCPD rule does not simply provide a blanket exception, but rather the rule requires the licensee to justify exceeding the public dose limit and demonstrate that it has the engineering and administrative controls in place to ensure that the licensee does not exceed 0.5 rem (5 mSv). We are at a loss to come up with a scenario in which a caretaker would need to be exposed to machine produced radiation in excess of the 1 mSv (100 mrem) limit proposed in the draft.
	Comment: Rule 64- Conditions requiring individual monitoring of occupational dose - is described only as being "is expanded and made more explicit in the new rule set." Its new wording is more restrictive, and creates a situation for monitoring workers not under the

	registrant's control, such as service engineers, vendor reps, and rotating students/trainees. This is unfairly burdensome to the registrant and need to be revised. Possible rewording is "A registrant shall ensure occupational monitoring to radiation from ... " Response: We are uncertain how the draft rule is more restrictive than the current rule. Under the current rule, a registrant is responsible for exposures resulting from radiation sources under its control. The Department does not understand what is meant by the comment that the draft rule "creates a situation for monitoring workers not under the registrant's control". The existing rules require the registrant to maintain control of areas in which sources are used or stored. That standard is not changing. The registrant must supply monitoring equipment to individuals under the conditions of R 325.5222(1)(a) to (e). Similarly, the draft rule requires the registrant to monitor radiation exposures to individuals under the conditions of R 333.5064(a) to (e). The Department does not believe there is any change in scope between the current standard and the draft rule. There are indeed differences in some of the dose thresholds which require monitoring to take place as the draft rule incorporates the more current dose standards of the NRC and the CRCPD SSRs. The proposed rule is virtually identical to these those standards.
	Comment: The proposed rule for adjusting the occupational dose from exposure to a single dosimeter outside of a lead apron worn for fluoroscopy is not the current standard. Please see NCRP Report No. 168. "Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures" (2010). Also it is not provided as an adjustment by Landauer, Inc. This needs to be revised to the current and simpler formula from a nationally recognized standard. Response: Since the NRC and the suggested state regulations both still use effective dose equivalent, which is based on the weighting factors in ICRP 1977a, and not effective dose, we want to keep the same system of estimating doses. Also, the proposed system to estimate dose to individuals exposed to x-rays while wearing a lead apron is identical to that used in the CRCPD SSRs and is also listed in an NRC regulatory issue summary as being an acceptable method to estimate occupational dose. We would also note that Landauer lists these special dose calculations are available. The following is copied from their web page:
	Comment: The Rules for Class AA installations have been "modified for style in the new rule set." Because these devices affect tissue specimen irradiators in surgery and mammography, it is unclear how these changes will impact medical use because it appears to mandate occupational monitoring, which is not justified for these devices. Response: The current industrial radiographic rules are not clear on the requirement of dosimetry. As a result, the Department issued guidance several years ago stating that personnel monitoring is not required for operators of class AA industrial radiographic units "of insufficient size to permit human occupancy". In draft R 333.5294, subrule (13) is added which states that personnel monitoring will be assigned to operators of class AA units having enclosures of "sufficient size to permit human occupancy". We are not aware of any specimen irradiators "of sufficient size to permit human occupancy" and do not believe this subrule will ever come into play.

