

4. Activities prior to the arrival of the inspection team on-site

Although the facility management was informed of the timing of the inspection one month in advance, this had not actually been necessary. According to the management, even an inspection without any notice period would have been feasible as far as the management was concerned. Difficulties could however arise if the inspection team were to arrive (without any previous notice) outside office hours or during the vacation period.

5. Advance preparations on-site

6. Escort and point of contact arrangements

These were found to be essential. The co-operative attitude of the escorts from the facility greatly facilitated the inspection. The presence of escorts did not in any way interfere with the inspection effort.

7. Other participants

8. Duration of inspection and initial visit respectively

A "real" inspection would most likely have required at least 3-5 days, probably even longer time, because of more extensive records examination and sample-taking (cf. remarks under 2 and 15-18). The actual duration of a "real" inspection would be highly dependent upon whether it took place during actual production or during an interim period. Also the quality of the "facility attachment" will have a considerable influence on the duration of an inspection.

A "real" initial visit would probably require at least 5 days for, inter alia, extensive verification of information supplied, photographic documentation of the equipment in order to facilitate future detection of any undeclared changes, and familiarization with the records system.

9. Measures to protect confidential information

Because of the special situation at the trial inspection (all inspectors being Swedish government employees already under oath), no conclusions can be drawn.

10. Opening conference

One hour was more than sufficient time. However, this presupposes that the inspectors are very well acquainted with the "facility attachment". In the case of frequent inspections at short intervals, the opening conference might be very brief.

11. Types of records needed and/or audited

It was not possible for the inspectors to know in advance exactly what information and data would constitute the minimum required to fulfil their mandate. "Excess" data had therefore to be requested in order to ensure that all relevant data would be included.