Public Comment – **I.D. No. HLT-15-24-00003-P**; Ionizing Radiation

These comments are submitted on behalf of the New York State Dental Association and the New York State Society of Oral & Maxillofacial Surgeons regarding the Department of Health's proposed regulatory changes on Ionizing Radiation.

According to the Department's own reporting in these proposed regulations, they acknowledge that more than half of the facilities using CT machines are dental offices. Moreover, oral surgery offices are one of the largest concentrations of CBCT machines in New York State.

While our associations appreciate the Department's commitment to the safety of dental patients and office staff, we do find further modifications to the proposed regulation necessary.

Regarding the Department's proposed registration fee increase, our associations fully support this. We agree that increasing the annual fee to $100 is overdue and will help fund the Department's oversight of this important program.

We also understand the proposal for the institution of a Quality Control program including the institution of annual testing by a licensed medical physicist. While we understand that proper calibration and operation of this equipment is critical, this is a significant expense and one we request further consideration of. Bearing this in mind, we do wonder whether there are a sufficient number of licensed medical physicists to conduct these tests.

The institution of a Quality Assurance program should help organize the equipment paperwork and maintain staff understanding of the equipment and its operations. Both NYSDA and NYSSOMS are in support of the proposed QA program apart from its accreditation mandate (16.65b8).

Formal accreditation programs like those from groups such as IAC or RAD, are excessive for the level and type of ionization being emitted by dental CBCTs. Numerous studies[1] confirm the level of radiation emitted from dental CBCTs are a fraction of that from medical CT machines.

Standards from accrediting groups are often crafted with much larger medical facilities in mind. Both general dentist and oral surgery offices are incredibly small when compared to large medical institutions that have large administrative staff to shoulder the duties included in the proposed accreditation process.

It is the experience of our members that formal accreditation programs are bureaucratically burdensome instead of patient-driven and safety-oriented and the exhaustive duties and

[1] Loubele, M, et al. "Comparison between effective radiation dose of CBCT and MSCT scanners for dentomaxillofacial applications." *PurMed*, PMID: 18639404, no. 10.1016, 18 July 2008.

requirements listed within the proposed QC regulations are sufficient by themselves to satisfy the Department's intended goals.

Proposing an accreditation requirement for dental CBCTs would be a significant financial and staffing burden to dental offices. It represents excessive, costly overregulation that currently is not supported by any known US government agency or group within organized dentistry. These costs would likely have to be borne by our patient population, increasing the cost of care, and possibly limiting access. The resulting cost and complexity would likely serve to inhibit the introduction of more of these valuable machines to other dental offices. These proposed accreditation programs are simply inappropriate for the size and scope of the dental CBCT.

We hope that the Department considers our concerns with part of these proposed regulations. We welcome any questions about these concerns and would love to dialogue with the Department about them.

Sincerely,

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