	Comment: Rule 54 is created which requires a registrant to develop, document, and implement a radiation protection program. In addition, Rule 54 requires the registrant to, at least annually, review the radiation protection program content and implementation. The records for "provisions of program" must be maintained indefinitely. This affects every registrant regardless of size. Has the Department developed any guidance as what the components of this program need or should include? How can the Department justify that this will not have a significant impact both time and cost on registrants? Due to how this rulemaking process is being conducted, this could be effective in a matter of weeks to a few months! While this intent is good, it will have significant impact and should not be published until the update of the Ionizing Radiation Rules is in its final phase and guidance is developed. Response: This rule was carried over from the NRC and CRCPD rules. We had intended to issue guidance documents to enable compliance. The Department agrees with the commenter that promulgation of this requirement will require further vetting. We intend to delete this rule and the accompanying records requirement (R 333.5078) from the draft.
	Comment: A new rule states that stereotactic breast biopsy machines shall be maintained in compliance with the FDA performance standards. Why is such a new rule required just for breast biopsy machines and not for any other imaging machine? Why is this even needed; what are the circumstances that would allow any machine to be used on patients that did not comply with FDA performance standards? This requires clarification and justification. Response: This was to correct an omission in the original rule promulgated in 2013. The FDA performance standard only covers the manufacturer and installer of the device. It does not cover the user. This rule was added to make it clear that the stereotactic breast biopsy machines need to be maintained to continue to meet the performance standard, even after they are installed and in use. In the current rules, mammography machines are required to be maintained in compliance with the FDA performance standards (R 325.5637) and CT machines are required to be maintained in compliance with the FDA performance standards (R 325.5709). Analogous rules for CT and mammography are created in the draft rules.
	Comment: A new rule requires a medical physicist evaluation of CT machines following a major component change, repair, or upgrade and forbids use until this is complete. This rule needs significant clarification as to what major components warrant another medical physicist evaluation. This definition must involve the expert user input from the medical physics and Radiology community and not be determined solely by the LARA. Response: Based on the comments we have received on this requirement, the Department will not be promulgating this subrule at this time. R 333.5717 will be modified as follows: R 333.5717 Quality control program. Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection.

	(d) Compliance with the provisions of this part. (e) Ongoing quality control. (2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits. (3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule. ~~(4) Additional evaluations shall be conducted when a CT scanner is disassembled or reassembled at the same or a new location or when major components of the unit are repaired or upgraded. The evaluation shall be used to determine whether the new or changed equipment meets the applicable standards of R 333.5709 and facility's quality control limits before clinical use. The evaluation shall be performed by the medical physicist or by qualified individuals under the direction of the medical physicist.~~
	Comment: Another new rule (718) makes the requirement to establish and review CT clinical protocols more explicit and essentially the responsibility on the medical physicist. This is unacceptable. The proposed rule state that clinical protocols established by the "facility", which could be anyone without CT or radiological experience, and the medical physicist. This is completely contrary to the recommendations of the American College of Radiology, Image Gently/Image Wisely and the CRCPD who recommend establishing a review committee/group that includes at least a CT radiologist, a CT technologist, and a medical physicist. To establish such a new rule that involves the clinical imaging of patients without the involvement of a CT radiologist is insupportable and must be revised or removed. Response: Based on this comment, the Department will not be promulgating this rule at this time. The protocol review requirement will be placed in the "conditions of operation", the same as the existing standard. The affected draft rules will be changed as follows: R 333.5713 Conditions of operation. Rule 713. **(1) The CT facility shall establish scanning protocols in consultation with the medical physicist.** ~~(1)~~**(2)** The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the technique and individual patient. This may be accomplished by reviewing dose indicator devices, if available, or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist. ~~(2)~~**(3)** A fixed CT scanner shall be operated from a shielded position behind a protective barrier pursuant to R 333.5711(4). ~~(3)~~**(4)** Staff personnel routinely working with or around radiation sources shall not be required by the registrant to restrain patients during CT examinations. If the procedure is permitted personnel exposure shall not exceed the limits in R 333.5057 to R 333.5059 or the procedure is prohibited. ~~(4)~~**(5)** When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient is held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body is struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam. ~~(5)~~**(6)** Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier. ~~(6)~~**(7)** Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Individual monitoring devices shall be permanently assigned to each occupationally exposed individual. Monitoring shall be

	continuous during employment as a radiation worker. ~~(7)~~**(8)** Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs. ~~(8)~~**(9)** Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of all other body parts shall meet the requirements of R 333.5065. ~~(9)~~**(10)** Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for a medical or dental reason. ~~(10)~~**(11)** A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons. … ~~R 333.5718 Review of clinical protocols~~ ~~Rule 718. (1) The CT facility shall establish scanning protocols in consultation with the medical physicist.~~ ~~(2) The medical physicist shall ensure that all protocols used clinically are adequate to obtain diagnostic image quality while minimizing radiation dose to the patient.~~ ~~(3) The CT facility shall document that all protocols in clinical use have been evaluated by the medical physicist.~~